Children's Environmental Health: A Comparison of Risk Assessment Approaches Taken by Canada, the United States, and the European Union

by

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ABSTRACT

Children come into contact with environmental pollutants on a daily basis. Air pollution, pesticides, chemicals, and lead are a few of the toxic substances which are transferred to children through water, air, soil, food, and skin contact. Exposure to these substances has been linked to a variety of child chronic health conditions, including spontaneous abortions, congenital defects, neurodevelopmental disorders, reproductive dysfunctions, endocrine dysfunction, and cancers. Because of this, governments have the responsibility to restrict exposures to these substances to ensure that intake is not unsafe.

Governments have utilized a risk assessment process to determine what levels of exposure are considered safe. The interpretation of the results of this process, however, has differed depending on which theory has been selected – the risk-based approach or the hazard-based approach. The risk-based approach attempts to avoid unacceptable risks through the quantification of exposure and harm. The hazard-based approach, aims to avoid exposures that result in significant harm and minimize all other exposures. The difference between the two is that the risk-based approach is focused on controlling the risk while the hazard-based approach completely removes the most caustic substances.

This thesis explores the impact the selected risk assessment approach may have on tolerances and standards set for children's exposures to environmental pollutants. The thesis will examine two case studies: (1) pesticide standards and (2) chemical standards. The United States and Canada have chosen to use a risk-based approach to determine acceptable risks from exposure. The European Union has utilized a hazard-based approach to set permissible exposure levels. This thesis will argue that the hazard-based approach is preferable for children's health and protection. Since there are a great many unknowns regarding how toxic exposure impacts children's health it is safer to avoid those chemicals which may negatively affect children's health rather than attempt to control the risk at a "safe" level.

The thesis will: (1) present information on what is known about health and toxic exposure, (2) illustrate that international efforts have failed to address environmental health, (3) discuss the differences between the two approaches to pesticide and chemical policies, and (4) provide policy recommendations.

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ACRONYMS

2, 4-D	2-4-Dichlorophenoxyacetic Acid
ADI	Acceptable Daily Intake
ALARA	As Low As Reasonably Achievable
ASHRAE	American Society of Heating, Refrigerating, and Air- Conditioning Engineers
BMD	Benchmark Dose
BPA	Bisphenol A
CDC	Center for Disease Control (United States)
СЕНАРЕ	Children's Environment and Health Action Plan for Europe
CHMS	Canadian Health Measures Survey (Canada)
COI	Costs Of Illness
CRC	Convention on the Rights of the Child (United Nations)
CSD	The Commission on Sustainable Development (United Nations)
DCBP	1,2-Dibromo-3-Chloropropane
DDE/DDT	Dichloro-Diphenyl-Trichloroethane
DEET	N,N-Diethyl-Meta-Toluamide
DEHP	Di(2-ethylhexyl) Phthalate
DINP	Diisononyl Phthalate
DRP	Diesel Related Pollutant
DSL	Domestic Substances List
EC	European Community
ECJ	European Court of Justice
EEA	European Union European Environment Agency
EEHC	European Environment and Health Committee
EPA	Environmental Protection Agency's (United States)
ETS	Environmental Tobacco Smoke
EU	European Union

FAO	Food and Agriculture Organization (United Nations)
FDA	Food and Drug Administration (United States)
FEMA	Federal Emergency Management Agency (United States)
FFDCA	Federal Food, Drugs, and Cosmetic Act (United States)
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act (United States)
FQPA	Food Quality Protection Act (United States)
G8	Group of Eight (Canada, France, Germany, Italy, Japan, Russia, United Kingdom, and the United States)
GAO	Government Accountability Office (United States)
НСВ	Hexachlorobenzne
HPV	High Productive Volume
IFM	Integrated Farm Management
KemI	Kemikalieinspektionen (Swedish Chemical Agency)
KSCA	Kid Safe Chemical Act (United States)
LOD	Limit of Analytical Determination
LOQ	Level Of Quantification
MCS	Multiple Chemical Sensitivity
MRL	Maximum Residue Level
NAAEC	North American Agreement on Environmental Cooperation
NAFTA	North American Free Trade Agreement
nDSL	Non-Domestic Substances List
NAS	National Academy of Science (United States)
NEHAPs	National Environment Health Plans
NHIS	National Health Interview Survey (United States)
NHANES	National Health And Nutrition Examination Survey (United States)
NOAEL	No Observed Adverse Effect Level

OECD	Organization for Economic Co-operation and Development
OP	Organophosphorous
PAHs	Polycyclic Aromatic Hydrocarbon
PBDEs	Polybrominated Diphenyl Ethers
PBiT	Persistence, Bioaccumulation, and Inherent Toxicity
PCBs	Polychlorinated Biphenyls
PCDDs	Polychlorinated Dibenzodiozins
PCPA	Pest Control Products Act (Canadian)
PCNB	Pentachloronitrobenzene
PFCs	Perfluorocarbon
PFOA	Per-flu Octanoic Acid
PM	Particulate Matter
PMRA	Pest Management Regulatory Agency (Canada)
POPs	Persistent Organic Pollutants
PRIMO	Pesticide RIsk Assessment Model
PSL	Priority Substances List
PVCs	Polyvinyl Chloride
QALY	Quality of Adjusted Life Years
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
SCALE	Science, Children, Awareness, Legislation and Evaluation (European Union)
SIDS	Sudden Infant Death Syndrome
TSCA	Toxic Substances Control Act (United States)
UK	United Kingdom
UN	United Nations
US	United States
USDA	US Department of Agriculture
VEL	Virtual Elimination List

VOCs	Volatile Organic Compounds
WHO	World Health Organization
WHO Europe	World Health Organization Regional Office for Europe
WTP	Willingness To Pay

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1. INTRODUCTION

1.1 Introduction

*Children are often exposed to a myriad of environmental hazards, often simultaneously, in varying doses at different stages of their development.*¹

On a daily basis, children are exposed to a number of toxic substances, including lead, mercury, air pollution, chemicals, and pesticides. These toxins are found in everyday life. Children swallow polluted water and foods, breathe in ozone and chemicals from outdoor and indoor air pollution, and absorb through their skin pesticides found on playgrounds and chemicals used inside homes. In order to control the level of exposure to these toxic substances responsible governments, especially in industrialized countries, have taken regulatory action restricting the use of and emissions from the offending agents.

In many ways, the methods by which responsible governments have limited toxic exposure have been similar. Governments have relied on scientific evidence, mathematical models, and exposure data to analyze the risks associated with exposure to specific substances. This data is used to determine what exposure rates or levels will be deemed legal or illegal, that is to say dangerous.

Though science has evolved in the last half-century to provide governments with the ability to predict the impact chemical substances have on both humans and the environment, there remains a great deal of uncertainty. Scientific understanding of the impact these toxic chemicals have on children's health is in early development, as researchers have yet to fully grasp how chemicals affect a child's endocrine system, reproductive development, neurodevelopmental growth, respiratory function, immune capacity, and behaviour.²

However, there exist two distinct methods for approaching this challenge of protecting children. The risk-based approach aims at controlling the risk. In contrast, the hazard-based approach aims to eliminate the most toxic substances, therefore removing the need to control the risk. In order to understand how these interpretative assessment approaches make a measureable impact on children's health, this introductory chapter will provide rationale as to why children's environmental health is worth considering. The five sections will include brief discussions of: (1) how children are different from adults, (2) the part environmental health plays on children's health outcomes, (3) the role science plays in the assessment process, (4) how children often are not included in the policy process, and (5) an outline of the layout of the thesis.

¹ P.J. Landrigan & J.E. Carlson, "Environmental Policy and Children's Health" (1995) 5:2 Future Child 34 at 41.

² E. Phipps, "Building a Dialogue Towards a National Strategy for Children's Health and Environment in Canada" (National Policy Consultation Series on Children's Health and Environment Interim Workshop Report, 14 September 2007) CPCHE at 35.

1.2 Children Are Not Little Adults

Children have different physical, biological, and social environments than adults.³ The physical environment of a child includes parks, playgrounds and yards, along with school buildings, daycares, and homes. Children spend eighty-five percent of their time indoors, in environments that may still contain lead paint, asbestos, or poor indoor air quality.⁴ Outside, children are exposed to a number of other chemicals that may not be part of an adult's daily exposure.⁵ Playgrounds, sports fields, and yards tend to be treated with pesticides. Since children spend more time playing and crawling in such areas than any adult, their contact with these pesticides is greater.⁶ Often these play areas are located near traffic zones, leading to an increased intake of particulate matter and ozone pollution. Children inhale more air per kilogram of body weight than adults do, which adds to the impact outdoor air pollution has on their body.⁷ In addition, children have a greater intake of food and drink⁸ per kilogram of body weight, resulting in greater exposure to the toxins⁹ present in these dietary items. "The average infant consumes six ounces of formula per kilogram of body weight. For the average male adult, this is the equivalent to drinking thirty-five cans of soda pop a day."¹⁰

The biological environment of a child consists of developmental changes that effects how toxins are absorbed by, distributed by, metabolized by, and interact with the biochemistry of the body.¹¹ Children undergo a number of physical changes during each stage of growth, including fetus, infant, young child, child, and adolescent.¹² During these periods of development, children are particularly vulnerable to harm from caustic substances. Their gene regulation, nervous system, immune system, reproductive system, and endocrine system are still experiencing a number of changes which leave them physically vulnerable to harm.¹³ The negative outcomes of exposure to caustic substances include abnormalities at birth, low birth weight, childhood asthma, cancer, neurodevelopmental deficits, and behavioural disorders.¹⁴

⁷ Cooper, supra note 5 at 41.

⁸In addition to food and water consumption , breast milk intake affects toxic intake.

¹¹ *Ibid.* at 12.

¹⁴ *Ibid.* at 1.

³ E. M. Lewit & L.S. Baker, "Children's Health and the Environment" (1995) 5:2 Future Child 8 at 8.

⁴ D.T. Wigle, *Child Health and the Environment*, (New York: Oxford University Press, 2003).

⁵ K. Cooper et al., *Environmental Standard Setting and Children's Health*, (Toronto: C.E.L.A., 2000) at 40.

⁶ L.R. Goldman & S. Koduru, "Chemicals in the Environment and Developmental Toxicity to Children: A Public Health and Policy Perspective" (2000) Environ. Health Perspect. 443 at 443.

⁹ Toxins include chemicals, lead, mercury, arsenic, cadmium, manganese, dioxins, and pesticides. *Wigle, supra* note 4.

¹⁰ Lewit supra note 3 at 15.

¹² P.J. Landrigan et al., "Children's Health and the Environment: Public Health Issues and Challenges for Risk Assessment" (2004) 112:2 Environ. Health Perspect., online: EHP http://www.ehponline.org/members/2003/6115/6115.html (last modified: February 2004).

¹³ Wigle, supra note 4.

The social environment of a child consists of his/her interaction with other children and family members "as well as the laws and regulations that affect day-to-day living."¹⁵ The places where children reside, the socio-economic class of their parents and care-takers, the school systems that they attend, and their access to health care influence exposure to and impact from toxins. These cultural, political, and economic differences may influence nutrition, sanitation, and quality of medical care.¹⁶ Along with these differences in their social settings, children experience different exposures due to varying regulatory tools used in respective regions.¹⁷ Many governments have exercised their authority over water regulation, food control, school building requirements, consumer safety, and air pollution to prevent or reduce childhood exposures to chemicals. However, these powers have been used in many ways and to varying degrees, resulting in differing levels of protection.

1.3 A New Area Of Understanding: Children's Environmental Health

The relationship humans have with their environment is ever-evolving. Though the realization that humans have an impact on environment has long been understood¹⁸, the recognition of the impact environment can have on children's health is relatively new. In fact, the area of environmental health in general is fairly novel.

Within the last century, a number of individual instances have occurred which have led to a better grasp of this relationship between environment and childhood health. Research indicated that childhood exposure to lead paint often resulted in cognitive and neurobehavioural deficits as early as 1904.¹⁹ In the 1920s, there were reports that exposure to radiation during pregnancy led to childhood retardation.²⁰ In the 1950s, the exposure to methyl mercury and its capacity to cause cerebral palsy in children was evident from the consumption of contaminated fish caught in Minamata Bay in Kyushu, Japan.²¹ The negative impact the chemical class of polychlorinated biphenyls (PCBs) had

¹⁶ Wigle, supra note 4 at 1.

¹⁷ Bearer, supra note 15 at 22.

¹⁸ It has been argued that as early as biblical times there was a general understanding of the relationship environment had on health. For instance, forbidden animal based foods were banned because they were "unclean". Research indicates that this religious principle aided in reducing human exposure to bacteria. Scientific progress by the Romans led to an increase in knowledge on health consequences due to environmental exposures. To address this, Romans instituted the first sewage system, hot and cold water, and regular bathing. However, with the passage of time, there has been a shift from viewing the relationship between environment and health as one where environment affects humans, to one where humans affect the environment. The 1962 publication, *Silent Spring*, by Rachel Carson highlighted this relationship, focusing on the harm pesticides were having on the environment, and therefore humans. H. Frumkin, "Beyond Toxicity Human Health and the Natural Environment" (2001) 20:3 Am. J. Prev. Med. 234 at 234; R. Carson, *Silent Spring* (New York: First Mariner Books, 1962); "History of Environmental Health" (Jersey, England: States of Jersey), online: States of Jersey

<http://www.gov.je/Health/public_health/health_protection/History+of+Environmental+Health.htm> (date accessed: 14 September 2009).

¹⁹ J.L. Gibson, "Painted Walls of Rooms as the Source of Lead Poisoning Amongst Queensland Children" (2005) 120 Public Health Rep. 301 at 301; J.J. Chisolm, "Removal of Lead Paint from Old Housing: The Need for a New Approach" (1986) 76:3 Am. J. Public Health 236 at 236.

²⁰ R.W. Miller, "How Environmental Hazards in Childhood Have Been Discovered: Carcinogens, Teratogens, Neurotoxicants, and Others" (2004) 113:4 Peds. 945 at 945.

²¹ *Ibid.* at 946.

¹⁵ C.F. Bearer, "Environmental Health Hazards: How Children Are Different from Adults" (1995) 5:2 Future Child11 at 11.

on children was discovered in 1968 when rice oil used in cooking had been contaminated by this substance.²² The exposure resulted in newborns and children having developmental delays, skin diseases, low birth weight, and cognitive deficits.²³ Similarly, instances of childhood cancer from consumption of pesticides such as alachlor in the 1980s resulted in an awareness of the potential for harm from pesticides in general.²⁴

In addition to these examples of cause-and effect between environment and childhood health, increases in chronic health conditions have led governments to begin to research additional relationships between exposure and harm, especially when government is the primary health insurer. Globally there has been an increase in obesity, asthma, autism, and other developmental disorders among children.²⁵ In the United States alone, almost five million children suffer from asthma.²⁶ This figure has increased rapidly over the last few decades.²⁷ Childhood cancer has increased, with melanoma, thyroid cancer, testicular cancer, and non-Hodgkin's lymphoma being the most common and leukemia and brain tumours increasing the most rapidly.²⁸ Birth defects have become the most common cause of infant mortality, with nearly one in every twenty-eight babies born with some form of birth abnormality.²⁹

The specific instances of harm from exposure and the increasing incidents of childhood chronic health conditions have led to an understanding of the potential impact environmental pollution can have on children's health. Because of this, many enlightened governments have integrated the impact exposure to substances make on health as part of the assessment of environmental risk which is permitted under policy.³⁰ Industrialized nations have initiated various efforts to include children's physical, biological, and social environments in setting chemical exposure standards and controlling pollution.

²⁹ Wargo, supra note 26 at 5.

²² *Ibid;* Y.L. Gao et al., "Blood Serum Levels of PCBs and PCDFs in Yucheng Women 14 Years after Exposure to Toxic Rice Oil" (1997) 33 Arch. Environ. Contam. Toxicol. 104 at 104; Y. J. Chen, "A 6-Year Follow-Up of Behavior and Activity Disorders in the Taiwan Yu-Cheng Children" (1994) 84:3 Am. J. Public Health 415 at 415.

²³ Wigle, supra note 4 at 138.

²⁴ G. Hoberg, Jr., "Risk, Science and Politics: Alachlor Regulation in Canada and the United States" (1990) 23 Can. J. Polt. Sci. 257 at 260.

²⁵ J.E. Carlson, "Exposure and Toxicants and Child Health: Comments and Questions" (2005) 15:1 Children, Youth, and Environs. 224 at 225.

²⁶ J. Wargo and L.E. Wargo, *The State of Children's Health and Environment*, (Los Angeles: C.H.E.C. 2002) at 5.

²⁷ *Ibid*.

²⁸ Wigle, supra note 4 at 4; Wargo, supra note 26 at 5.

³⁰ P. Bennett, "Governing Environmental Risk: Regulation, Insurance and Moral Economy" (1999) 23:2 Prgss. Hum. Geo. 189 at 191.

1.4 Predicting Risks To Children's Health Through An Uncertain Science

In attempts to control or prevent exposure to toxins found in a child's daily environment, international and national policy has been drafted. At an international level, a number of doctrines have provided awareness of the environmental health issues that children face, but few have included mandates which result in a reduction in exposure. These doctrines will be discussed in chapter three.³¹

Although these international efforts have led to an increasing awareness of the vulnerabilities of children, they have failed to "actually act to specifically protect them".³² As a result, federal governments are left to create regulatory policy on caustic substances. Due to the number of different environmental pollutants, such as air pollution, water contamination, residues on foods, and indoor toxins, governments have relied on a number of different statutes respective to each. Tools in statutes to regulate may include licensing requirements for substances prior to their use or production, pollution plans restricting the amount of a substance that may be present in the environment, and/or standards set in the statute for chemical exposure.³³

In order to establish permissible tolerances of exposure, governing bodies rely on scientific evaluations. These groups utilize data on toxicity and exposure to determine whether or not a standard for substance exposure needs to be legislated, and if so, at what level. The use of scientific evidence in this way is a relatively new phenomenon, instigated both by the evolution of scientific capabilities and by a greater pressure by the public in developed nations to regulate industry.³⁴

This process is now identified as the risk assessment process. It has been defined as "principally a scientific activity" which "consists of an attempt to estimate the hazardous properties of a chemical in the environment and to determine the risks to human health that may result from exposure".³⁵ This process is the basis by which children's health is considered and protected throughout environmental policy. However, while the activity is science based there remains a great deal of unknowns or knowledge gaps. Because the study of the impact substance exposure has on children is relatively new, there are a number of uncertainties as to what a negative outcomes therefore reducing the accuracy of this estimation. "There are simply too many uncertainties inherent in the process in terms of 1) basic

³¹ Carlson, supra note 25 at 227.

³² *Ibid*.

³³ Landrigan 1995, supra note 1 at 35.

³⁴ Public pressure and awareness increased during the 1960s, due in part to Rachel Carson's *Silent Spring*. In response, a number of nation-states instituted a formal procedure mandating science as an evaluation tool. The United States was one of the first countries to document that a scientific evaluation shall be made. The US National Research Council's (NRC) report, *Risk Assessment in the Federal Government: Managing the Process* [hereinafter the "Red Book"], held that a risk analysis of substances shall be performed prior to political consideration of any standards. R.E. Lofstedt, "A European Perspective on the NRC Red Book, Risk Assessment in the Federal Government: Managing the Process" (2003) 9 Hum. Ecol. Risk Assess. 1327 at 1328; National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, 1983); *Carson, supra* note 18; National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (Washington, D.C.: National Academy Press, 1983).

³⁵ Landrigan 1995, supra note 1 at 37.

insufficiency of data; 2) lack of methodologies for key steps in the process; and 3) the difficult of reproducing or ensuring consistency and equal levels of professionalism and expertise across highly complex analyses."³⁶

Because of these uncertainties, governments have relied on "a particular framing of knowledge"³⁷ to aid in interpreting the outcomes of risk assessments. The two primary frameworks that have been used by most developed nations are the risk-based approach and the hazard-based approach. The objective of the risk-based approach is:

"...to avoid unacceptable risks. These decisions are therefore based on *unacceptable risk* considerations using a quantitative and/or qualitative comparison between exposure and inherent properties. The risk-based mechanisms are used to evaluate if the pressures imposed by exposure-based mechanisms are sufficient to reduce risks to an acceptable level or if additional measures are needed."³⁸

The hazard-based approach consists of three tiers. At each level of evaluation, the substance is evaluated, and if it passes with the necessary requirements, it advances to the next tier. The first tier is the hazard-based decision, where the objective is:

"...to avoid exposure to chemicals that pose a specific potential hazard. These decisions are therefore based on *risk avoidance* considerations. The risk avoidance considerations leading to hazard-based decisions are based on the conclusion that any exposure to a chemical with these specific inherent chemical properties is unacceptable regardless of whether or not the risks will actually occur."³⁹

If the substance does not possess the properties of harm which eliminate it in tier one, the review progresses to the second tier where exposure-based decisions are made. The goal of this tier is:

"...a clean(er) environment, based on pollution prevention. These decisions are therefore based on *exposure minimization* considerations and are applied to all chemicals uniformly or to groups of chemicals used in certain processes. The exposure-based decisions are made irrespective of the inherent chemical properties. They provide continuous pressures to reduce pollution."⁴⁰

In those circumstances where the substance does not possess inherent chemical properties that cause it to be eliminated under tier one, and has not been selected for minimization under the second stage of the evaluation, then the substance will be evaluated for risk using the same criteria as the risk-based approach.⁴¹

As this thesis will argue, use of the hazard-based approach results in more protective standards and regulations than use of the risk-based approach. One of the reasons for this is that the risk-based approach relies solely on scientific formulations to determine what levels of exposure are safe. However, because of the great number of unknowns

⁴⁰ Ibid.

³⁶ T. McClenaghan et al., "Environmental Standard Setting and Children's Health in Canada: Injecting Precaution into Risk Assessment" (2003) 12:2 J. Environ. Law Prct. 141 at 150.

³⁷ Bennett, supra note 30 at 190.

³⁸ B. Hansen & M. Blainey, "REACH: A Step Change in the Management of Chemicals" (2006) 15:3 Reciel. 270 at 273.

³⁹ *Ibid.* at 274.

⁴¹ *Ibid*. at 275.

surrounding this field of science, particularly the impact toxic exposure has on children's health, it is not very scientific.⁴² It has been said that "[w]hile [the risk-based approach] can provide a generally reliable means of predicting acute effects from high dose exposures, it falls far short in the most important areas of environmental concern: chronic effects from long-term, low dose exposure."⁴³ And, unfortunately, before this predictive tool can be validated, exposure for many years must occur to "obtain empirical feedback, which is necessary (for them as for all of us) to confirm or correct their theories."⁴⁴

The impact that these weak predictions, even when only slightly inaccurate, can make on children is substantial. Nearly seventy thousand chemicals are on the international market, and nearly five hundred of these substances are detectable in human tissue.⁴⁵ Because a child is exposed to this many chemicals on a daily basis, any inaccuracy in the risk-based approach would make a negative impact on their health. This is particularly true as very little is understood about vulnerabilities due to exposure to a number of chemicals at once, known as Multiple Chemical Sensitivity (MCS).⁴⁶ With an increase in childhood disease rates, as mentioned earlier, it may be that the imprecision in these estimates coupled with the scientific uncertainties is having a significant impact on children's health.

The hazard-based approach aims to eliminate some of the uncertainties which are inherent in the risk assessment process. Based on the idea that precaution should be taken, this interpretation of the scientific process eliminates products that may cause substantial physical harm. "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."⁴⁷ Using this overlay in the risk assessment process provides a safety net whereby caustic chemicals are immediately banned rather than an estimate of safe exposure made. Since there are so many unknowns surrounding how chemicals affect children's health, particularly their ability to cause cancer⁴⁸, this approach rids the childhood exposure to the most likely offending toxins.

⁴² R. A. Pollak, "Government Risk Regulation" (1996) 545 Ann. Amrcn. Acad. Pltcl. Scnc. 25 at 25.

⁴³ *McClenaghan, supra* note 36 at 9.

⁴⁴ *Pollak, supra* note 42 at 28.

⁴⁵ *Wargo, supra* note 26 at 4.

⁴⁶ *Ibid*. at 8.

⁴⁷ *McClenaghan*, *supra* note 36 at 19.

⁴⁸ L. Goldman, "Chemicals and Children's Environment: What We Don't Know about Risks" (1998) 106:3 Environ. Health. Perspect. Supp. 875 at 875.

1.5 The Failure To Consider Children In The Risk Assessment Process

It is more than the mere selection of an interpretative approach which aids or hinders in the protection of children's health. It is also the consideration, or lack thereof, of children in the first place. "The fact that risk assessments do not usually consider children's unique risks is a major flaw \dots "⁴⁹ If children's unique physical, biological, and social settings are not incorporated in the assessment process, then there is no way of knowing if harm occurs to a child at a specific dose.

As already discussed, the differences between children and adults are vast, and therefore impact the type and quantity of exposures they have. However, until the 1990s, assessments tended not to include children's vulnerabilities in the estimate of harm. While individual substances, such as lead, were evaluated for their impact on children, it was not a consistent process included in all environmental policy. In fact, most of the efforts to do so were reactionary after a long period of harm was evident. Due to a food scare in 1991 when it was found that the pesticide Aldicarb used on bananas left residues not "potentially high enough to make a child acutely ill"⁵⁰, the US government commissioned a research report into the unknown effects pesticides were having on children. Though this publication, *Pesticides in the Diets of Infants and Children*, was focused on pesticides, it did produce awareness that children are physically different in many ways than adults.⁵¹

What will be discussed throughout this thesis is that even in those circumstances where children are specifically mentioned in the environmental legislation, the interpretative approach to the assessment process makes a clear difference. Those who utilize the risk-based approach continue to permit exposure to caustic substances, even though in limited amounts. Meanwhile, those nations that have integrated children's physiological differences into the assessment process and use the hazard-based approach tend to achieve more stringent standards and an overall elimination of potentially toxic substances, the outcome of which is a reduced childhood exposure to toxins.

⁴⁹ Landrigan 1995, supra note 1 at 39.

⁵⁰ Goldman, supra note 48 at 27.

⁵¹ While children are now integrated in the assessment process in most developed nations, there continues to be a fragmented approach whereby children may be protected under one environmental policy and not another, as will be highlighted in this thesis. This needs to be remedied for children to be protected, no matter the approach taken. *Landrigan 2004, supra* note 12 at 257; J.L. Aber, J. Brooks-Gunn, & R.A. Maynard, Effects of Welfare Reform on Teenage Parents and their Children" (1998) 106:3 Environ. Health. Perspect. Supp. 53 at 53.

1.6 Outline Of This Thesis

This thesis will discuss in further detail the impact the interpretative approach taken to the risk assessment process can have on children's health. In doing so, three jurisdictions have been selected for review, Canada, the European Union (EU), and the United States (US). The US and Canada both use the risk-based approach in regulating toxins, in contrast to the hazard-based approach employed by the EU. In order to provide context about the different standards that result from these two approaches, two case studies have been selected. The first case study is a review of pesticide regulation by each government. The second case study is a review of chemical legislation in place in each jurisdiction.

Chapter two of the thesis will provide an in-depth overview of the differences between children's physical and biological settings which lead to an increase in the inhalation, absorption, and digestion of substances. The purpose of this review is to put the prevalence of the problem into context. It is not merely an issue of childhood consumption of pesticides or inhalation of chemicals, but rather an issue that affects every aspect of children's daily life.

Chapter three outlines the different international efforts which have been made pertaining to children's environmental health. What will be apparent from this chapter is though many developed nations have participated in international forums and doctrines that aim to reduce exposure, these doctrines do not mandate specific requirements of each signatory. Without such requirements, little success has come from these doctrines. In a limited number of instances, general environmental health issues have been addressed with specific requirements. These policies have been capable of reducing or eliminating exposures to specific toxins. However, the chemicals selected for these international efforts have only been the very most caustic.

Chapter four provides a comparison of the level of risk to the children of the US and Canada with those of the EU. Because of the approaches taken by the North American jurisdictions, their policies have been weaker. Their use of the risk-based approach aims to control the risk to children, yet because of the scientific uncertainties inherent in the process, this is an inaccurate process that results in children taking in more toxins than those residing in the EU. The EU has applied a hazard-based approach which attempts to reduce the overall use of all toxins and endeavours to eliminate those substances with a significant impact on children's health. By banning these specific substances, the EU has effectively eliminated the concern that they may have, as the risk-based approach might not correctly estimating safe levels of exposure. This chapter will utilize pesticide and chemical regulations as examples of each approach.

The last chapter will provide recommendations for how the US and Canada can modify their current approach to risk assessment to provide better protection for children's health. This chapter will also include concluding remarks on the impact science makes on the approach and the advantages of utilizing a cautionary overlay in the assessment process.

2. WHY ARE CHILDREN DIFFERENT? A REVIEW OF EPIDEMIOLOGY AND SCIENCE

2.1 Introduction

Before reviewing policy considerations relevant to children's environmental health, it is important to understand the differences between children and adults. Children are a vulnerable subpopulation who have unique physiology, behaviour, and mental capacity. From conception to adulthood, a child has a limited capacity to ward off the negative consequences of environmental pollutants.⁵² Early stages of the developing immune system, nervous system, and endocrine system fail to offer the same levels of protection from environmental toxins that are active in adulthood. Additionally, behavioural and environmental differences, such as outdoor play, crawling, and school attendance, compound the susceptibilities of children. A child also has a reduced potential, compared to an adult, to combat toxins as they eat more food and drink more water relative to body weight and breathe more air per kilogram of body weight.⁵³ Developing mental capacity leaves children unable to make reasonable decisions regarding exposure, particularly in early stages of life. The concept of exposure is foreign to children, and particular behaviours, such as hand-to-mouth actions, lead to added contact with pollutants.

In this chapter, epidemiological studies obtained through databases, including Pubmed and Toxnet, are highlighted in the appropriate sections. It is evident from these studies that further research needs to be conducted, particularly in the form of biomonitoring, which is the analysis of blood, tissue, and urine for a specific toxic substance. At this point, research performed tends to lack clear case-control groups or is unable to take into consideration confounding factors. These study concerns are not always attributable to poor research design but rather to the inability to isolate children from specific pollutants and control for genetic influences. What can be observed from these studies is that there is a clear basis for concern. Negative health outcomes due to environmental exposures indicate that there is a causational relationship, but what is yet to be defined is under what circumstances or what exposure levels the negative health outcomes occur. It may be that these determinations need not be made before policy action is taken.

This chapter is divided into two sections. The first provides an overview of the developmental stages of growth and the specific vulnerabilities during these times. The developmental stages reviewed are that of infancy, toddler and young child, and adolescence. The second portion of the chapter provides an analysis of exposure pathways, i.e. what mediums expose children to pollutants. Pathways considered are outdoor air, indoor air, food, water, and soil. The objective of this chapter is to illustrate that the differences between a child's and an adult's daily life leave a children susceptible to unnecessary harm.

⁵² Wigle, supra note 4.

⁵³ *Ibid.* at 1.

2.2 The Vulnerability Of The Child

The medical community recognized physiological and behavioural differences of children during the late 1800s.⁵⁴ First in Europe, then in North America, the specialization of children's medicine took hold in medical practice and became a norm.⁵⁵ Central to this medical specialization is that a child's body is not that of a "little adult"⁵⁶, but functionally and developmentally different during maturation. Awareness of childhood health has led to special consideration of pharmaceutical intake, surgical methods, and diagnostic tools. Within recent decades, the pediatric community has acknowledged that child health should be independently considered by more than solely by the medical community. There are a multitude of determinants of health, including social networks, education, employment conditions, culture, economic status, gender, health services, child development, biology, genetics, and physical environments.⁵⁷ While no one determinant can be isolated when establishing the cause and prevention of disease, the consideration of environmental exposure has often been neglected. Because of this, the American Academy of Pediatrics has held out the determination of environmental exposures as essential in detecting, treating, and preventing diseases and offering an accurate diagnosis.

Environment-related caused conditions result in over three million deaths of children under the age of five per year.⁵⁸ This linkage between environmental pollutants and deaths and disease each year makes a lasting impact on the global society. Although the extent of exposure and the consequences of are naturally greater in developing nations, the exposure rates in countries such as Canada, the United States, and parts of Europe are alarming. While accidental injuries remain the leading cause of childhood death in Canada and the United States, there has been a disconcerting increase of environmentally induced diseases. From 1974 to 1984 the incidence rates of childhood cancer increased fifteen percent, and have remained relatively constant since.⁵⁹ Incidence rates of childhood cancer vary from 144 to 159 per 1,000,000 children.⁶⁰ Recent levelling trends may be an indication of a persistent rate of exposure to some

⁵⁹ Wigle, supra note 4, at 4.

⁵⁴ P.E. Luecke, Jr., "The History of Pediatrics at Baylor University Medical Center" (2004) 17(1) Bayl. Univ. Med. Cent. 56, online: PubMed Central ">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1200641/> (last modified: January 2004).

⁵⁵ E.A.C. Hubal et al., "Children's Exposure Assessment: A Review of Factors Influencing Children's Exposures, and the Data Available to Characterize and Assess that Exposure" (2000) 108:6 Environ. Health Perspect. 475, online: Environ. Health Perspect. < http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1638158/pdf/envhper00307-0041.pdf> (last modified: June 2000).

⁵⁶ P.S. Guzelian, C.J. Henry, & S.S. Olin, *Similarities and Differences Between Children and Adults: Implications for Risk Assessment* (Washington, D.C.: I.L.S.I. Press, 1992) at 1; M. Sharpe, "In Harm's Way: Children's Environmental Health" (2002) 4:6 J.E.M. 93, online: J.E.M. <

http://www.rsc.org/delivery/_ArticleLinking/DisplayArticleForFree.cfm?doi=b210561f&JournalCode=EM> (last modified: December 2002).

⁵⁷ I. Kickbusch, *Health Promotion Glossary*, WHO, WHO/HPR/HEP/98.1 (1998).

⁵⁸ *The Environment and Health for Children and their Mothers*, WHO, (2005), online: WHO </br><www.who.int/mediacentre/factsheets/fs284/en/> (date accessed: 13 July 2008).

⁶⁰ National Cancer Institute of Canada, *Canadian Cancer Statistics Special Topic: Childhood Cancer (Ages 0 to 14)*, (2008), online http://www.cancer.ca/Canada-

wide/About%20cancer/Cancer%20statistics/Canadian%20Cancer%20Statistics/~/media/CCS/Canada%20wide/Files %20List/English%20files%20heading/pdf%20not%20in%20publications%20section/2008%20special%20topics%20 -CCS%20stats-English%20PDF_20526213.ashx> (date accessed: 2 January 2009).

cancer causing toxins, as well as reduced environmental tobacco smoke (ETS), chemical exposures (pesticides residues in foodstuff), and lead exposures. Over the last twenty years, childhood asthma cases have escalated fourfold, with twelve percent of Canadian children treated for asthma and 29,000 children hospitalized for asthma related illnesses.⁶¹

While it is important to acknowledge that environmental contaminants and hazards affect or induce adult morbidity and mortality, children's vulnerability is greater due to their disproportionately high exposure rate and biological susceptibility.⁶² This chapter examines how children are more vulnerable to the harmful effects of environmental hazards. Discussion will focus on the physiological and biological differences between children and adults, the exposure routes, and the conditions related to specific toxicants.

⁶¹ Canada, Environment Canada, "Children's Environmental Health" (2005), online < http://www.environment-canada.ca/EnviroZine/english/issues/20/feature2_e.cfm> (last modified: 21 May 2005).

 ⁶² P.J. Landrigan et al., "Children's Health and the Environment: A New Agenda for Prevention Research" (1998)
 106: Suppl 3 Environ. Health Perspect. 787, online: Environ. Health Perspect. <

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1533065/pdf/envhper00538-0017.pdf> (last modified: June 1998).

2.2.1 The Developmental Stages

During a child's transformation from fetus to young adult, he or she progresses through a number of developmental stages. These developmental stages of growth affect how, and with what impact, environmental exposures take place. While the terminology of children's environmental health indicates that the focus is merely on exposure while a child, literature on the topic has established that the concern extends beyond childhood ages.⁶³ Obviously exposure by a woman who is pregnant may affect the fetus. However, a mother's exposure prior to conception may as well. For instance, epidemiological studies have determined that preconceptional exposure to carcinogens during sperm or oocyte maturation may result in transgenerational carcinogenesis (one of the steps in transmission of tumor susceptibility).⁶⁴ Additionally a mother's exposure before conception may affect her future children. For instance, the grandmother's exposure may affect the mother's ovum formation during her fetal stage of development, which, in turn, may harm her fetus when she is pregnant.⁶⁵ Women exposed to PCBs prior to conception have been found to pass PCBs on to infants while breastfeeding due to the ability of PCBs to bioaccumulate in fatty tissue.⁶⁶ Adult onset of cancer may be a result of fetal or childhood exposures.⁶⁷ Japanese adults who are atomic bomb survivors have been found to have an increased risk of breast cancer, though exposed in childhood.⁶⁸ Because toxin exposure can occur prior to conception and throughout childhood, and evidence of harm may not be evident until adulthood, it is necessary that developmental stages of the child considered must extend from preconception to adulthood.

Literature on this topic tends to include preconception, fetus, infancy, toddler, young child, childhood, and adolescence.⁶⁹ However, slight definitional differences exist. For some studies, consideration of pregnancy is segregated into trimesters. Studies have found that due to the developmental differences between the first trimester and the second through third trimesters, exposure concerns differ. For instance, during the first trimester, the fertilized embryo undergoes periods of cell proliferation and tissue differentiation, essential to DNA synthesis.⁷⁰ The risk for cardiac defects has been associated with first trimester exposure to some herbicides and rodenticides, though

⁶⁷ *Cooper, supra* note 5 at 13.

⁶³*Wigle, supra* note 13, at 6; Canadian Partnership for Children's Health and Environment, "Child Health and the Environment – A Primer" (2005), online: C.P.C.H.E. <

http://www.healthyenvironmentforkids.ca/img_upload/13297cd6a147585a24c1c6233d8d96d8/Primer.pdf> (last modified: August 2005); *Cooper, supra* note 5 at 67.

⁶⁴ L.S. Birnbaum & S.E. Fenton, "Cancer and Developmental Exposure to Endocrine Disruptors" (2003) 111:4 Environ. Health Perspect. 389 at 390.

⁶⁵ C.F. Bearer, "Environmental Health Hazards: How Children Are Different from Adults" (1995) 5:11 Future Child. 11 at 14.

⁶⁶ W.J. Rogan & B.C. Gladen, "PCBs, DDE, and Child Development at 18 and 24 months" (1991) Ann. Epidemiol. 407 at 407.

⁶⁸A. Olshan et al., "Workshop to Identify Critical Windows of Exposure for Children's Health: Cancer Work Group Summary" (2000) 108:S3 Environ. Health Perspect. Supp., online: Environ. Health Perspect.
<www.ehp.org/members/2000/suppl-3/595-5970lshan/olshan-full.html> (date accessed: 19 November 2008); National Research Council, Committee on Biological Effects of Ionizing Radiation, *Health Effects of Exposure to Low Levels of Ionizing Radiation (BEIR V)* (Washington, D.C.: National Academy Press, 1990).

⁶⁹ Wigle, supra note 4; Cooper, supra note 5.

⁷⁰ Cooper, supra note 5 at 45.

not so in second or third trimesters.⁷¹ Throughout the pregnancy, exposure to environmental contaminants may occur since compounds are capable of crossing the placenta.⁷² It is thought that fat-soluble, lipophilic compounds (like that of polycyclic aromatic hydrocarbons and ethanol) are able to enter into the fetal circulation system.⁷³ Little is known as to what ability, if any, the fetus has to protect itself from this exposure.

The following subsections examine the developmental stages of infancy, toddler and young childhood, and adolescence, as these areas have been closely examined in epidemiological studies. Fetal exposure as well as adult onset of disease will be highlighted in the subsections dealing with the appropriate exposure pathways in the following section.

2.2.1.1 Infancy

Consideration of infancy by literature on children's environmental health includes that of the newborn age to six months and six months to one year of age.⁷⁴ Some prefer dividing the period of infancy between neonatal (up to one month) and postneonatal (one month to 1 year of age).⁷⁵ With either method of analysis, what is noteworthy are the ongoing developmental changes prior to one year of age. Infant growth is a period where the body undergoes rapid change, during which the organ systems are vulnerable and incapable of defence and repair of damage done.⁷⁶ Exposure pathways, such as lungs, skin, and digestive tract, are still developing, leaving the body's protective system less than optimal.⁷⁷ Examples of harm done during this time period are prevalent in the literature; lead absorption is a case in point. As an infant's body has a greater need for calcium during the developing months (this need continues into early childhood), absorption rates are greater.⁷⁸ If lead is introduced into the system, the body absorbs it believing it to be calcium. Because of this, an adult's body will take in ten percent of ingested lead, whereas a child who is two years of age will absorb fifty percent of lead introduced into the system.⁷⁹

Inhalation during infancy is different than in childhood and adulthood.⁸⁰ Infants and young children have a greater exchange of air than adults while having smaller lungs.⁸¹ The lung volume doubles within four months, and alveoli average half of that of an average adult.⁸² This higher surface to volume ratio provides a greater avenue for intake of

⁷⁶ P.J. Landrigan, "Children as a Vulnerable Population" (2004) 17:1 Int. J. Occup. Med. Tox. 175 at 176.

⁷⁹ *Ibid*. at 20.

⁷¹ Wigle, supra note 4 at 1.

⁷² Bearer, supra note 15 at 19.

⁷³ Ibid.

⁷⁴ Canadian Partnership, supra note 63.

⁷⁵ Wigle, supra note 4.

⁷⁷ *Bearer*, *supra* note 15 at 12.

⁷⁸ *Ibid*. at 18.

⁸⁰ E.E. Ziegler et al., "Absorption and Retention of Lead by Infants" (1978) 12:1 Pediatr. Res. 29 at 32.

⁸¹ W.S. Tyler et al., "Comparison of Daily and Seasonal Exposures of Young Monkeys to Ozone" (1988) 50:2 Toxicology 131 at 131.

⁸² A.A. Hislop, "Airway and Blood Vessel Interaction During Lung Development" (2002) 201:4 J. Anat. 325 at 330.

air pollutants.⁸³ Behavioural differences, such as hand-to-mouth, eating, and playing on the floor, result in a greater level of exposure and intake of pollutants.⁸⁴

Dermal exposure during infancy to pollutants and toxins is different than that of an adult or even a child. Young children and infants have a larger surface-to-volume ratio⁸⁵ and therefore may take in three times the exposed pollutant than that of an adult. Infant production of the thick dead cell layer of the epidermis (keratin) is not produced until three to five days following birth.⁸⁶ In pre-term infants, the susceptibility to absorption is even greater. A study of sodium salicylate (a non-steroidal anti-inflammatory drug (NSAID)) dermal exposure in preterm babies demonstrated that the absorption was greater in infants under thirty weeks of gestation⁸⁷ and that there was little formation of keratinized stratum corneum (thick exterior skin cells).⁸⁸

Other areas of dramatic development during infancy include that of the neurological system and the immune system. While neither acts as an exposure pathway like that of the digestive, respiratory, and dermal systems, the rapid development of these systems leaves them susceptible to permanent harm. Brain cells divide, migrate, differentiate, establish synaptic connections, and apoptosize during this developmental stage.⁸⁹ The head circumference of an infant increases on average 2 cm per month until two months of age, and 1.5 cm from two months to four months of age.⁹⁰ The posterior fontanel (a portion of the skull) does not close before the second month of infancy in order to allow for brain development. The blood-brain barrier, essential in the protection of the brain from pollutants, does not fully develop until about six months of age.⁹¹ Brain cells continue to increase in numbers for the first two years of life. A child's immune system is not yet fully formed, with TH-2 (humoral immunity dominant) and TH-1 (cellular immunity dominant) phenotypes development not occurring until three to five days after birth.⁹² Interruption during any one of these stages can cause irreparable harm.⁹³ Incidence of harm to brain function from exposure to alcohol⁹⁴, eETS⁹⁵, and lead⁹⁶ has been well documented.

⁸³ Wigle, supra note 4 at 13.

⁸⁴ V.M. Weaver, T.J. Buckley, & J.D. Groopman, "Approaches to Environmental Exposure Assessment in Children" 106:S3 Environ. Health Perspect. 827 at 827.

⁸⁵Wigle, supra note 4 at 165.

⁸⁶ Ibid.

⁸⁷ N. Barker, J. Hadgraft, & N. Rutter, "Skin Permeability in the Newborn" (1987) 88:4 J. Invet. Dermatol. 409 at 409.

⁸⁸ K.T. Hoang, *Dermal Exposure Assessment: Principles and Applications* (Washington, D.C.: U.S. Environmental Protection Agency, 1992) (EPA/600/8-91/011B) at 30.

⁸⁹ T. Schettler, "Toxic Threats to Neurologic Development of Children" (2001) 109:6 Environ. Health Perspect. 813 at 817.

⁹⁰ "Developmental Milestones" (Washington, D.C.: NICHCY), online: NICHCY

<http://www.nichcy.org/Disabilities/Milestones/Pages/Default.aspx> (date accessed: 16 October 2008); "Developmental Milestones" (Ann Arbor, MI: University of Michigan Health System), online: University of Michigan <http://www.med.umich.edu/yourchild/topics/devmile.htm> (date accessed: 16 October 2008).

⁹¹ *Cooper, supra* note 5 at 46.

⁹² J. Schwartz, "Air Pollution and Children's Health" (2004) 113:4 Pediatrics 1037 at 1037.

⁹³ Landrigan 2004b, supra note 76 at 176; Schettler, supra note 89 at 816.

2.2.1.2 Toddler And Childhood

There is a continuation of growth and maturation from toddler to that of child. As with the infant, lung capacity, neurological and immune system function, digestive faculty, and dermal protection is developing. External physical change takes place as the toddler is able to crawl and walk, and head weight and body length shift to become more proportionally similar to that of an adult.⁹⁷

Many of the developmental concerns present later in infancy are also common in toddler and early childhood development. Although physiological differences play a part in exposure, behavioural differences have been found to result in greater susceptibility.⁹⁸ As the infant grows, mobility, and therefore pathway exposure, increases. Hand-to-mouth behaviour, crawling, and increased touching of objects are just a few of the ways that toddlers are exposed to different contaminants than an infant is. Additionally, it is at this point in childhood that outdoor exposure may increase and the child is introduced to new indoor environments, such as in daycare and school.

The US National Academy of Science, in the publication *Pesticides in the Diets of Infants and Children* [hereinafter *NAS report*], found that though children may be physically more susceptible to contaminants, it is the difference in exposure that more often leads to a greater intake of pesticides.⁹⁹ The average child between the ages of one and five will take in three to four times more food per unit of body weight than an adult.¹⁰⁰ Not only does the amount of consumption differ, but so does the diet. Children tend to eat more milk, dairy, vegetables, fruits, and soft drinks than adults.¹⁰¹

⁹⁷ R. Tomanari, "Stages of Growth Child Development-Early Childhood (Birth to Eight Years), Middle Childhood (Eight to Twelve Years)" (State University), online: StateUniversity.Com < http://education.stateuniversity.com/pages/1826/Child-Development-Stages-Growth.html> (date accessed: 15 November 2008); U.S., Department of Education "Goals 2000:Reforming Education to Improve Student Achievement" (Washington, D.C.: Department of Education, 1998), online: US Department of Education <htp://www.ed.gov/pubs.G2KReforming/> (date accessed: 15 November 2008).

⁹⁸ Sharpe, supra note 56 at 93.

⁹⁹ National Research Council, *Pesticides in the Diets of Infants and Children*, (Washington, D.C.: National Academy Press, 1993) at 4.

¹⁰⁰ Sharpe, supra note 56 at 94.

¹⁰¹ Children's Environmental Health Network, *A Child-Safe U.S. Chemical Policy*, (Washington, D.C.: C.E.H.N., 2007), online: C.E.H.N. < http://www.cehn.org/Child_Safe_Chemicals_Policy_may_2_2007.htm> (last updated: 10 May 2007); *Wargo, supra* note 26 at 6.

⁹⁴ C.R. Goodlett, B.L. Marcussen, J.R. West, "A Single Day of Alcohol Exposure During the Brain Growth Spurt Induces Brain Weight Restriction and Cerebellar Paurkinje Cell Loss" (1990) 7:2 Alcohol 107 at 107.

⁹⁵ J.R. DiFranza, C.A. Aligne, & M. Weitzman, "Prenatal and Postnatal Environmental Tobacco Smoke Exposure and Children's Health" (2004) 113:4 Pediatrics 1007 at 1007.

⁹⁶ P.M. Lavoie & B. Bailey, "Lead Poisoning from "Lead-Free" Paint" (2004) 170:6 Can. Med. Assoc. J. 956 at 956; D.R. Brown, "Neonatal Lead Exposure in the Rat: Decreased Learning as a Function of Age and Blood Lead Concentrations" (1975) 32:3 Toxicol. Appl. Pharmacol. 628 at 628; T.I. Lidsky & J.S. Schneider, "Lead Neurotoxicity in Children: Basic Mechanisms and Clinical Correlates" (2003) 126:1 Brain 5 at 5.

Evidence indicates that a toddler's or young child's exposure to some contaminants may be greater because of increased time spent on the floor or other indoor surfaces.¹⁰² An adult's breathing space is on average four to six feet from the ground, whereas the child's is much closer to the ground.¹⁰³ Chemicals such as polyvinyl chloride (PVCs) found in vinyl flooring, insecticides used to control indoor pests, and pesticides in lawns are inhaled because of this close exposure.¹⁰⁴ A well documented case of inhalation of mercury by a young child when exposed to interior latex paint occurred in Michigan. The four-year-old boy was diagnosed with acrodynia (which means "painful extremities"), a rare form of mercury poisoning, following the application of 17 gallons of paint that exceeded US Environmental Protection Agency's (US EPA) standards for mercury (used as a paint preservative). Other family members were asymptomatic. A number of factors influenced the young boy's greater inhalation of mercury over that of other family members. As a toddler, his indoor environment was most often confined to the house. Secondly, at this age, a child is mobile and often spends a great deal of time on the ground surface where there was a larger concentration of mercury vapour because it is heavier than air.¹⁰⁵ And lastly, the child's intake of air per unit of body weight was greater than that an adult.

2.2.1.3 Adolescence

During adolescence, the body is more prepared for exposure to environmental hazards due to the increased lung function, developed dermal system, and matured neurological system. However, the body is undergoing many changes which cause it to be more susceptible to harm. It is during this period that fertility (production of viable gametes) and a mature reproductive state through the development of secondary sex characteristics are achieved. Simultaneously, the body undergoes growth of skeleton, muscle, and viscera, and experiences changes in muscle and fat composition.¹⁰⁶

It is during adolescence that certain effects of earlier exposure may be visible. Early onset of puberty and precocious puberty has both been linked with environmental hazards. Medical research has traditionally held that less than one percent of girls show signs of puberty (breast development or growth of pubic hair) before the age of eight years.¹⁰⁷ Yet, recent studies have indicated that there may be a clear shift in these numbers. Herman-Giddens et al. found that

http://library.med.utah.edu/kw/human_reprod/lectures/pubertal_midlife/> (last accessed: 4 November 2008).

¹⁰² U.S., Environmental Protection Agency, *A Decade of Children's Environmental Health Research: Highlights* from EPA's Science to Achieve Results Program, (Washington, D.C.: U.S. Environmental Protection Agency, 2007) at 22.

¹⁰³ Bearer, supra note 65 at 12.

¹⁰⁴ *Ibid; Sharpe, supra* 56 at 94; *Wigle, supra note* 4 at 11-12.

¹⁰⁵ P.S. Guzelian, C.J. Henry, & S.S. Olin *Similarities and Differences Between Children and Adults: Implications for Risk Assessment* (Washington, D.C.: ILSO Press International Life Sciences Institute, 1992).

¹⁰⁶ S. Milligan, "Reproductive Life History" (London: King's College London, 2003), online: King's College London

<http://209.85.173.132/search?q=cache:54jflu_SYdYJ:www.kcl.ac.uk/depsta/biomedical/stuartmilligan/ppt/pubbscsh .pps+reproductive+life+history+powerpoint+puberty&hl=en&ct=clnk&cd=1> (date accessed: 14 November 2008); K. Parker Jones, *The Beginning and End of Reproductive Life: Pubertal and Midlife Changes* (Salt Lake: University of Utah College of Medicine, 1987), online: U of U College of Medicine <

¹⁰⁷ J.C. Rockett, C.D. Lynch, & G.M. Buck, "Biomarkers for Assessing Reproductive Development and Health: Park 1 – Pubertal Development" (2004) 112:1 Environ. Health Perspect. 105 at 105.

girls in the United States are developing pubertal characteristics as young as three-years-old (one to three percent), and 6.7 to 27.2 percent of girls are developing pubertal characteristics by age seven.¹⁰⁸ Further research in the area has found that exposure to mycoestrogens (mycoestrogen zearalenone (ZEA)) and other estrogen disrupter pollution present in organochlorine pesticides, polychlorinated biphenyls, bisphenol-A, alkylphenolic chemicals, and some fungicides¹⁰⁹, may produce central precocious puberty.¹¹⁰ Though research has begun to make progress on determining the cause-and-effect of precocious puberty, there remain a number of gaps in knowledge. One reason for this is that puberty is a multifaceted process and has a multitude of triggers.¹¹¹ Furthermore, the exposures may have occurred earlier in life but take effect with the onset of puberty. Interestingly, rather than early onset of puberty, the Third National Health And Nutrition Examination Survey (NHANES III) found a link between lead levels and delayed first menstrual period and pubic hair for girls.¹¹²

Adolescence is more than the onset of puberty. It is a time of change in behaviours, settings, and the introduction of the workplace environment. An increase in choice provides adolescents with greater exposure and accidental injury.¹¹³ This may include illegal drug and alcohol consumption, as well as increased use of prescription pharmaceuticals.¹¹⁴ One example of poor behavioural choices that resulted in pollutant exposure was shown when some children in Hamilton, Ontario, broke into a metal recycling plant and removed mercury and other materials from the site in September 1993. Nearly 300 children displayed physical signs of mercury exposure.¹¹⁵ These changes in ingestion and inhalation may alter the affects of environmental exposures.¹¹⁶ This is often a time when adolescents begin to work, therefore incorporating another indoor or outdoor environment.¹¹⁷ Though occupational

¹¹² National Center for Health Statistics, *Third National Health and Nutrition Examination Survey (NHANES III) Public-Use Data Files* (Washington, D.C.: Center for Disease Control, 2008), online: CDC
http://www.cdc.gov/nchs/products/elec_prods/subject/nhanes3.htm> (last modified: 2 November 2008); *Rockett, supra* note 107 at 105; T. Wu, G.M. Buck, & P. Mendola, "Blood Lead Levels and Sexual Maturation in US Girls: The Third National Health and Nutrition Examination Survey, 1988-1994" (2003) 111:5 Environ. Health Perspect. 737 at 739.

¹¹³ M.S. Golub, "Adolescent Health and the Environment" (2000) 108:4 Environ. Health Perspect. 355 at 356.

¹¹⁴ *Cooper, supra* note 5 at 47; S.G. Millstein et al., "Health-risk Behaviors and Health Concerns Among Young Adolescents" (1992) 89:3 Am. Acad. Pediatrics 422 at 422.

¹¹⁵ L. George et al., "The Mercury Emergency in Hamilton School Children: A Follow-Up Analysis" (1996) 87:4 Can. J. Public Health 224 at 224.

¹¹⁶ *Golub*, *supra* note 113 at 356.

¹⁰⁸ M.E. Herman-Giddens et al., "Secondary Sexual Characteristics and Menses in Young Girls Seen in Office Practice: A Study from the Pediatric Research in Office Settings Network" (1997) 99:4 Pediatrics 505 at 507; *Rockett, supra* note 107 at 105; R.L. Rosenfield et al., "Current Age of Onset Puberty", (2000) 106:3 Pediatrics 622 at 622; R.Y. Wang, L.L. Needham, & D.B. Barr, "Effects of Environmental Agents on the Attainment of Puberty: Considerations When Assessing Exposure to Environmental Chemicals in the National Children's Study" (2005) 113:8 Environ. Health Perspect. 1100 at 1100.

¹⁰⁹ C.R. Tyler, S. Jobling, & J.P Simpter, "Endocrine Disruption in Wildlife: A Critical Review of the Evidence" (1998) 28:4 Crit. Rev. Toxicol. 319 at 320.

¹¹⁰ F. Massart et al., "High Growth Rate of Girls with Precocious Puberty Exposed to Extrogenic Mycotoxins" (2008) 152:5 J. Pediatr. 690 at 690.

¹¹¹ *Rockett, supra* note 107 at 105.

¹¹⁷ Canadian Partnership, supra note 63.

environmental health is often addressed by governments, the thresholds for standards are set for adults, not developing children.

2.2.2 Exposure Pathways

The prior section highlighted that exposure to contaminants at different developmental stages may affect the health outcomes from that exposure. As the child matures the body gains capacity to defend itself against pollutants. Nevertheless, the exposure pathways influence health outcomes even into adulthood. This section provides a general outline of how infants, children, and adults come into contact with environmental contaminants.

The World Health Organization has stressed that environmental contaminants are only one factor affecting health outcomes. Social, cultural, educational, and occupational settings play important roles. Some examples include:

- Pesticide exposure has been found to be higher for those who live in rural areas.¹¹⁸
- Exposures to chemical by-products are greater for adults who have industrial occupations.¹¹⁹
- Where schools are located plays an essential role in how much pollution exposure a child has.
 Unfortunately, schools are often built on land sites which were considered unattractive for living or office space.¹²⁰
- Economic status, and the often closely related topic of access to health services, commonly affects health outcomes. Low-income housing developments are often crowded and may be infested with pests. Use of pesticides and insecticides are often the first line of defense by landlords in these circumstances.¹²¹
- First signs of disease may be neglected due to healthcare costs, particularly where a government supported health care system is not in place.
- Health outcomes are also affected by gender, biology, and genetics.

Primary mediums of exposure identified by the US EPA are outdoor air, indoor air, food, drinking water and soil.¹²² These exposure pathways are based on ingestion, inhalation, and dermal exposure. Relevant examples of such will

¹¹⁸ T.E. Arbuckle, Z. Lin, & L.S. Mery, "An Exploratory Analysis of the Effect of Pesticide Exposure on the Risk of Spontaneous Abortion in an Ontario Farm Population" (2001) 109:8 Environ. Health Perspect. 851 at 851; L.S. Azaroff, "Biomarkers of Exposure to Organophosphorous Insecticides Among Farmers' Families in Rural El Salvador: Factors Associated with Exposure" (1999) 80:2 Environ. Res. 138 at 138; J.S. LaKind et al., "Methodology for Characterizing Distributions of Incremental Body Burdens of 2,3,7,8-TCDD and DDE from Breast Milk in North American Nursing Infants" (2000) 59:8 J. Toxiocol. Env. Health Part A 605 at 605; *Wigle, supra note 4* at 171.

¹¹⁹ Arbuckle, supra note 118 at 851; Wigle, supra note 4 at 304-306; T.E. Arbuckle & L.E. Sever, "Pesticide Exposures and Fetal Death: A Review of the Epidemiologic Literature" (1998) 28:3 Crit. Rev. Toxicol. 229 at 262.

¹²⁰ S.K. Cummins & R.J. Jackson, "The Built Environment and Children's Health" (2001) 48:5 Pediatr. Clin. N. Am., online: Pediatr. Clin. N. Am. < http://bhn.arizona.edu/files/resources/builtenvironment.pdf> (date accessed: 10 October 2008).

¹²¹ V.A. Rauh, G.L. Chew, & R.S. Garfinkel, "Deteriorated Housing Contributes to High Cockroach Allergen Levels in Inner-City Households" (2002) 110:2 Environ. Health Perspect. Supps. 323 at 327; S. Srinivasan, L.R. O'Fallon, & A. Dearry, "Creating Healthy Communities, Healthy Homes, Healthy People: Initiating a Research Agenda on the Built Environment and Public Health" (2003) 93:9 Am. J. Public Health 1446 at 1447.

¹²² E. Flynn et al., *Indoor Air Pollutants Affecting Child Health*, (Washington, D.C.: U.S. Agency for Toxic Substances and Disease Registry, 2000) at 11; *Cooper, supra* note 5.

be outlined below. However, it is important to note, as mentioned before, that during the stages of preconception and fetal development, exposure may take place through the ingestion, inhalation, or dermal exposure of the mother or father. The mothers' exposure through ingestion, inhalation, or absorption to pollutants may cross into the placenta and expose the fetus. Additionally, exposures to toxins prior to pregnancy that may be retained in fatty tissue may be released during pregnancy as the woman's body uses up this tissue for nourishment. For instance, lead, retained in bone marrow, may be released during the third trimester of pregnancy when bone turnover increases.¹²³

Health Canada has outlined specific exposure pathways for each medium of exposure. This includes inhalation, skin contact, and ingestion. Inhalation is defined by Health Canada as breathing in a substance such as gas, vapour, or airborne particles. Skin contact is considered as a pathway since water, soil, and air can be absorbed through the dermal layer. Ingestion is the swallowing of something containing a contaminant, during which the mouth, throat, stomach, and/or intestines can absorb the toxins.¹²⁴

2.2.2.1 Outdoor Air

Outdoor air pollution is taken into the body in two ways– inhalation and absorption. Exposure to air pollutants occurs during the fetal stage as well as from infancy through adulthood. Studies indicate that outdoor air pollution is positively associated with morbidity and mortality rates in both adults and children. Historical case studies have illustrated the harmful effects that may result from prolonged exposure. In Meuse Valley, Belgium (1930), Donora, Pennsylvania (1948), and London, United Kingdom (1952), change in weather pattern resulted in high levels of particulate matter trapped in one area.¹²⁵ In each of these cases, deaths for the total population from respiratory conditions increased as did deaths from other causes with respiratory complications.¹²⁶

Specific air pollutants of concern include ozone, carbon monoxide, nitrogen oxide, sulphur dioxide, total suspended particulate¹²⁷, and particulate matter (PM). Toxic metals, such as lead, cadmium, and copper, are also often measureable in air. Inhalation of pesticides and chemicals may also occur. Major sources of air emissions are automobiles, industry, burning of coal and oil, combustion, and solvents.

¹²³ Commission for Environmental Cooperation, *Children's Health and the Environment in North America; A First Report on Available Indicators and Measures*, (Quebec: Secretariat – Commission for Environmental Cooperation, 2006), online: C.E.C. < http://www.cec.org/files/PDF/POLLUTANTS/CEH-Indicators-fin_en.pdf > (last modified: 10 February 2008); E.K. Silbergeld, "Lead in Bone: Implications for Toxicology During Pregnancy and Lactation" (1991) 91 Environ. Health Perspect. 63 at 66.

¹²⁴ Canada, *Investigating Human Exposure to Contaminants in the Environment: A Handbook for Exposure Calculations* (Ottawa: Minister of National Health and Welfare, Minister of Supply and Services Canada, 1995), online: Health Canada < http://dsp-psd.pwgsc.gc.ca/Collection/H49-96-1-1995E-1.pdf> (date accessed: 12 November 2008).

¹²⁵ J. Schwartz, "What Are People Dying of on High Air Pollution Days?" (1994) 64:1 Environ. Res. 26 at 26.

¹²⁶ Schwartz, supra note 92 at 26-27.

¹²⁷ Total suspended particulate (tsp) was replaced in 1987 by the US EPA with particulate matter (PM-10) which is a measurement of smaller particles. Particulate matter is a measurement of molecules of solid or gas pollution.; U.S., Environmental Protection Agency, "Particulate Matter (PM-10)" (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency < http://www.epa.gov/airtrends/aqtrnd95/pm10.html> (lasted modified: 21 May 2009).

Literature on health conditions due to air pollution hold that exposure may increase infant mortality and incidence of upper and lower respiratory infections in children.¹²⁸ Infant health, such as birth weight, appears to be associated with air pollutants, particularly exposure during prenatal or neonatal development to carbon monoxide.¹²⁹ There is some indication that concentrations of elevated particulate matter PM-10¹³⁰, though not PM-2.5, may be related to sudden infant death syndrome (SIDS).¹³¹ Observed ill-health effects in children have been linked to increased levels of PM-2.5, PM-10, nitrogen oxide, and sulphur dioxide. Respiratory diseases often associated with air pollution are pneumonia, acute bronchitis, and asthma.¹³² There is an indication of increased asthma in Canada, where twelve percent of children, approximately one million, have been diagnosed. This is four times more children than were diagnosed with asthma in Canada twenty years ago.¹³³ Research suggests that childhood asthma has increased due to air pollution, specifically exposure to PM, nitrogen oxide, and sulphur dioxide.¹³⁴ Even neglect diagnosis twenty-five years ago would not explain this disparity.

While infants have a more limited exposure to outdoor air, there is a diversification of inhalation areas for toddlers, children, and adolescents, as mobility and transportation increases with daycare, school, and work. Studies indicate that there is an association between traffic-related air pollution and coughing, though this appears to decrease with age.¹³⁵ Traffic density, air composition, and the percentage of time downwind influence the components of air pollution that affect children during transport to school.¹³⁶ Health complications of traffic related exposure include

¹³¹ Woodruff 1997, supra note 128 at 610-611; Woodruff 2006, supra note at 786.

¹²⁸ J. Currie & M. Neidell, "Air Pollution and Infant Health: What Can We Learn from California's Recent Experience?" (2005) 120:3 Q. J. Econ. 1003 at 1011; K.R. Smith et al., "Indoor Air Pollution in Developing Countries and Acute Lower Respiratory Infections in Children" 2000 55:6 Thorax 518 at 520; *Schwartz, supra* note 92 at 5; T.J. Woodruff, J.D. Parker, & K.C. Schoendorf, "Fine Particulate Matter (PM2.5) Air Pollution and Selected Causes of Postneonatal Infant Mortality in California" (2006) 114:5 Environ. Health Perspect. 786 at 788; T.J. Woodruff, J. Grillo, & K.C. Schoendorf, "The Relationship Between Selected Causes of Postneonatal Infant Mortality and Particulate Air Pollution in the United States" (1997) 105:6 Environ. Health Perspect. 608 at 608.

¹²⁹ *Woodruff 1997, supra* note 128 at 608; B. Ritz & F. Yu, "The Effect of Ambient Carbon Monoxide on Low Birth Weight Among Children Born in Southern California Between 1989 and 1993" (1999) 107:17 Environ. Health Perspect. 17 at 22.

¹³⁰ Particulate matter is defined as PM-10 or PM-2.5 determined by an aerodynamic diameter of 10 micrometers (PM-10) or a particle less than 2.5 micrometers (PM-2.5); U.S., Environmental Protection Agency, "Particulate Matter" (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency < http://www.epa.gov/airtrends/pm.html> (last modified: 6 October 2009).

¹³² D.V. Bates, "The Effects of Air Pollution on Children" (1995) 103:S6 Environ. Health Perspect. Supps. 49 at 49;
C. Braun-Fahrlander et al., "Air Pollution and Respiratory Symptoms in Pre-School Children" (1990) 45:5 Arch.
Environ. Health; C.A. Pope, III, "Respiratory Hospital Admissions Associated with PM10 Pollution in Utah, Salt Lake, and Cache Valleys" (1991) 46:2 Arch. Environ. Health 90 at 90.

¹³³ Canadian Partnership, supra note 63.

¹³⁴A.G. Barnett et al., "Air Pollution and Child Respiratory Health: A Case-Crossover Study in Australia and New Zealand" (2005) 171:11 Am. J. Resp. Crit. Care 1271 at 1274; *Pope 1991, supra* note 132 at 90; *Schwartz, supra* note 92 at 6.

¹³⁵ U. Gehring et al., "Traffic-Related Air Pollution and Respiratory Health During the First 2 Yrs of Life" (2002) 19:4 Eur. Respir. J. 690 at 690, 695-6.

¹³⁶ Schwartz, supra note 92 at 1039.

allergic rhinitis, wheezing, and allergic reactions (to pollen, house dust mites, milk, and/or eggs).¹³⁷ The method of transportation, i.e. automobile or bus, appears to influence ill-health effects. The University of California, Los Angeles (UCLA) Children's School Bus Exposure Study found that diesel related pollutant (DRP) concentrations from self pollution were in fact higher when bus windows were closed or children were in older buses.¹³⁸

Inhalation of hard metals, pesticides, and chemicals in outdoor air are also a concern. Children at play are often exposed to chemicals used to treat wood playground equipment¹³⁹ or insecticides that have been used at school to prevent rodent infestation¹⁴⁰. Children tend to play outside in the afternoon which is the time that ozone levels are the highest.¹⁴¹ Although there has been a decrease in the number of American children living in locations where one or more measured air pollutants exceeded national air quality (down from 28 to 24 percent from 1990 to 1998)¹⁴², the increase in asthma rates indicates that the problem is far from solved.

¹³⁷ U. Krämer et al., "Traffic-Related Air Pollution is Associated with Atopy in Children Living in Urban Areas" (2000) 11:1 Epidemiology 64 at 64.

¹³⁸ L.D. Sabin, "Characterizing the Range of Children's Air Pollutant Exposure During School Bus Commutes" (2005) 15 J. Expo. Anal. Environ. Epidemiol. 377 at 377 & 378; "Children's Exposures Due to School Bus Commutes: Results from the Recent ARB-Sponsored Study" (Air Resources Board, California Environmental Protection Agency, 20 November 2003), online: CA Environmental Protection Agency < ftp://ftp.arb.ca.gov/carbis/research/health/healthup/nov03.pdf> (last modified: 20 November 2003).

¹³⁹ *Goldman, supra* note 6 at 443; H.F. Hemond & H.M. Solo-Gabriele, "Children's Exposure to Arsenic from CCA-Treated Wooden Decks and Playgrounds Structures" (2004) 24:1 Int. J. 51 at 51; R. Jagels, "Health Hazards of Natural and Introduced Chemical Components of Boatbuilding Woods" (1985) 8:3 Am. J. Ind. Med. 241 at 242.

¹⁴⁰ *Cooper, supra* note 5 at 303-304.

¹⁴¹ *Ibid.* at 305.

¹⁴²Sharpe, supra note 56 at 95.

2.2.2.2 Indoor Air

Indoor air makes up a large part of our built environment. With people spending over ninety percent of their time indoors¹⁴³, it is a necessary component of consideration when analyzing children's environmental health. While both adults and children spend a great deal of time indoors, their exposure differs in many ways. As mentioned before, children have a lower inhalation space, therefore breathing in toxins from at ground level at a higher rate than adults.¹⁴⁴ Infants and toddlers are often placed on the floor and ingest, inhale, and absorb chemicals associated with vinyl flooring and carpeting, such as volatile organic chemicals and formaldehyde. Pesticides used on indoor perimeter areas, such as flea bombs, emit chemicals inhaled by infants and small children at play on the ground.¹⁴⁵ Furthermore, while adults tend to work in office space or manufacturing areas governed by occupational policy, children are often educated in school buildings that lack appropriate ventilation systems¹⁴⁶, are built near landfills¹⁴⁷, or are substandard structures.¹⁴⁸ Whereas ventilation regulations pertaining to industrial buildings are under federal mandate, state and local building codes govern over school systems. Often responsibility for implication of building codes lies with local school boards and is poorly regulated. In 1999, a sample survey in New York City found that many public schools exposed children to a number of hazards, including lead.¹⁴⁹ Similarly, a 1998 survey conducted by California Department of Health Services found seventy-eight percent of public schools contained lead paint, thirty-eight percent of the public schools had flaking or peeling lead paint, and eighteen percent had water-lead levels that exceeded US EPA drinking water standards.¹⁵⁰ Poor air quality has been a result of prior recommendations by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) that reduced classroom size during the 1930s and again in 1973 due to high heating costs. Revision of this recommendation to increase classroom size to a minimum of 15 cubic foot per minute per person (cfm/person) was made in direct response to poor indoor air quality. However, many schools remain at ventilation rates of 5 cfm/person or less.¹⁵¹

Lead is only one of the indoor pollutants to which infants and children may be exposed. Other contaminants include molds, carbon monoxide, pesticides, home products (shampoo, cosmetics, etc.), and chemical household cleaners.

¹⁴⁹ *Ibid*.

¹⁴³ P. Beamer, A. Castano, & J.O. Leckie, "Vertical Profile Particulate Matter Measurements in a California Daycare" (2002) Proceedings: Indoor Air 103 at 103.

¹⁴⁴ *Wigle, supra note 4* at 11-12.

¹⁴⁵ Bearer, supra note 15 at 15.

¹⁴⁶ G. Smedje, D. Norback, & C. Edling, "Asthma Among Secondary Schoolchildren in Relation to the School Environment" (1997) 27:11 Clin. Exp. Allergy 1270 at 1271.

¹⁴⁷ M. Pastor, Jr., J.L. Sadd, & R. Morello-Frosch, "Who's Minding the Kids? Pollution, Public Schools, and Environmental Justice in Los Angeles" (2002) 83:1 Soc. Sci. Quarterly 263 at 263-264.

¹⁴⁸ *Cummins*, *supra* note 120.

¹⁵⁰ Ibid; California Department of Health Services, "Lead Hazards in California's Public Elementary Schools and Child Care Facilities: Report to the California State Legislature", online: CA DHS http://www.cdph.ca.gov/programs/CLPPB/Pages/default.aspx (date accessed: 20 November 2008).

¹⁵¹ U.S. Environmental Protection Agency, "IAQ Reference Guide Appendix C – Codes and Regulations", online: US EPA <http://www.epa.gov/iaq/schools/tfs/guidec.html#Ventilation-Related%20Regulations> (last modified: 23 December 2007).

Building materials, such as asbestos and formaldehyde, may be inhaled or absorbed by children. Dust mites, pet dander, and tobacco smoke may be part of the indoor air; but these aspects are typically outside the control of legislation and are within the realm of individual choice, and cannot be discussed within the context of this thesis.¹⁵²

Literature indicates that lead exposure is still a concern for children's health. Though lead content in gasoline and paint has been prohibited in many nations, inhalation, absorption, and ingestion of lead still occurs. Often this is a result of lead paint used in older homes in disrepair.¹⁵³ It is one of the earliest contaminants recognized as harmful to children. Exposure to lead as an infant or child has been shown to negatively affect behaviour and intelligence and cause learning disabilities, microcytic anemia, and reduced growth.¹⁵⁴ Different families restoring pre-1930s homes are at risk.

While the air pollutant carbon monoxide is often associated with outdoor air pollution, it is also a negative component of indoor air quality. Unlike ozone, which has a half-life and high reactivity and dissipates in seven to ten minutes¹⁵⁵, PM, carbon monoxide, and nitrogen oxide are present indoors. Carbon monoxide tends to be one of the more concerning gases indoors due to the use of biomass fuels to heat and cook in many nations. While the jurisdictions considered in this thesis do not typically utilize biomass fuels, wood stoves are still a large component of heating within some of these locales.¹⁵⁶ Carbon monoxide has long been associated with mortality, due to its interference with oxygen transport to the tissues.¹⁵⁷ More recent studies have indicated that carbon monoxide is associated with infant mortality¹⁵⁸, low birth weight¹⁵⁹, and intrauterine growth retardation in rats¹⁶⁰. Housing developments located near heavy traffic areas are often are exposed to carbon monoxide. This is commonly affiliated with low-income housing since these developments are frequently constructed in areas near traffic – areas that are

¹⁵² With regards to environmental tobacco smoke, England has taken action to prevent foster children from exposure by prohibiting any new placements with carers who smoke. M. Horne, "Smoking Foster Carers to Lose Kids" *The Sunday Times* (9 April 2006), online: Sunday Times <

http://www.timesonline.co.uk/tol/news/uk/scotland/article703574.ece> (last modified: 9 April 2006).

¹⁵³ Srinivasan, supra note 121 at 153.

¹⁵⁴ J.M. Burns et al., "Lifetime Low-Level Exposure to Environmental Lead and Children's Emotional and Behavioral Development at Ages 11-13 Years: The Port Pirie Cohort Study" (1999) 149:8 Am. J. Epidemiol. 740 at 747; *Cummins, supra* note 120; M. Smith et al., "The Effects of Lead Exposure on Urban Children: The Institute of Child Health/Southhampton Study" (1983) 47:1 Dev. Med. Child Neurol. Suppl. 1 at 1.

¹⁵⁵ Schwartz, supra note 92 at 1038; C.J. Weschler, "Ozone in Indoor Environments: Concentration and Chemistry" (2000) 10:4 Indoor Air 269 at 271.

¹⁵⁶ W.C. Maier et al., "Indoor Risk Factors for Asthma and Wheezing Among Seattle School Children" (1997) 105:2 Environ. Health Perspect. 208 at 211.

¹⁵⁷ L.J. Folinsbee, "Human Health Effects of Air Pollution" (1993) 100:45 Environ. Health Perspect. 45 at 48.

¹⁵⁸ Currie, supra note 128 at 1008.

¹⁵⁹ *Ritz, supra* note 129 at 22.

¹⁶⁰ D.J. Garvey & L.D. Longo, "Chronic Low Level Maternal Carbon Monoxide Exposure and Fetal Growth and Development" (1978) 19:1 Biol. Reprod. 8 at 12.

considered less than attractive to those with the economic capacity to be selective.¹⁶¹ Differentiation between indoor and outdoor exposure of carbon monoxide is difficult for studies and results in knowledge gaps.

Indoor pesticide and chemical exposure has been linked with fetal deaths¹⁶², birth defects¹⁶³, limb anomalies¹⁶⁴, orofacial clefts¹⁶⁵, cancers¹⁶⁶, immunological disorders¹⁶⁷, reproductive anomalies¹⁶⁸, neurological disorders¹⁶⁹, and behavioural disorders¹⁷⁰. Within the United States, pesticides are used in over ninety percent of homes.¹⁷¹ If not applied in accordance with instructions, pesticides can remain in the indoor environment for weeks, months, or years.¹⁷² Due to the runoff of pesticides and insecticides on nearby farms, contaminated soil is brought indoors through footwear and clothing. Additionally, these pollutants are absorbed by soil and transported into the water system.¹⁷³ Evidence indicates that those children who reside near agricultural areas have greater exposure than those in urban settings.¹⁷⁴ Although increased exposure for children near agricultural areas occurs outdoors, it is also elevated indoors when one or more of the parents are employed in agriculture. Household dust and soil samples taken from families employed in farm work in Washington State tested for organophosphorous (OP) insecticides contained higher levels of toxins than comparative households nearby.¹⁷⁵ This indoor contamination occurs through transport of outdoor soil to indoor floors and work clothes brought indoors.¹⁷⁶ Although exposure is unavoidable in

¹⁶⁵ *Ibid*.

¹⁷⁰ Wigle, supra note 4 at 5.

¹⁷¹ B. Eskenazi et al., "Methodologic and Logistic Issues in Conducting Longitudinal Birth Cohort Studies: Lessons Learned from the Centers for Children's Environmental Health and Disease Prevention Research" (2005) 113:10 Environ. Health Perspect. 1419 at 1423; P.J. Landrigan, "Risk Assessment for Children and Other Sensitive Populations" (1999) 895:1 Ann. N.Y. Acad. Sci. 1 at 3.

¹⁷² C. Baum & M. Shannon, "Environmental Toxins: Cutting the Risks" (1995) 12:7 Contemp. Pediatr. 20 at 20; *Flynn, supra* note 122 at 131.

¹⁷³ In many jurisdictions, drinking water warnings are broadcast due to agricultural runoff. R. Kellogg et al., "Environmental Indicators of Pesticide Leaching and Runoff from Farm Fields" (Agricultural Productivity: Data, Methods, and Measures, Washington, D.C., 9-10 March 2000), online: U.S. Department of Agriculture < http://www.nrcs.usda.gov/technical/NRI/pubs/eip_pap.html> (last modified: March 2000).

¹⁷⁴ N.J. Simcox et al., "Pesticides in Household Dust and Soil: Exposure Pathways for Children of Agricultural Families" (1995) 103:12 Environ. Health Perspect. 1126 at 1126.

¹⁷⁵ *Ibid.* at 1133.

¹⁷⁶ *Ibid.* at 1126.

¹⁶¹ S.A. Bashir, "Home Is Where the Harm Is: Inadequate Housing as a Public Health Crisis" (2002) 92:5 Am. J. Public Health 733 at 733.

¹⁶² T.E. Arbuckle et al., "Exposure to Phenoxy Herbicides and the Risk of Spontaneous Abortion" (1999) 10:6 Epidemiology 752 at 752.

¹⁶³ Arbuckle 1998, supra note 119 at 230.

¹⁶⁴*Ibid*.

¹⁶⁶ Wigle, supra note 4 at 169-170.

¹⁶⁷*Flynn, supra* note 122 at 6 and 116.

¹⁶⁸ *Wigle, supra* note 13 at 168-169.

¹⁶⁹ R.A. Fenske et al., "Lessons Learned for the Assessment of Children's Pesticide Exposure: Critical Sampling and Analytical Issues for Future Studies" (2005) 113:10 Environ. Health Perspect. 1455 at 1456; *Schettler, supra* note 89 at 815.

agricultural regions, evidence indicates that it is unjustifiably high in some regions where farmers apply more than the recommended quantity.¹⁷⁷ A study conducted in the United Kingdom (UK) found that only thirty-eight percent of produce manufacturers read the complete instructions before using a pesticide for the first time¹⁷⁸, demonstrating how excessive use may occur.

Other indoor exposure to pesticides occurs in a number of ways, including insect repellent, weed killer, rat poison, and some dog flea shampoos.¹⁷⁹ The US EPA has found that levels of pesticides to be as high as 100 ug/g in carpet samples.¹⁸⁰ Research indicates that pesticide use or storage indoors is immense, with one study determining ninety-seven percent of Minnesota homes store pesticide inside and eighty-eight percent using pesticides within the last year,¹⁸¹ and another study concluding that pesticides are used in ninety percent of all US households.¹⁸² Children who are of age to attend school often are exposed to additional pesticides used indoors to combat insect infestations and parameter sprays for pest prevention.¹⁸³

Chemical exposure is of particular concern for those residing in sub-standard low-income housing. With over six million United States urban children living below the poverty level, the exposure rates are high and worth noting.¹⁸⁴ One study conducted in Seattle, Washington, found concentrations of polycyclic aromatic hydrocarbon (PAHs) ranging from three to 290 micrograms/g, lead from 250 to 2250 micrograms/g, and PCBs from 210 to 1900 ng/g.¹⁸⁵ Authors Roberts and Dickey concluded that with a reduction in exposure to these indoor pollutants, Seattle would be able to reduce immediate health costs and long-term health risks.¹⁸⁶

Chemicals can be found throughout the home and school atmospheres. While the impact of both pesticides and chemicals will be expanded upon throughout this paper, it is noteworthy to explain their correlation with indoor air environments. Chemicals are present in clothing, food, packaging, toys, shampoos, computers, hospitals, and

http://healthychild.org/blog/comments/pesticides_in_your_home/> (last modified: 16 December 2008).

¹⁸⁰ R.G. Lewis, R.C. Fortmann, & D.E. Camann, "Evaluation of Methods for Monitoring the Potential Exposure of Small Children to Pesticides in the Residential Environment" (1994) 26:1 Arch. Environ. Contam. Toxicol. 37 at 37.

¹⁸¹ J.L. Adgate et al., "Pesticide Storage and Use Patterns in Minnesota Households with Children" (2000) 10:2 J. Expo. Anal. Environ. Epidemiol. 159 at 159; G.S. Berkowitz et al., "Exposure to Indoor Pesticides during Pregnancy in a Multiethnic, Urban Cohort" (2003) 111:1 Environ. Health Perspect. 79 at 79.

¹⁸² Lewis, supra note 180 at 37; E.P. Savage et al., "Household Pesticide Usage in the United States" (1981) 36:6 Arch. Environ. Health 304 at 304.

¹⁸⁴ Wigle, supra note 4 at 177.

¹⁸⁶ *Ibid.* at 143.

¹⁷⁷ M. Pollan, *The Omnivore's Dilemma: A Natural History of Four Meals*, (New York: Penguin Group USA, 2006).

¹⁷⁸ G. Avory & D. Coggon, "Determinants of Safe Behaviour in Farmers when Working with Pesticides" (1994) 44:5 Occup. Med. 236 at 237.

¹⁷⁹ W. Baue, "Pesticides in Your Home" (2008), online: Healthy Child Healthy World <

¹⁸³ T. Godish, "Indoor Environment Notebook: Everything You Wanted to Know about Indoor Air Pollution and More" (2008), online: Bell State University < http://publish.bsu.edu/ien/archives/2000/012700.htm> (last modified: 01 September 2008).

¹⁸⁵ J.W. Roberts & P. Dickey, "Exposure of Children to Pollutants in House Dust and Indoor Air" (1995) 143 Rev. Environ. Contam. Toxicol. 143 at 143.

workplaces along with other items and environments. While some are necessary for good health (hospital disinfectants, water chlorification, etc.) others have known negative effects (chlorinated pesticides, N,N-Diethyl-Meta_toluamide (DEET), persistent organic pollutants (POPs), etc.).¹⁸⁷ Ingestion and inhalation of phthalates (diisononyl phthalate (DINP) and di(2-ethylhexyl) phthalate (DEHP)) in polyvinyl chloride (PVCs) found in some toys and plastic products have been associated with asthma¹⁸⁸, birth defects and early onset of puberty¹⁸⁹. These chemicals have been identified as a human carcinogen.¹⁹⁰

Indoor formaldehyde exposure, through inhalation, ingestion, and absorption, has been linked to increased allergic sensitization to common aeroallergens¹⁹¹ and airway irritation.¹⁹² Formaldehyde has been found in wood products, pressed wood furniture, environmental tobacco smoke, some drapes, and some glues.¹⁹³ Evidence of high levels of exposure was found in house trailers provided by the Federal Emergency Management Agency (FEMA) for displaced Katrina and Rita hurricane and Iowa flood (2008) survivors.¹⁹⁴

While some building substances, such as asbestos, have declined in use, a child's exposure is still possible. Originally used for fireproofing and insulation between the 1940s and the 1970s¹⁹⁵, inhalation of asbestos has been found to cause lung disease (asbestosis) and mesothelioma.¹⁹⁶ Historically, much of a child's exposure to asbestos was via a parent. If a parent worked in industrial areas where asbestos materials were common, work clothing brought home

¹⁸⁷ Canadian Partnership, supra note 63.

¹⁸⁸ K.M. Shea, "Pediatric Exposure and Potential Toxicity of Phthalate Plasticizers" (2003) 111:6 Am. Acad. Pediatrics 1467 at 1468; M.H. Garrett et al., "Indoor Airborne Fungal Spores, House Dampness and Associations with Environmental Factors and Respiratory Health in Children" (1998) 28:4 Clin. Exp. Allergy 459 at 461-462.

¹⁸⁹ *Wang, supra* note 108 at 1100.

¹⁹⁰ U.S. Department of Health and Human Services, National Toxicology Program, *11th Report on Carcinogens*, (Washington, D.C.: NIH, 2008), online: NIH < http://ntp.niehs.nih.gov/?objectid=72016262-BDB7-CEBA-FA60E922B18C2540> (date accessed: 1 November 2008).

¹⁹¹ J.J. Quackenboss et al., "Formaldehyde Exposure and Acute Health Effects Study" (1989) 15 Environ. Int. 169 at 169.

¹⁹² *Ibid*; K.B. Rumchev et al., "Domestic Exposure to Formaldehyde Significantly Increases the Risk of Asthma in Young Children" (2002) 20:2 Eur. Respir. J. 403 at 403.

¹⁹³ U.S., Environmental Protection Agency, *An Introduction to Indoor Air Quality* (Washington, D.C.: US Environmental Protection Agency, 2009), online: US EPA < http://www.epa.gov/iaq/formalde.html> (last modified:27 October 2009).

¹⁹⁴ C.Y. Rao et al., "Characterization of Airborne Molds, Endotoxins, and Glucans in Homes in New Orleans after Hurricanes Katrina and Rita" (2007) 73:5 Appl. Environ. Microbiol. 1630 at 1630.

¹⁹⁵ American Academy of Pediatrics, *How Can I Protect My Child from Environmental Hazards in Our Home?*, (Illinois: Am. Acad. Pediatrics, 2005), online: AAP < http://www.aap.org/publiced/BR_Environment.htm> (last modified: 5 March 2005).

¹⁹⁶ CDC, Agency for Toxic Substances & Disease Registry, *Toxicological Profile for Asbestos*, (Washington, D.C.: CDC, 2008), online: CDC < http://www.atsdr.cdc.gov/toxprofiles/tp61.html#bookmark07> (last modified: September 2001).

provided another exposure route.¹⁹⁷ Cases of women inhaling asbestos and then exposing her infant via breast milk have been documented.¹⁹⁸

2.2.2.3 Food

The consumption of food products are a source of exposure for infants, children, and adolescents. While regulatory agencies monitor what is sold, literature on children's environmental health debates whether current food standards (permissible pesticides, chemicals, and metals) take into consideration the behaviour and lifestyle of a child.¹⁹⁹ Exposure to pesticides, metals, and toxins via breast milk, infant formula, fruit, vegetable, and animal consumption may result in negative health impacts for the developing child. As mentioned earlier, a child's behavioural and physiological differences greatly diverge from that of an adult. For the infant, breast milk tends to be the only source of nutrients. Use of infant formula and baby food may be introduced as the child gets older. Young children tend to consume larger quantities per body weight of fruit and vegetables.²⁰⁰ These various aspects of consumption lead to unique exposure pathways for infants and children.

The consumption of breast milk during the first months of life is beneficial to growth and development. A number of international organizations, such as the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF), have recommended breastfeeding until two years of age or longer.²⁰¹ National medical associations and government entities have stressed that "breast is best".²⁰² Breast milk provides the first defense from disease for the newborn. Antibodies (IgG, IgA, IgM, IgD, and IgE) are present in breast milk²⁰³, providing a barrier to pathogens introduced to a child. Evidence indicates that children are not capable of producing these antibodies on their own until six months of age, which is often an issue for infants who are only formula fed.²⁰⁴ For many decades the medical community has been aware that bottle-fed infants are more prone to neonatal infections.²⁰⁵ While there is little doubt that breast milk is the best option, exposure to environmental toxins may still take place. Chemicals such

¹⁹⁷ D. Ozonoff, *Failed Warnings: Asbestos-Related Disease and Industrial Medicine* (New York: Oxford University Press) 139 at 139.

¹⁹⁸ J.J. Chisolm, "Fouling One's Own Nest" (1978) 62:4 Pediatrics 614 at 615.

¹⁹⁹ Children's Environmental Health Network, *Pesticides*, (Washington, D.C.: C.E.H.N., 2007), online: C.E.H.N. < http://www.cehn.org/cehn/education/pesticides.html> (last updated: 13 October 2004); E. Groth et al. *Do You Know what You're Eating? An Analysis of US Government Data on Pesticide Residues in Foods* (Washington, D.C.: Consumers Union of United States, 1999).

 $^{^{200}}$ *Cooper, supra* note 5 at 41-42.

²⁰¹ UNICEF, Division of Human Resources, *Breastfeeding Guidelines*, (New York: UN, 2000), online: UNICEF http://www.un.org/womenwatch/osagi/pdf/UNICEFBreastfeeinguidelines.pdf> (last accessed: 12 November 2008).

²⁰² UNICEF, *Breast is Best. How UNICEF's Baby Friendly Initiative is Supporting Breastfeeding in the UK*, (London: UNICEF, 2008), online: UNICEF < http://www.unicef.org.uk/features/feature_detail.asp?feature=32> (last accessed: 21 November 2008).

²⁰³J. Newman, "How Breast Milk Protects Newborns" (1995) 273 Sci. Am. 58 at 58.

²⁰⁴ *Ibid*; L.K. Pickering, "Modulation of the Immune System by Human Milk and Infant Formula Containing Nucleotides" (1998) 110:2 Am. Acad. Pediatrics 242 at 242.

²⁰⁵ L.A. Hanson & J. Winberg, "Breast Milk and Defence Against Infection in the Newborn" (1972) 47:256 Arch. Dis. Child. 845 at 845-846.

as PCBs, dichloro-diphenyl-trichloroethane (DDT), and polybrominated diphenyl ethers (PBDEs) present in a mother's body may be transferred to the newborn via breast milk.²⁰⁶ These forms of POPs tend to bioaccumulate in fatty tissue and are transferable through breast milk. Furthermore, because they bioaccumulate in mammals, they tend to be transferred and biomagnify up the food chain.²⁰⁷ POPs tend to have a half-life of two to ten years, are persistent, fat-seeking (lipophilic), and are endocrine disruptors.

The harmful effects of some POPs were identified as early as the 1970s.²⁰⁸ Responsible governments have restricted the use of DDT and PCBs, resulting in a reduction in exposure via breast milk.²⁰⁹ Within Canada, the US, and Europe, PCB levels in breast milk have decreased.^{210 211}

Longitudinal monitoring of breast milk in Sweden²¹² demonstrated that PBDE levels in breast milk were increasing greatly, and therefore infant consumption was also on the rise. As a result, the government took regulatory action to phase out exposure. However, increased rates of PBDEs are still evident in North America where regulation on the chemical has not been passed.²¹³

Even with government intervention, because of POPs' long-term capacity to survive in the environment and animal life, exposure in future generations continues. Subpopulations are often more susceptible to higher exposure levels due to their unique diets. Inuit women in Canada have been found to have ten times the PCB levels than that of women in southern Canada.²¹⁴ Other arctic populations have shown similar increased levels of POPs, which

²⁰⁹ McKeown, ibid.

²¹⁰ A.G. Crann & D.A. Haines, "Twenty-Five Years of Surveillance for Contaminants in Human Breast Milk" (1998)
 35:4 Arch. Environ. Contam. Toxicol. 702 at 707-708.

²¹¹ The Stockholm Convention signed in 1995 calls for a global reduction of use of POPs; UN EP, *Stockholm Convention on Persistent Organic Pollutants*, UNEP/POPS/POPRC.4/INF/9 (2008), online: UNEP < http://chm.pops.int/Portals/0/Repository/convention_text/UNEP-POPS-COP-CONVTEXT-FULL.English.PDF> (last modified: 22 May 2001).

²¹² Sweden is one of the few countries that has established a government program that monitors breast milk for pollutants. The program began in 1967. G.M. Solomon & P.M. Weiss, "Chemical Contaminants in Breast Milk: Time Trends and Regional Variability" (2002) 110:6 Environ. Health Perspect. 339 at 339; The Collaborative on Health and the Environment, *Breastmilk Biomonitoring* (Bolinas, CA: Collaborative on Health and the Environment, 2003), online: CEH < http://www.healthandenvironment.org/articles/partnership_calls/136> (last modified: 20 March 2003).

²¹³ Canada, Health Canada, *PBDE Flame Retardants and Human Health* (Ottawa: Minister of Health, 2006), online: Health Canada < http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/environ/pbde-eng.php> (last modified: August 2009).

²¹⁴ *Wigle, supra note 4* at 150; E. Dewailly et al., "Inuit Exposure to Organochlorines through the Aquatic Food Chain in Arctic Quebec" (1993) 101:7 Environ. Health Perspect. 618 at 618-619.

²⁰⁶ A. Larson, "Environmental Health: Chemicals in Breast Milk" (2008) SSRN, online: SSRN http://ssrn.com/abstract=1278397> (last modified: 21 October 2008).

²⁰⁷ K. Hooper & T.A. McDonald, "The PBDEs: An Emerging Environmental Challenge and Another Reason for Breast-Milk Monitoring Programs" (2000) 108:5 Environ. Health Perspect. 387 at 387.

²⁰⁸ R.D. Kimbrough, "Toxicological Implication of Human Milk Residues as Indicated by Toxicological and Epidemiological Studies" *Chemical Contaminants in Human Milk*, (Boca Raton: CRC Press, 1991); D. McKeown, *Environmental Threats to Children: Understanding the Risks, Enabling Prevention* (Toronto: Toronto Public Health, 2005), online: Toronto Public Health < http://www.toronto.ca/health/hphe/pdf/tr_environmental_threats_all.pdf> (last modified: September 2005).

demonstrates the chemicals' capability of travel and its longevity.²¹⁵ Populations with high dietary intakes of aquatic wildlife, such as seals, whales, and sharks, tend to have elevated levels of POPs because of the chemicals' ability to magnify (up to thousands of times greater than originating levels) in fatty tissues of these animals.²¹⁶ Another source of contamination through ingestion by infants is baby formula. The water, the bottle, and the formula used influence the exposure levels. Commercial infant formula has been approved by both medical communities and regulating government agencies as a safe and effective substitute to breast milk. Infant formula tends to fit into one of three categories: cow's milk, soy-based, or protein hydrolysate (for those with milk allergies).²¹⁷ Additionally, these types of infant formula come in either powdered, concentrated liquid, or ready-to-use form.²¹⁸

While government entities, such as the US Food and Drug Administration (US FDA), approve infant formula prior to public sale, there are still uncertainties as to the effects of consumption of formula on infant health. Recent concern over detected trace amounts of industrial chemical melamine in the US has led consumer groups and the Illinois attorney general to pressure the EPA for a recall.²¹⁹ The negative effects of melamine exposure include kidney and bladder stones, kidney failure, and death.²²⁰ In nations where manufacturing oversight is less stringent, infant formula has been found to contain diethylene glycol (thickening agent found in antifreeze)²²¹ as well as purposefully including of melamine to raise protein levels.²²²

Even without the concerns pertaining to toxicity of infant formula, there are issues about the safety of the ingredients themselves. Epidemiological studies and data on soy infant formula are lacking, though the product is being used by twenty-five percent of all US formula consumers.²²³ Similar to some of the recent studies on soy products and

²¹⁵ B. Fängström et al., "A Retrospective Study of PBDEs and PCBs in Human Milk from the Faroe Islands" (2005) 4:12 Environ. Health Global Access Sci. Sourc 12 at 19.

²¹⁶ Even with all this evidence against POPs, the benefits of breast milk greatly outweigh that of the risks from consumption.; United Nations Environment Programme Chemicals, A Guide to the Stockholm Convention on Persistent Organic Pollutants, (Geneva: UNEP, 2005), online: UNEP < http://www.pops.int/documents/guidance/beg_guide.pdf> (date accessed: 11 December 2008).

²¹⁷ Mayo Clinic, *Infant Formula: Which Formula is Right for Your Baby?*, (Rochester: Mayo Clinic, 2008), online: MayoClinic < http://www.mayoclinic.com/health/infant-formula/PR00058> (date modified: 1 July 2008).

²¹⁸ *Ibid*.

²¹⁹ M. Mendoza, "Calls for National Infant Recall Spread" *Associated Press* (28 November 2008), online: AJC < http://www.ajc.com/health/content/health/stories/2008/11/28/infant_formula_recall.html> (last modified: 28 November 2008).

²²⁰ L. Layton, "FDA Draws Fire Over Chemicals In Baby Formula" *The Washington Post* (27 November 2008), online: Washington Post < http://www.washingtonpost.com/wp-

 $dyn/content/article/2008/11/26/AR2008112600386.html > \ (last modified: 27 \ November \ 2008).$

²²¹ E. Harris, "Nigerian Death Toll Rises in Tainted Formula Case" *Seattle PI* (12 November 2008), online: Seattle PI < http://www.seattlepi.com/national/1105ap_af_nigeria_fatal_formula.html> (last modified: 12 November 2008).

²²² M. Fan, "6 Chinese Infants Died in Milk Crisis" *Washington Post* (12 November 2008), online: Washington Post < http://www.washingtonpost.com/wp-dyn/content/article/2008/12/02/AR2008120203355.html> (last modified: 12 November 2008).

²²³ A. Chen & W.J. Rogan, "Isoflavones in Soy Infant Formula: A Review of Evidence for Endocrine and Other Activity in Infants" (2004) 24:1 Annu. Rev. Nutr. 33 at 34; A. Karadag et al., "Soy Formulas and Hypothyroidism" (2004) 89:11 Arch. Dis. Child. 1077 at 1077.

thyroid complications for adults²²⁴, there is uncertainty whether soy-based formula affects the endocrine system.²²⁵ These formulas contain genistein and daidzein, which are phytoestrogens that affect hormonal activity.²²⁶

Historically, concerns surrounding infant formula focused on lead poisoning. Lead was a component of solder used to seal cans, including those that contained infant formula. In 1972, the US FDA worked with manufacturers to cease the use of lead solder in these foods. Within fifteen years, lead levels in these products had been reduced eighty to ninety percent.²²⁷ While lead content in canning has basically been eliminated, recent literature indicates that the current use of plastics for bottles and packaging of infant formula is not safe.²²⁸ The use of bisphenol A (BPA) to strengthen plastics and make resins in cans has resulted in leaching of the toxin into the formula. With ninety-three percent of people residing in the US possessing BPA in their bodies²²⁹, consumer groups have voiced concern over the continued use of this product. BPA has been found to mimic anthropogenic estrogens.²³⁰ It has been linked to breast cancer, prostate cancer, hyperactivity, obesity, miscarriage, insulin resistance, and reproductive malformation.²³¹

The current acceptable levels of BPA consumption as set by the US EPA is 50 ug/kg body weight/day.²³² However, recent studies indicate that this level is not safe.²³³ Additionally, the ability to measure one's intake is near

²²⁷ U.S. Food and Drug Administration, FDA Efforts to Reduce Lead Levels in Food (Washington, D.C.: US FDA, 1988), online: US FDA http://www.fda.gov/bbs/topics/ANSWERS/ANS00227.html (last modified: 5 August 1988).

²²⁸ "Preliminary Report finds Possible Link to Hormonal Problems" *MSNBC News*, (17 April 2008), online: MSNBC Online < http://www.msnbc.msn.com/id/24143555/> (last modified: 17 April 2008); C. Brede et al., "Increased Migration Levels of Bisphenol A from Polycarbonate Baby Bottles after Dishwashing, Boiling and Brushing" (2003) 20:7 Food Addit. Contam. 684 at 684.

²²⁹ D. Gutierrez, *FDA Claims Cancer – Causing Chemical in Infant Formula is "Safe"*, online: Natural News < http://www.naturalnews.com/023594.html> (last modified: 9 July 2008).

²³⁰ H.W. Kuo, "Trace Determination of Bisphenol A and Phytoestrogens in Infant Formula Powders by Gas Chromatography-Mass Spectrometry" (2004) 1027:1-2 J. Chromatogr. 67 at 67.

²³¹ Healthy Legacy, *Guide to Safer Children's Products*, online: Healthy Environment for Kids < http://www.healthyenvironmentforkids.ca/img_upload/13297cd6a147585a24c1c6233d8d96d8/IATP_Guide_Safer_C hildren_Products.pdf> (last accessed: 6 December 2008); The Work Group for Safe Markets, *Baby's Toxic Bottle Bisphenol A Leaching from Popular Baby Bottles*, online: CBS News <

http://www.cbsnews.com/htdocs/pdf/BabysToxicBottle.pdf> (last accessed: 12 November 2008).

²³² Work Group for Safe Markets, Ibid.

²³³ R. Gibson, *Toxic Baby Bottles Scientific Study Finds Leaching Chemicals in Clear Plastic Baby Bottles* (Los Angeles: Environment California Research & Policy Center, 2007), online: Environment California < http://www.environmentcalifornia.org/uploads/wm/HH/wmHHMkJT2OLz4Nc4kXzynQ/Toxic-Baby-Bottels.pdf> (date accessed: 12 November 2008); G. Shaw, "Bisphenol A is Found Neurotoxic in Primates and is Associated with Health Risks in Humans: Questions Raised about Safe Exposure Levels" (2008) 8:19 Neurology Today 10 at 10.

²²⁴ F. Balmir et al., "An Extract of Soy Flour Influences Serum Cholesterol and Thyroid Hormones in Rates and Hamsters" (1996) 126:12 J. Nutr. 3046 at 3046; W.A. Forsythe, III, "Soy Protein, Thyroid Regulation and Cholesterol Metabolism" (1995) 125:S3 J. Nutr. 619S at 620S.

²²⁵ Chen, supra note 223 at 34 & 48.

²²⁶ Ibid. at 34; K.D. Setchell et al., "Exposure of Infants to Phyto-Oestrogens from Soy-Based Infant Formula" (1997) 9070 Lancet 23, online: Lancet < http://web.ebscohost.com/ehost/detail?vid=1&hid=3&sid=aecce885-935f-4f99b90f-266795192f03%40sessionmgr13&bdata=JnNpdGU9ZWhvc3QtbGl2ZQ%3d%3d#db=aph&AN=9707161061> (last modified: 5 July 1997).

impossible.²³⁴ Similar concern has been voiced over plasticizers used in baby food and infant formula.²³⁵ In a study on infant formula and baby food in glass jars, researchers found the presence of one or more of the eleven phthalates tested for in fifty percent of the sample.²³⁶ The most common phthalate found was DEHP, a chemical that may emulate estrogens.²³⁷

Aside from toxins directly from the formula or the bottle, the water mixed with the powdered formula may expose the child to additional toxins. A description of water contaminants is included in the following section. However, it is important to note that lead, POPs, and methylmercury may be present in the water used in powder infant formula. The average infant consumes six ounces of formula per kilogram of body weight, which is comparable to a male adult consuming thirty-five cans of soda a day.²³⁸ This results in a high intake of metals and toxins, including lead, which is not safe at any level.²³⁹ Furthermore, water standards are not set with the formula-fed infant in mind.²⁴⁰

As infants are weaned off breast milk and infant formula, consumption of vegetables and fruits increase. Throughout childhood a person's dietary intake differs from that of an adult. As mentioned earlier, there is a greater consumption by a child of fruit, vegetables, and fruit juice than an adult. The use of pesticides and insecticides on commercial crops or personal gardens leaves residues that may be ingested. It was estimated by one study that one out of every four times a child under the age of five eats a peach, the child is exposed to unsafe levels of organophosphate insecticides.²⁴¹ The consumption of pesticides has been found to cause brain cancer, leukemia, non-Hodgkin's lymphoma²⁴², Wilms' Tumor, and Ewing's Sarcoma²⁴³ as well as affects the nervous system and endocrine system.²⁴⁴ Different developmental stages of children result in different organ susceptibility to chemical exposure. The toxiokenetic and tociodynamic functions of a young child have yet to fully develop, resulting in inability to expel toxins in the same fashion as an adult.²⁴⁵

²³⁴ Work Group for Safe Markets, supra note 231.

²³⁵ D. Feldman & A. Krishnan, "Estrogens in Unexpected Places: Possible Implications for Researchers and Consumers" (1995) 103 Environ. Health Perspect. Suppl. 129 at 132.

²³⁶ European Environment and Health Committee, *Sweden*, EEHC WHO, 2009, online: EEHC WHO <<u>http://www.euro.who.int/eehc/implementation/20051019_2</u>> (last modified: 17 February 2009).

²³⁷ P.K. Eagon et al., "Di (2-ethylhexyl) Phthalate-Induced Changes in Liver Estrogen Metabolism and Hyperplasia" (1994) 58:5 Int. J. Cancer 736 at 736; C.A. Harris et al., "The Estrogenic Activity of Phthalate Esters In Vitro" (1997) 105:8 Environ. Health Perspect. 802 at 802 & 808.

²³⁸ Bearer, supra note 15 at 15.

²³⁹ *Lidsky, supra* note 96 at 15.

²⁴⁰ Bearer, supra note 15 at 18.

²⁴¹ S.H. Zahm & M.H. Ward, "Pesticides and Childhood Cancer" (1998) 106:S3 Environ. Health Perspect. Suppl. 893 at 893.

²⁴² Wigle, supra note 4 at 169.

²⁴³ Zahm, supra note 241 at 898.

²⁴⁴ *McKeown, supra* note 208.

²⁴⁵ Sharpe, supra note 56 at 93.

Baby foods derived from pureed vegetables and fruits have been found to contain pesticides or pesticide metabolite residues.²⁴⁶ A study conducted by The Environmental Working Group and the National Campaign for Pesticide Policy Reform on eight brand-name baby foods found sixteen pesticides. Fifty-three percent of the baby food jars contained traces of one pesticide and eighteen percent contained two or more pesticides.²⁴⁷ Evidence of the effect of pesticides on the human population has been found in historical case-studies. For instance, in 1959 over 4,000 people became ill due to contaminated seed. Use of hexachlorobenzne (HCB) on seed grain between 1954 and 1959 caused negative health effects including skin lesions, colic, metabolic disorders, and adverse effects on infant reproductive systems.²⁴⁸ In the 1980s and early 1990s, there were incidents of illness due to aldicarb pesticides. This pesticide is taken up through the root of the vegetable and is not able to be removed through washing the fruit or vegetable.²⁴⁹ Though aldicarb was used on banana crops within legal limits, because of the high consumption of the fruit by children, pesticide manufacturers prohibited sale of the pesticide for this produce within the US.²⁵⁰

Legislation has been passed to reduce pesticide exposure by children. For instance, the US 1996 Food Quality Protection Act (FQPA) amended prior law with the inclusion of a child specific safety factor. A ten-fold safety margin is applied in setting the maximum residue level (MRL).²⁵¹ This new standard is to take into account specific food intake, average body weight, and the pesticide residue levels under good agricultural practices.²⁵² While the ten-fold factor has reduced the ingestion of pesticides, there are still concerns around the current exposure levels. The standards do not take into consideration differences in consumption due to ethnicity, regional differences in diet, and exposure from home garden vegetables and fruits.

The US FDA conducts daily tests of about forty food samples.²⁵³ Detectable traces of residues are found in fifty-six percent of fruit, forty-one percent of grain, thirty-two percent of fish or shellfish, and thirty-one percent of vegetable products.²⁵⁴ Residue levels that exceeded the maximum federal level were found on more than five percent of domestic strawberries, spinach, red beets, head lettuce, and leafy vegetables.²⁵⁵ In a study conducted by the Danish

²⁴⁶ Wigle, supra note 4 at 175.

²⁴⁷ "Forum: Pesticides in Baby Food" (1995) 103:12 Environ. Health Perspect., online: EHP < http://www.ehponline.org/docs/1995/103-12/forum.html> (last modified: 27 November 1995).

²⁴⁸ Organic Ltd., "Pesticides", online: Organic Ltd < http://organic.com.au/pesticides/> (last accessed: 23 November 2008).

²⁴⁹ Goldman, supra note 6 at 443.

²⁵⁰ Wigle, supra note 4 at 175-176.

²⁵¹ Children's Environmental Health Network, supra note 101.

²⁵² B. Oh, "Pesticide Residues for Food Safety and Environment Protection" (2001) Food & Fertilizer Tech. Cntr., online: Food & Fertilizer Tech. Cntr. < http://www.agnet.org/library/eb/495/ > (last accessed: 6 November 2008).

²⁵³Goldman, supra note 6 at 444.

 $^{^{254}}$ Wigle, supra note 4 at 176.

²⁵⁵ *Ibid*.

Veterinary and Food Administration in 1996 and 1997, high levels of mycotoxins, PCB, and nitrates were found in vegetables, grains, beef, and veal, despite regulatory action.²⁵⁶

Consumption of organic foods²⁵⁷ has increased as a result of this ongoing concern over pesticide consumption. In Europe, there has been a five to seven percent increase in organic purchases per year. Two of the largest Swedish groceries have reported an eighteen and thirty percent increase in organic purchases.²⁵⁸ Within the US, organic sales make up about two percent of the food market.²⁵⁹

Data is lacking to determine with certainty whether or not organic food products are always better than conventionally grown produce for children. However, studies indicate that by increasing organic fruit, vegetable, and juice consumption a child's exposure level will shift from that of uncertain risk to negligible risk.²⁶⁰ A study conducted at the University of Washington found a lower concentration of organophosphate insecticides in urine of children whose diet consists of organic foods than those who consume conventionally grown foods.²⁶¹ Similarly, a study conducted at Emery University found that children who switched from conventional diets to organic diets for five days had a reduced level of pesticide by-products from organophosphates, including malathion and chlorphyrifos.²⁶²

Pesticides are not only a concern in produce. Due to the fact that conventionally grown feed is used in non-organic or non-free-fed animals, chemicals that bioaccumulate are transferred to humans during consumption. Animal fat and hen eggs have been found to contain pesticides or pesticide metabolites.²⁶³ In the US, 11 x 10⁹lb of recycled animal fat per year is used in animal feed from animals which may have toxins that bioaccumulated during the animal's lifetime.²⁶⁴ In addition to animal by-product and pesticide treated feed, antibiotics are used by some countries to increase growth in livestock. It is estimated that more than seventy percent of antibiotics manufactured in the US are

²⁶⁰ *Ibid.* at 382.

²⁶¹ *Ibid*.

 263 Wigle, supra note 4 at 176.

²⁵⁶ European Environment and Health Committee, supra note 236.

²⁵⁷ The definition of organic foods has been established under US law, *Organic Foods Protection Act of 1990*. However, the definitions differ based on location and legislation (or lack thereof). *Organic Foods Production Act of 1990* Title 21 of P.L. 101-624.

²⁵⁸ The Swedish Institute, *Fact Sheet: Environment*, (Stockholm: Swedish Institute, 2008), online: Sweden.se < http://www.sweden.se/upload/Sweden_se/english/factsheets/SI/SI_FS1_clear_goals_shape_%20Swedish_%20enviro nmental_%20policy/SI_FactSheetEnvironment-150DPI.pdf > (date accessed: 3 November 2008).

²⁵⁹ C.L. Curl, R.A. Fenske, & K. Elgethun, "Organophosphorus Pesticide Exposure of Urban and Suburban Preschool Children with Organic and Conventional Diets" (2003) 111:3 Environ. Health Perspect. 377 at 377.

²⁶² C. Lu et al., "Organic Diets Significantly Lower Children's Dietary Exposure to Organophosphorus Pesticides" (2006) 114:2 Environ. Health Perspect. 260 at 263.

²⁶⁴ P. Walker et al., "Public Health Implications of Meat Production and Consumption" (2007) 8:4 Public Health Nutr. 348 at 350.

used in livestock.²⁶⁵ Pesticides or pesticide metabolites are found in animal fat and eggs. The most commonly detected chemicals are PCP (35%) and DDE (21%).²⁶⁶

Evidence indicates that wildlife is susceptible to high levels of accumulation of pesticides, depending on exposure. There may be an increase of toxicity in wildlife of up to one hundred times that of original exposure rates.²⁶⁷ This has a negative impact on children who consume wild game.

2.2.2.4 Water

Levels of exposure to environmental toxins found in water vary and are dependent upon the source of the water, the region, and the regulatory standards (or lack thereof). Children may be exposed to water through inhalation, dermal absorption, or ingestion. Toxins and chemicals of concern include lead, methyl mercury, pesticides, and POPs. Children have a greater intake of water relative to their body weight²⁶⁸ and have different physiological and behavioural traits which leave them more vulnerable than adults. As referenced in the previous section, infants consuming water in place of milk or as an additive to infant formula are more susceptible to negative health effects from chemical exposure. Young children often are exposed to water contaminants through play, such as swimming, or contaminated piping in schools.

Water pollution is more apparent in developing nations where sewage, industrial waste, and agricultural run-off drain into the reservoir or river sources. For instance, in India over 1500 million litres of sewage a day is generated, majority of which flows into rivers or other dumping sites.²⁶⁹ Illnesses directly associated with this high level of exposure include staph infections, diarrhoea, cholera, arsenicosis, E Coli, salmonella, and intestinal worms.²⁷⁰ While not as extreme, similar disease patterns have occurred in developed nations. Often these health effects are associated with low-income or impoverished locations. Low-rent areas often have become debilitated and neglected, resulting in lead piping or solder remaining tolerated or unknown to tenants. Water provided to migrant farm workers in North Carolina tested positive for fecal coliform (26%) or coliform (44%).²⁷¹ Much of this is a direct result of overcrowding, poor living accommodations, and the need for sanitation systems.²⁷² For some, water from wells or

²⁶⁵ *Ibid.* at 353.

 $^{^{266}}$ Wigle, supra note 4 at 176.

²⁶⁷ H.M. Thompson, "Interactions Between Pesticides; A Review of Reported Effects and their Implications for Wildlife Risk Assessment" (1996) 5:2 Ecotoxicology 59 at 70.

 $^{^{268}}$ *Cooper, supra* note 5 at 41.

²⁶⁹ Centre for Science and Environment, "CSE Draft Dossier: Health and Environment" (2006), online: CSE < http://www.cseindia.org/programme/health/pdf/conf2006/a1water.pdf > (last accessed: 11 December 2008).

²⁷⁰ *Ibid; UNICEF, supra* note 202; World Health Organization, *Food Safety and Foodborne Illness* (Geneva: WHO, 2007), online: WHO < http://www.who.int/mediacentre/factsheets/fs237/en/> (date accessed: 6 December 2008).

²⁷¹ S. Ciesielski, "The Microbiologic Quality of Drinking Water in North Carolina Migrant Labor Camps" (1991)
81:6 Am. J. Public Health 762 at 762; G.W. Evans & E. Kantrowitz, "Socioeconomic Status and Health: The Potential Role of Environmental Risk Exposure" (2002) Annu. Rev. Publ. Health 303 at 307.

²⁷² Ciesielski, Ibid. at 763.

rain basins serves as a drinking water source. In some areas where ground or air pollution is at lower levels²⁷³ this may not be problematic. However, in regions where industrial waste or air pollution contaminates the soil and air²⁷⁴, use of this water may expose children and adults to unnecessary toxins. Evidence indicates that in the US, low-income populations bare the greatest burden of exposure with very little quality control. For instance, Latino populations residing near the US and Mexico border in Texas consume polluted water which results in a large number of waterborne diseases.²⁷⁵ Only one percent of the over 842 Hispanic communities (colonias) in Texas, has public sewage systems.²⁷⁶ Over 200,000 people reside in these unincorporated subdivisions, a number of which are children.²⁷⁷ The Rio Grande has elevated levels of mercury content which exceed the state standards.²⁷⁸ A recent study conducted by the US Geological Survey found low levels of man-made chemicals in public water supplies after being treated for consumption.²⁷⁹ About 130 chemicals were found in the waters prior to being tested. Around two-thirds remained after treatment.²⁸⁰

Lead is one of the pollutants detected in water. Older piping and solder often contain lead which may leach into the water stream.²⁸¹ In older school buildings and homes, replacement of these products may not have occurred. Furthermore, replacement may be the responsibility of the municipality if the lead piping lies within a public area. While lead piping use reduced in the 1950s, lead solder was used on copper pipes until the 1980s (1986 in the US).²⁸² The US EPA has estimated that between ten and twenty percent of lead content in children is derived from tap water.²⁸³ Regional differences influence the levels of lead in water due to piping. Those who live in an area with soft water tend to have greater amounts of leaching of lead into the water.²⁸⁴ Lead has been found to have a negative

²⁷⁷ *Ibid*.

²⁷⁸ *Ibid*.

²⁸⁰ *Ibid*.

²⁸¹ *Cooper, supra* note 5 at 44.

²⁸² Ontario Ministry of Environment, *Lead and Drinking Water – Questions and Answers*, (Toronto: Ontario Ministry of Environment, 2007), online: ON Ministry of Environment

<http://www.ene.gov.on.ca/en/water/tapwater/qna.php> (date accessed: 4 December 2008); J.L. Pirkle et al., "Exposure of the US Population to Lead, 1991-1994" (1998) 106:11 Environ. Health Perspect. 745 at 748.

²⁸³ L. Bower, *Drinking Water: Lead-Pipe and Lead-Solder Concerns* (Healthy House Institute , 2000), online: Healthy House Institute < http://www.healthyhouseinstitute.com/a_662-

²⁷³ Some examples of the least polluted cities include Flagstaff, Arizona, and Fairbanks, Alaska. For a complete list of the least polluted cities see: American Lung Association, *State of the Air: 2008* (Washington, D.C.: American Lung Association, 2008), online: American Lung Association < http://www.stateoftheair.org/2008/cleanest-cities/least-polluted-short-term-pm.html> (date accessed: 14 May 2009).

²⁷⁴ Some examples of the most polluted cities include Pittsburgh, Pennsylvania, and Los Angeles, California. For a complete list of the most polluted cities see: *American Lung Association, ibid.*

²⁷⁵ *Evans, supra* note 271 at 308.

²⁷⁶ R. Metzger, J.L. Delgado, & R. Herrell, "Environmental Health and Hispanic Children" (1995) 103:S6 Environ. Health Perspect. 25 at 30.

²⁷⁹ U.S. Department of the Interior, *Man-Made Chemicals Found in Drinking Water at Low Levels* (Washington, D.C.: U.S.G.S., 2008), online: USGS.Gov < http://www.usgs.gov/newsroom/article.asp?ID=2086> (last updated: 5 December 2008).

Drinking_Water_Lead_Pipe_and_Lead_Solder_Concerns> (date accessed: 2 December 2008).

²⁸⁴ U.S. Food and Drug Administration, supra note 227.

impact on intellectual and physical development, even with small amounts of consumption.²⁸⁵ Some schools have taken the precaution of running the faucets at the start of the day to ensure that children do not consume water which sat in piping overnight.²⁸⁶

The awareness of the harmful effects of lead has resulted in a reduction in exposure. However, other chemicals and toxins remain in the water which may have negative health effects on infants and children. In areas where ground water from well sources is used, consumption of pesticides may occur. Agricultural run-off into surrounding areas is absorbed in the soil of these surrounding areas and is not capable of being monitored by government entities.²⁸⁷ Over 130 pesticides have been detected in groundwater, including aldicarb, atrazine, dichlorodiphenyldichloroethylene (DDE), dieldrin, and 1,2-dibromo-3-chloropropane (DCBP).²⁸⁸ Pesticides have been found in animals and wildlife as a result of consumption of pesticide-polluted water.²⁸⁹ Even if a child is not exposed to the polluted water directly, he or she may consume pesticides which have bioaccumulated in animal fat.

The disinfection by-products (DBP) used to ensure water quality standards are met have been found to cause negative developmental outcomes, fetal deaths, birth defects, low birth weight, and cancer.²⁹⁰ The reaction of the chemical chlorine and the organic material in untreated water produces DBPs, which include trihalomethanes (THMs), haloacetic acids, haloacetonitriles, haloketones, halophenols, and halogenated furanones.²⁹¹ There is still much debate over the negative effects of DBPs and data lacking as to linkage. Nevertheless, some studies have found an association between THMs and stillbirth, spontaneous abortions, low birth weight, and birth defects.²⁹² Due to the number of confounding factors, it is difficult to assess a clear linkage between DBPs and cancer. However, some studies have established an association between exposure and brain cancer and adult bladder cancer.²⁹³

Exposure to water pollutants through dermal absorption occurs in many recreational settings. For instance, by the mid-1980s the Great Lakes contained over 800 chemical substances as a result of industry, agricultural, and urban

²⁸⁵ U.S. Environmental Protection Agency, Actions You Can Take to Reduce Lead in Drinking Water, (Washington, D.C.: US EPA, 1993), online: US EPA < http://www.epa.gov/OGWDW/lead/lead1.html > (date accessed: 21 November 2008).

²⁸⁶ U.S. Environmental Protection Agency, *Testing Schools and Child Care Centers for Lead in the Drinking Water*, (Washington, D.C.: US EPA 2006), online: US EPA http://www.epa.gov/ogwdw/lead/testing.htm (date accessed: 3 December 2008).

²⁸⁷ *Cooper, supra* note 5 at 55.

²⁸⁸ Wigle, supra note 4 at 179.

²⁸⁹ P. Brown et al., "*Identification of Pesticide Poisoning in Wildlife*" (1996) 754:1-2 J. Chromatogr. A. 463 at 464; *Thompson, supra* 263 at 59.

²⁹⁰ *Wigle, supra note 4* at 335-345.

²⁹¹ *Ibid.* at 334-335.

²⁹² *Ibid;* M.J. Nieuwenhuijsen, "Chlorination Disinfection Byproducts in Water and their Association with Adverse Reproductive Outcomes: A Review" (2000) 57:2 Occup. Environ. Med. 73 at 73 & 81.

²⁹³ *Wigle, supra note 4* at 341-342; J.J. Cutler et al., "Childhood Leukemia in Woburn, Massachusetts" (1986) 101:2 Public Health Rep. 201 at 204; B.A. Mueller et al., "Residential Water Source and the Risk of Childhood Brain Tumors" (2008) 116:6 Differences 6 at 554.

surroundings.²⁹⁴ Though a concern for wildlife and the environment in general, it is especially worrisome for children and infants exposed to game and fish life that feeds off the lakes and for those who participate in recreational sports in those waters.²⁹⁵

2.2.2.5 Soil

There are a variety of ways in which soil and ground pollution occurs. Industrial sludge, agricultural run-off, automobile emissions, and construction by-products are just a few of the methods by which ground areas are polluted. Children tend to spend more of their time near the ground, especially in play areas.²⁹⁶ They often have direct exposure to dirt and soil, which is not the case for most adults. Because of a child's hand-to-mouth behaviour, greater inhalation for body weight, and direct skin contact, contaminants that might be mitigated for adults are taken in by children. It has been estimated that children between the age of two and six ingest 250 mg of dirt daily while at play outside.²⁹⁷ Some children, however, consume much more – up to twenty-five to sixty grams of soil a day.²⁹⁸ Because of the child's ongoing developmental stages, the ability to expel these toxins is reduced and there is a greater susceptibility to disease. The activity of eating dirt is not considered abnormal in young children who are undergoing an exploratory phase.²⁹⁹

Lead in play areas has reduced with the elimination of the metal from gasoline, exposure still is of concern for young children at play. Within Ontario, residential areas tend to have lead levels less than 100 parts per million.³⁰⁰ Though there is minimal risk from this low level, some areas have greater amounts because of proximity to industry or in a historic region where lead-based products are still present.³⁰¹ Garden areas may contain lead as a result of chipped

²⁹⁴ N.W. Tremblay & A.P. Gilman, "Human Health, the Great Lakes, and the Environmental Pollution: A 1994 Perspective" (1995) 103 Environ. Health Perspect. Suppl. 3 at 3.

²⁹⁵ *Ibid.* at 4; B.L. Johnson et al., "Public Health Implications of Persistent Toxic Substances in the Great Lakes and St. Lawrence Basins" (1998) 24:3 J. Great Lakes Res. 698 at 698.

²⁹⁶ Canadian Partnership, supra note 63.

²⁹⁷ J.K. Hawley, "Assessment of Health Risk from Exposure to Contaminated Soil" (1985) 5:4 Risk Anal. 289 at 292;
M.L. Lepow et al., "Role of Airborne Lead in Increased Body Burden of Lead in Hartford Children" (1974) 7
Environ. Health Perspect. 99 at 100.

²⁹⁸ E. J. Calabrese et al., "Soil Ingestion: A Concern for Acute Toxicity in Children" (2008) 116:5 Gene 1354 at 1354
-1355.

²⁹⁹ "The Hazards and Benefits of Eating Dirt" *About Kids Health News* (2007), online: AboutKidsHealth http://www.aboutkidshealth.ca/News/The-hazards-and-benefits-of-eating-dirt.aspx?articleID=1--38&categoryID=news-type" http://www.aboutkidshealth.ca/News/The-hazards-and-benefits-of-eating-dirt.aspx?articleID=1--38&categoryID=news-type" http://www.aboutkidshealth.ca/News/The-hazards-and-benefits-of-eating-dirt.aspx?articleID=1--38&categoryID=news-type" http://www.aboutkidshealth.ca/News/The-hazards-and-benefits-of-eating-dirt.aspx?articleID=1--38&categoryID=news-type" http://www.aboutkidshealth.ca/News/The-hazards-and-benefits-of-eating-dirt.aspx?articleID=1--38&categoryID=news-type" http://www.aboutkidshealth.ca/News/The-hazards-and-benefits-of-eating-dirt.aspx?articleID=1--38&categoryID=news-type

³⁰⁰ Ontario, *Lead and Drinking Water – Questions and Answers* (Toronto: Ontario Ministry of the Environment, 2007), online: ON Ministry of Environment http://www.ene.gov.on.ca/en/water/tapwater/gna.php (date accessed: 4 December 2008); Ontario, *What You Should Know about Lead in Soil* (Toronto: Ontario Ministry of the Environment, 2007), online: ON Ministry of Environment http://www.ene.gov.on.ca/en/water/tapwater/gna.php (date accessed: 4 December 2008); Ontario, *What You Should Know about Lead in Soil* (Toronto: Ontario Ministry of the Environment, 2007), online: ON Ministry of Environment http://www.ene.gov.on.ca/publications/6683e.php> (date accessed: 12 November 2008).

paint from the exterior of an older home. Lead has been found to cause vomiting, diarrhea, convulsions, and intellectual development delay.³⁰²

Industrial waste and agricultural run-off influence the quality of soil and levels of pollution. Children who reside near farmland or industry often have elevated exposure levels. A number of studies have found that agricultural workers have increased health risks because of inhalation of pesticides. In terms of children, direct contact with soil brought into the house from work areas may provide exposure.³⁰³ A study conducted in Central Valley, California, found that house dust may have contaminants transferred from outdoor rural soil. Ingestion of diazinon and chlorphyrifos by children could exceed the US EPA levels because of this transfer from soil pollutants indoors.³⁰⁴ Literature indicates that these compounds, when inhaled, ingested, or absorbed by children, cause Hodgkin disease, brain cancer, and leukemia.³⁰⁵

Poor monitoring has led to incomplete conclusions as to the impact of sludge exposure. This industrial by-product contains nutrients, organic matter, and chemical waste in varying quantities. Though not scientifically linked, cases of infection presumed to be associated with sludge use have been reported. In Menifee, California, reports of children and adults falling ill began after nearby farmland used sludge for fertilizer.³⁰⁶ As a result, the Californian county of Kern has banned Los Angeles from dumping nearly 250,000 tonnes of sewage sludge on county farms.³⁰⁷ There have been reports of illnesses associated with thirty-nine separate incidents of exposure to sewage sludge in fifteen states.³⁰⁸ Illnesses thought to be affiliated with exposure include respiratory, gastrointestinal, headaches, and skin disorders.³⁰⁹ Use of sludge on hayfields in Georgia³¹⁰ resulted in the death of dairy cows who consumed the feed.³¹¹

³⁰⁶ K. Brusch, "Residents Fear Renewed Use of Sludge on Farmland will Bring Health Problems" *North Carolina Times* (2004), online: NC Times

http://www.nctimes.com/articles/2004/04/11/news/california/23_29_374_1_04.txt> (date accessed: 2 December 2008).

³⁰⁷ S. Chawkins, "LA Fights Kern County Sludge Ban" Los Angeles Times (2006).

³⁰⁸ E.Z. Harrison & S. R. Oakes, "Investigation of Alleged Health Incidents Associated with Land Application of Sewage Sludges" (2002) 12:4 New Sol. 387 at 390.

³⁰⁹ *Ibid;* C. Snyder & P.H. Snyder, "The Dirty Work of Promoting 'Recycling' of American's Sewage Sludge" (2008) 11:4 Int. J. Occup. Environ. Health 415 at 419 -420.

³⁰² Canada, *Effects of Lead on Human Health* (Ottawa: Health Canada, 2008), online: Health Canada http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/environ/lead-plomb-eng.php (date accessed: 14 April 2009).

³⁰³ *Simcox, supra* note 174 at 1126.

³⁰⁴ M.A. Bradman et al., "Pesticide Exposures to Children from California's Central Valley: Results of a Pilot Study" (1997) 7:2 J. Expo. Anal. Env. Epid. 217 at 217.

³⁰⁵ C.L. Curl et al., "Evaluation of Take-Home Organophosphorus Pesticide Exposure Among Agricultural Workers and their Children" (2002) 110:12 Environ. Health Perspect. A787 at A787; C. Leowenherz et al., "Biological Monitoring of Organophosphorus Pesticide Exposure among Children of Agricultural Works in Central Washington State" (1997) 105:12 Environ. Health Perspect. 1344 at 1350.

³¹⁰ \$550,000 in damages was awarded to the Boyce family for death of cows due to sludge use.

³¹¹ J. Lee, "Sludge Spread on Fields is Fodder for Lawsuits" *The New York Times* (2008), online: NY Times < http://www.nytimes.com/2003/06/26/national/26SLUD.html> (last modified: 26 June 2003).

The ASARCO Smelter in Ruston, Washington illustrates the impact industry can make on soil. In operation from 1890 to 1986, this plant produced copper, emitting arsenic and lead into the air as a by-product. As heavy metals, both fell to the ground and were absorbed by soil.³¹² With the company bankrupt, the necessary \$164 million to clean up the site has yet to be produced by officials.³¹³ Until the appropriate precautions have been taken the land the company occupied, as well as nearby land polluted by emissions, is not liveable.³¹⁴

While pesticides have been covered under food consumption and air inhalation, it is important to note that direct contact with these chemicals may result in dermal absorption. Pesticides and insecticides are used by schools, landlords, and home-owners to eliminate unwanted pests. Caution has to be taken to prevent direct contact with these products, particularly since they have long staying power, particularly if applied incorrectly.

2.2 Conclusion

This chapter has outlined how children differ from adults and how these differences facilitate exposure to environmental pollutants. Chronic health conditions such as respiratory illnesses, asthma, allergies, and eczema are some of the less severe results of exposure. Linkages between pollutants and cancer, spontaneous abortion, birth defects and abnormalities, intellectual delay, and immunological and neurological disorders emphasize the seriousness of these exposures. With nearly 120 million children in North America³¹⁵ and over 100 million children residing in the Europe Union³¹⁶, the costs to the health care system, of lost school days, of lost work days for parents, and to society as a whole due to these chronic health conditions are escalating. Cancer remains one of the leading causes of disease-related deaths in children and asthma is increasing rapidly (one in five in children residing in Canada has asthma)³¹⁷. Within Canada alone, low birth weight and birth defects resulted in 30,000 hospitalizations and 1,500 deaths in one year.³¹⁸ Because of the increasing incident rates of childhood onset of chronic health conditions, it is prudent that policy takes into account the uniqueness of a child.

http://www.medicalnewstoday.com/articles/110513.php> (last modified: 10 June 2008).

³¹² T. Nguyen, "Be Alert in the Dirt: Keeping Children Safe in the Dirt" (Seattle: Public Health Seattle & King County, 2008), online: Public Health Seattle http://www.doh.wa.gov/ehp/ts/school/alertindirtpres.pdf> (date accessed: 2 December 2008).

³¹³ D. Chircop, "Asarco Soil, Groundwater Cleanup in Everett at Risk" *Snohomish County Herald* (28 October 2008), online: HeraldNet < http://www.heraldnet.com/article/20081028/NEWS01/710289900/0/ENT> (last modified: 28 October 2008).

³¹⁴ Washington State, Asarco Ordered to Demolish Houses, Sample Soil and Conduct other Pre-Cleanup Activities in Northeast Everett (Olympia, WA: Department of Ecology, State of Washington, 1997), online: WA Department of Ecology http://www.ecy.wa.gov/news/1997news/97-040.html (date accessed: 2 December 2008).

³¹⁵ Growing Up in North America: Child Health and Safety in Canada, the United States and Mexico (The Annie E. Casey Foundation, 2007), online: Annie E. Casey Foundation

http://www.aecf.org/upload/PublicationFiles/DA3622H5035.pdf> (date accessed: 1 June 2009).

³¹⁶ V. Holdsworth, *Cool Facts and Figures about the EU* (London: Europe in the UK, 2008), online: Europe in the UK http://www.europe.org.uk/index/-/id/259/> (date accessed: 17 December 2008).

³¹⁷ D. Coulombe, "\$12 Million Invested in Improving the Health of Children Suffering from Asthma and Allergies" *Medical News Today* (10 June 2008), online: Medical News Today <

³¹⁸Canadian Partnership, supra note 63.

3. CHILDREN'S ENVIRONMENTAL HEALTH: INTERNATIONAL EFFORTS

3.1 Introduction

The last chapter's outline of the numerous ill effects for children associated with environmental toxin. Children's unique exposure to those toxins clearly mandates their respective government's protection. Due to the migrating impacts of pollutants, for instance chemical transport through waterways or the transfer of particle matter across boundaries, the issues associated with a child's environmental exposure would be, in part, best addressed at the international level. However, international agreements, have for the most part, failed to successfully reduce the exposures children face to outdoor pollution, water contamination, or built environmental toxins. While efforts taken by worldwide organizations, such as the World Health Organization (WHO), the United Nations (UN), and the meetings of the Group of Eight (G8 – Canada, France, Germany, Italy, Japan, Russia, United Kingdom, and the United States) have assisted in bringing awareness to the issues, they have been unable to require nation-states to take specific actions with respect to exposure rates. International agreements which specifically link the harmful effects of environmental pollutants to negative health outcomes are few, and even less common when expressly considering the subpopulation of children. Those that do highlight children tend to be vague in language and do not stipulate well defined requirements, such as air quality standards, reduction of explicit water pollutants, reform of agricultural practices to diminish pesticide runoff, or the mandating of school building ventilation systems.

This chapter provides a discussion of the international agreements and regional efforts which have relevance to children's environmental health. What is essential to take away from this chapter is that though children's environmental health has been a topic of discussion at the international level, tangible objectives have not been required of nation-states. Whereas policy on environmental health in general has gradually gained footing at both national and international levels, attention on children's environmental health has been even more piecemeal. The following section outlines some of the tangential agreements which have helped shape children's environmental health at an international level. Thereafter, attention is given to the international and regional agreements which are directly relevant to the field of children's environmental health. It should be noted that few of these agreements have demonstrated measurable changes in exposure rates or reduced pollution. As this thesis utilizes the ill-effects of pesticide and chemical exposure on children's health as a case study, the third section offers an assessment of international and regional agreements which directly address these toxins.

3.2 Focus On The Environment And Health: Tangential Agreements

The topic of children's environmental health is relatively new, with most relevant policy having taken effect in the later part of the twentieth century. Much of the early legislation was a reaction to specific pollutants, such as for lead, asbestos, and radon. There are a number of reasons for policy progress in the area of children's environmental health to have occurred recently. Firstly, many common chemical pollutants were a product of industrialization and wartime efforts.³¹⁹ "During the last 50 years hundreds of thousands of chemicals have been developed and the production of synthetic chemicals has increased from 1.3 billion lbs in 1940 to 320 billion lbs in 1980."³²⁰ In part,

³¹⁹ R. R. Orford, "Diagnosing and Treating Environmental Health Problems" (1991) 74:11 Minn. Med. 7 at 7.

³²⁰ Orford, Ibid. at 7; Children's Environmental Health Network, supra note 101.

the recent legislative development has been due to the rapidly increasing measures taken in both environmental law and public health policy. To provide an in-depth review of environmental law and public health policy would be impractical within the confines of this thesis, and that is not the purpose of this chapter. However, it is noteworthy to highlight the relatively rapid growth in both environmental law and public health policy. This has made a direct impact on the international environmental health forum. Without awareness at a local or national level, the likelihood of the ability of international efforts to pressure industrialized nations to advance the protection of children's health is improbable.

The relationship between population health and the environment is one that grew over the course of the twentieth century, largely motivated by separate cases of epidemics directly linked to toxic exposure. Instances of "killer smog" in Meuse Valley, Belgium (1930), Donora, Pennsylvania (1948), and London, United Kingdom (1952) resulted in death, respiratory disease, and hospitalizations.³²¹ Recognition of the linkage between smog and negative health outcomes shaped US President Truman's acknowledgement that government and industry must combat air pollution. In his message to the United States Technical Conference on Air Pollution in 1950 Truman emphasized that "the health hazards arising from air pollution, as shown by the Donora disaster, are especially important."³²² In 1955, Los Angeles was one of the first regions in the US to set limits for nitrogen, ozone, sulphur dioxide, and carbon monoxide³²³, in response to dense smog which resulted in a halt of industry and schools in October 1954.³²⁴

Similar case studies can be found for mercury, lead, asbestos, and radium; a piecemeal approach taken by the judiciary and legislative bodies, acting after instances of harm were well documented. While lead paint was recognized as toxic when ingested as early as 1904³²⁵, it was not until 1970 that the US Surgeon General officially recognized the harmful effects lead had on children. In 1978 household use of lead paint was banned, demonstrating the slow rate of linkage of a toxin and public health, and subsequent legal action.³²⁶ The relationship between public health and pollutant exposure rates is best illustrated by litigation surrounding the "Radium Girls". These "girls" were in fact women employed by the US Radium Corporation from 1917 to 1926 who suffered a number of illnesses,

³²¹ A. Ciocco & D.J. Thompson, "A Follow-Up of Donora Ten Years After: Methodology and Findings" (1961) 51:2 Am. J. Public Health 155 at 155; B. Kovarik, "Environmental History Timeline", online: Radford University < http://www.runet.edu/~wkovarik/envhist/> (date accessed: 4 January 2009).

³²² J.T. Woolley & G. Peters, "The American Presidency Project" (Santa Barbara, CA: The American Presidency Project), online: The American Presidency Project < http://www.presidency.ucsb.edu/ws/index.php?pid=13459> (date accessed: 4 January 2009).

³²³ L.C. McCabe, *The Identification of the Air Pollution Problem* (Geneva: World Health Organization, 1961) at 40.

³²⁴ B. Kovarik, supra note 321.

³²⁵ Identification of lead's harmful effects on children was first presented by J.L. Gibson of Queensland, Australia, in 1904; *Gibson, supra* note 19 at 301.

³²⁶ S. Tong, Y.E. Schirnding, & T. Prapamontol, "Environmental Lead Exposure: A Public Health Problem of Global Dimensions" (2000) 78 Bull. World Health Organ. 1068, online: Bulletin of the WHO < http://www.scielosp.org/scielo.php?pid=S0042-9686200000900003&script=sci_arttext&tlng=en> (date accessed: 14 October 2008).

often resulting in death, due to exposure to radium. Evidence in the case indicated that the employer knew of the ramifications of exposure. Victory for the "Radium Girls" lent itself to more stringent labour standards.³²⁷

While the advertised relationship between toxins and poor health assisted in closing the gap between health outcomes and the environmental issues, it is important to observe that the initial stages of environmental health regulation were due to the progression both of environmental law and public health policy. Both medicine and the preservation of the environment have made progress technologically, scientifically, and legally within the last century. These are just a few of the reasons for the relatively new field of environmental health. For instance public health has had a long history, routed in pandemics and outbreaks³²⁸, however epidemiological study of disease patterns is relatively new.³²⁹ The prevention of infectious diseases shifted medical attention towards chronic health conditions. This move towards studying cause of chronic health conditions, rather than just infectious diseases, has allowed health professionals to recognize that environmental exposure leads to negative health outcomes.

Health science has evolved; so has environmental law. Early international environmental law was limited in scope and authority. The 1968 Biosphere Conference recognized the lack of international governance on the matters of air and water pollution, deforestation, and overuse of land.³³⁰ "Until this point in history the nations of the world have lacked considered, comprehensive policies for managing the environment. It has become clear, however, that earnest and bold departures from the past will have to be taken nationally and internationally if significant progress is to be made."³³¹ Following this, influential doctrines, such as the 1972 United Nations Convention on the Human Environment (Stockholm Declaration), the 1987 Brundtland Report (Our Common Future), and the 1992 United Nations Conference on Environment and Development (UNCED)(Earth Summit), were formulated.

3.2.1 Agenda 21

One of the more noteworthy international agreements on environment health is Agenda 21. A product of the United Nations Conference on Environment and Development meeting held in Rio de Janeiro in June 1992, the agenda directly links health, environment, and sustainable development. The doctrine, adopted by 179 governments, emphasized the relationship between human health and the environment: "human beings are at the centre of concerns for sustainable development. They are entitled to a healthy and productive life in harmony with nature."³³² The declaration set objectives to be met, with an emphasis on local authorities taking on much responsibility for

³²⁷La Porte V. United States Radium Corporation, 13 F. Supp. 263, 264 (D.N.J. 1935).

³²⁸ Notable outbreaks include the Black Death of 1348 and the Sixth cholera pandemic (1899-1923), both of which spread across Europe.

³²⁹ Physician John Snow is credited with the conception of epidemiology while studying the cholera outbreak in London, UK, in 1854; D. Cameron & I. Jones, "John Snow, the Broad Street Pump and Modern Epidemiology" (1983) 12:4 Int. J. Epidemiol. 393 at 393.

 ³³⁰ P. Sands, *Principles of International Environmental Law*, (Cambridge: Cambridge University Press, 2003) at 34.
 ³³¹ *Ibid*.

³³² Agenda 21, The Rio Declaration on Environment and Development, Distr. General (A/CONF.151/26) (1992); Y. Von Schirnding, "Health and Sustainable Development: Can We Rise to the Challenge?" (2002) 360:9333 The Lancet 632 at 632.

implementing these goals. These targets were reaffirmed in the Millennium Summit of 2000, along with the goal of reducing the number of people living in poverty by half by 2015.³³³

Although Agenda 21 was not the first gathering where sustainable development was addressed at an international level³³⁴, it was innovative in linking health with environmental issues.³³⁵ Health, water, energy, biodiversity, and agriculture were identified as key areas of concern. Chapter 25 of Agenda 21 addresses children and youth specifically, stressing the importance of including children in the dialogue on sustainable development.³³⁶ However, while there is great importance in bringing attention to these issues at an international level, the standards set by this declaration are nonbinding. Furthermore, the issues of children's environmental health differ greatly per region, and therefore the ability to set obligatory requirements that are regionally specific, becomes difficult. The Commission on Sustainable Development (CSD) Indicators of Sustainable Development considers children only in the context of nutrition, mortality, infectious diseases, and educational status.³³⁷ Because of the economic, health, and environmental differences between nation-states, the objectives set by the UN have been ones already met by developed nations. For instance, the disease rates of malaria and tuberculosis resulting from poor environmental standards is basically nonexistent in western nations, but it is a prominent problem in developing nations. An international doctrine such as Agenda 21 is helpful in promoting awareness, but leaves the specific standards which may have been beneficial in diminishing childhood environmental exposures to be set by respective national governments.

Local initiatives resulting from Agenda 21 have been influential in addressing negative effects on childhood health from to hazardous exposures. Though unsuccessful in mandating specific efforts be taken by governments, Agenda 21 was significant in motivating a number of municipal-level projects.³³⁸ Because of the undefined methods by which local Agenda 21 (Local 21) projects are to be implemented, there is a great deal of variety in the projects. Therefore, some of these local efforts had a direct effect on childhood health, whereas others were responsible for improving of the general welfare of the population. For instance, in Nottingham, UK, the local council has worked with the region's largest employer to decrease traffic and car use through carpooling.³³⁹ In Sweden, local Agenda 21 projects have worked in conjunction with child daycare centres and schools in efforts to lessen behaviours which

³³³ United Nations Millennium Declaration, GA Res. A/55/L.2 (2000), online: UN < http://www.un.org/millennium/declaration/ares552e.htm> (date accessed: 4 January 2009).

³³⁴ The term "sustainable development" was first used at the international level by the World Commission on Environment and Development (WCED), known as the Bundtland Commission, in 1983. *Report of the World Commission on Environment and Development: Our Common Future*, UNGA, 1983, UN A/42/427.

³³⁵ Von Schirnding, supra note 332.

³³⁶ Agenda 21, supra note 332.

³³⁷ Economic and Social Affairs United Nations, *Indicators of Sustainable Development: Guidelines and Methodologies*, UN ESC, 2007, No. E.08.II.A.2, online: UN ESC < http://www.un.org/esa/sustdev/natlinfo/indicators/guidelines.pdf> (date accessed: 3 June 2009).

³³⁸ B. Tuxworth, "From Environment to Sustainability: Surveys and Analysis of Local Agenda 21 Process Development in UK Local Authorities" (1996) 1:3 Local Environ. 277 at 277.

³³⁹ Friends of the Earth, *Local Agenda 21 Must Have Hard Targets and Timetables*, online: FOE < http://www.foe.co.uk/resource/press_releases/0114la21.html> (last modified: 14 January 1998).

impact environment and health.³⁴⁰ In West Devon, UK³⁴¹, the assessment of "quality of life" has been redefined to include personal safety, cheerfulness, and health.³⁴²

While Agenda 21 resulted in a number of local and municipal-level action plans, it has also been an awareness tool at a national level. Many signatory nations created sustainable development plans following the summit. Some national governments have been criticized for not incorporating economic development considerations, as well as failing to evaluate success or failures.³⁴³ Member states of the European Union, though, have published National Environment Health Plans (NEHAPs) as a result of the Agenda 21, and the 1994 World Health Organization Regional Office for Europe's (WHO Europe) Second European Conference on Europe and Health, which have required greater accountability by governments.³⁴⁴

Agenda 21 may have made an impact in some locales, but it has not been safe from criticism. The focus of the declaration was to force local authorities to take action to promote sustainable development. Though Agenda 21 is recognized as an opportunity for municipal governments to take innovative actions, funding and the necessary authoritative control to do so may not be present.³⁴⁵ "The difficulty lies in establishing the relative balance between delegation and control which can create a strategy ... yet lay the groundwork for effective structures which will allow LA21 to develop its own momentum in the longer term."³⁴⁶ Additionally, displeasure with the terminology used, which was influenced by industrialized language, has been voiced.³⁴⁷ Also, Agenda 21 did not take into consideration the differing political climates and unique roles non-governmental parties may play.³⁴⁸ Furthermore, implementation into the US political culture was not achieved. The Bush administration of the time was hesitant to embrace the Rio Declaration as a monumental international doctrine because "the American life-style is not up for negotiation".³⁴⁹

³⁴⁶ *Freeman, supra* note 345 at 68.

³⁴⁸ *Ibid.* at 783.

³⁴⁰ S.A. Jorby, "Local Agenda 21 in Four Swedish Municipalities: A Tool Towards Sustainability?" (2002) 45:2 J. Environ. Plann. Manage. 219 at 230.

³⁴¹ *Ibid.* at 222.

³⁴² Friends of the Earth, supra note 339.

³⁴³ C. F. Corvalán, T. Kjellström, & K.R. Smith, "Health, Environment and Sustainable Development. Identifying Links and Indicators to Promote Action" (1999) 10 Development 656 at 656.

³⁴⁴ *Environmental Health Action Plan for Europe*, (Copenhagen: World Health Organization Regional Office for Europe, 1994), online: WHO Europe < http://www.euro.who.int/document/HEV/ehape.pdf> (date accessed: 3 June 2009).

³⁴⁵ C. Freeman, S. Littlewood, & D. Whitney, "Local Government and Emerging Models of Participation in the Local Agenda 21 Process" (1996) 39:1 J. Environ. Plann. Manage. 65 at 65; T. Hart, G. Haughton, & J. Peck, "Accountability and the Non-Elected Local State: Calling Training and Enterprise Councils to Local Account" (1996) 30:4 Reg. Stud. 429 at 430; P. Selman, "Local Agenda 21: Substance or Spin?" (1998) 41:5 J. Environ. Plann. Manage. 533 at 550-551.

³⁴⁷ T. Doyle, "Sustainable Development and Agenda 21: the Secular Bible of Global Free Markets and Plurist Democracy" (1998) 19:4 Third World Q. 771.

³⁴⁹ P. Elmer-Dewitt, "Rich vs. Poor" (1992) 139:22 Time 22 at 22; N. Low, *Consuming Cities: The Urban Environment in the Global Economy After the Rio Declaration*, (London: Routledge, 2000) at 56.

3.2.2 Regional Agreements

Agenda 21 serves as an example of an international agreement which has made an impact on the field of children's environmental health, though perhaps not intentionally. Similarly, transnational agreements in both North America and Europe have been effective in linking health and the environment. Just as with Agenda 21, the efforts have often been reactionary and do not necessarily assess the exposure rates with an awareness of the susceptibility of a child. However, regional agreements tend to include more specific requirements which may make an impact on a child's exposure. While many of these agreements are voluntary, because the agreement is often addressing an issue in urgent need of attention there is follow-through. Within the EU, many of the standards or programs on environmental health are legal requirements.

On a more practical level, the use of regional agreements have been beneficial in identifying transnational concerns and working towards remedying the environmental harms committed. With over 120 regional environmental treaties, it is impossible and unnecessary to review them within the confines of this thesis.³⁵⁰ However, it is noteworthy to indicate that successful transnational agreements have been drafted, providing a context for future agreements with a focus on children's environmental health.

For the most part, these agreements have been retroactive, repairing damage done to the environment and the overall health of the population. For instance, the US-Canada Great Lakes Binational Toxic Strategy³⁵¹ aims at reducing persistent toxic substances currently present in the Great Lakes. Signed in April 1997, this agreement specifies reduction targets for aldrin/dieldrin, benzo(a)pyrene, chlordane, DDT, hexachlorobenzene, alkyl-lead, mercury, mirex, octachlorostyrene, PCBs, dioxins and furans, and toxaphene.³⁵² While one of the first agreements of this type signed between Canada and the United States, criticism has been made of the voluntary requirements and ability to revise timeframes introduced in the framework.³⁵³ Nevertheless, this agreement demonstrates that concern over specific pollutants and concentrated organizational efforts to combat those pollutants can be successful in reducing exposure rates.³⁵⁴ Similar agreements have been structured ?"between the United States and Mexico. The Border Smog Reduction Act of 1998³⁵⁵ applies to the San Diego metropolitan area. The objective of the act is to reduce

³⁵⁰ D. Vogel, "Trading Up and Governing Across: Transnational Governance and Environmental Protection" (1997) 4:4 J. Eur. Public Policy at 566.

³⁵¹ U.S., *Great Lakes Binational Toxics Strategy* (Washington, D.C.: US EPA, 1997), online: US EPA < http://www.epa.gov/glnpo/p2/bns.html> (last accessed: 15 January 2009).

³⁵² *Ibid*.

³⁵³ T.C. Beierle & D.M. Konisky, "What Are We Gaining from Stakeholder Involvement? Observations from Environmental Planning in the Great Lakes" (2001) 19:4 Environ. Plann. C 515 at 516; Canada, *Great Lakes Binational Toxics Strategy*, (Ottawa: Environment Canada, 2001), online: Environment Canada http://www.on.ec.gc.ca/laws/tenth-ijc-response/toxics_strategy-e.html (date accessed: 19 July 2008).

³⁵⁴ M. Valiante, P. Muldoon, & L. Botts, "Ecosystem Governance: Lessons from the Great Lakes" O. Young ed., *Global Governance* (Bonston: Massachusetts Institute of Technology, 1997) 197 at 223.

³⁵⁵ "Passed in 1998, the Border Smog Reduction Act was drafted by the US in response to the San Diego Air Pollution Control District's finding that 7,000 vehicles registered in Mexico and driven daily to the US produce up to 14% of the region's total air pollution." R. Stern, *Addressing Cross Boundary Air Pollution: A Comparative Case Study of the US-Mexico Border and the Hong Kong-Guangdong Board* (Hong Kong: Civic Exchange, 2001), online:

regional air pollution from non-commercial vehicles by preventing re-entry into the San Diego US border more than twice a month.³⁵⁶ Though the objective of the agreement is not children in particular, obviously reducing air pollutants in the region for the general public is beneficial to the vulnerable populations.

The Canada-United States Border Air Quality Strategy is another example of a regional effort that has led to the positive reduction of air pollution exposure in children. Signed in 1997, the agreement aims to reduce sulphur dioxide and nitrogen oxide emissions. Projects and research borne out of this agreement have included consideration of children. Health Canada has funded research on childhood respiratory disease using the BC Linked Health Database to review air quality in the British Columbia Georgia Basin and Washington State Puget Sound areas.³⁵⁷

Analysis of industrialized nations, such as Canada and the United States, indicates that the number of transboundary agreements have increased due to a growing awareness of environmental harm done, both in the science community and the general public.³⁵⁸ Within the United States, where strong lobbying groups exist, this external pressure on government for environmental protection has played an influential role in shaping regional agreements.³⁵⁹ The Great Lakes Binational Toxics Strategy illustrates how cooperation amongst a number of parties may influence regional action to reduce pollution. Parties active in the efforts to reduce Great Lakes pollution included government at the federal, state/provincial, and local levels, as well as industry (American Automobile Manufacturers Association, Canadian Chemical Producers' Association, etc.) and non-governmental organizations (Ecology Center of Ann Arbor, Great Lakes United, etc.).³⁶⁰ Although goals set, such as the reduction of mercury release into the Great Lakes Basin of ninety percent by Canada by 2000 and fifty percent by the US by 2006, have not been met, efforts by the two countries have been positive (78% and 40% respectively).³⁶¹

Much of the regional attention given to transboundary pollution has been a result of economic and trade related agreements. In Europe, the creation of the European Union has permitted a centralized power to govern over environmental issues which exceed the abilities and boundaries of a federal government. Within North America, the pressures of environmentalists and public concerns influenced the formulation of the North American Free Trade

³⁵⁶ U.S., *Press Release: Border Smog Reduction Law to Take Effect Next Week* (Washington, D.C.: U.S. Borders and Customs, 1999), online: U.S. Borders and Customs http://www.cbp.gov/hot-new/pressrel.1999.0426-00.htm> (last modified: 26 April 1999); "Selected Border-Related Environmental Laws and Regulations" (2002), online: University of San Diego http://www.sandiego.edu/lrc/broaderborders/envlaws.html> (date accessed: 3 January 2009).

³⁵⁷ Canada, *Canada-United States Border Air Quality Strategy: Georgia Basin Puget Sound International Airshed Strategy* (Ottawa: Health Canada, 2006), online: Health Canada http://www.hc-sc.gc.ca/ewh-semt/air/out-ext/georgia_basin-eng.php (last modified: 1 November 2006).

³⁵⁸ R.W. Hahn & K.R. Richards, "The Internationalization of Environmental Regulation" (1989) 30 Harv. Int. Law J. 421 at 423.

³⁵⁹ *Ibid.* at 426.

³⁶⁰ U.S., "Great Lakes Binational Toxics Strategy Five Year Perspective" (Washington, D.C.: U.S. Environmental Protection Agency, 2002), online: U.S. E.P.A. http://www.epa.gov/bns/reports/5YearPerspective/5Year.html (online: 12 January 2009).

³⁶¹ *Ibid*.

Civic-Exchange.Org < http://rachelestern.com/documents/CivicExchange_Stern_2001.pdf> (last modified: October 2001) at 13.

Agreement (NAFTA). As NAFTA, and the parallel agreement North American Agreement on Environmental Cooperation (NAAEC), has the capacity to positively influence children's environmental health in both Canada and the United States, it will be covered in greater detail in the third section of this chapter.

The European Union was originally formulated as a single economic market in efforts to create harmonization following the Second World War (WWII).³⁶² It has been this unification and centralized governance which has led to the strengthening of environmental protection within member states.³⁶³ Although not one of the original objectives of the European Community (EC) (the predecessor to the European Union), "environmental policy is now one of the most important and highly regulated areas of EU competence."³⁶⁴ This is a result of a number of factors, including increased distress by individuals over environmental deterioration, the global impact of heavily publicized environmental disasters, and "the politicization of the environmental movement in the 1970s and 1980s."³⁶⁵ Much more than the strengthened concerns over environmental harms, it was the threat that member-state policy may disturb the single market that encouraged EU environmental policy-making.³⁶⁶ In 1997, the Amsterdam Treaty provided a basis for environmental consideration in Article 6, which states that "Environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities referred to in Article 3, in particular with a view to promoting sustainable development."³⁶⁷

While environmental law has clearly moved into an area of shared domain between the supranational government and federal control, public health policy still remains largely a national issue.³⁶⁸ Though the topic of a unified public health system is an area of great contention within the EU community, the need for some level of supranational governance in this field has been recognized. Response to recent cases of "mad cow" disease and elevated levels of dioxin in Irish pork products illustrate the EU's capacity to monitor and ban food products.³⁶⁹

Two EU programs tangentially relevant to children's environmental health are the 2002 Sixth Environment Action Plan 2010: Our Future, Our Choice (6th EAP) and The European Environment and Health Action Plan 2004-2010 (Health Strategy). Both emphasize the link between the environment and health. Two key pieces of legislation aiding in these objectives are: the Water Framework Directive (2000) and the 2006 Regulation on Registration and

³⁶⁵ *Ibid*.

³⁶⁷ E.C., *Treaty of Amsterdam Amending the Treaty on European Union, the Treaties Establishing the European Communities and Certain Related Acts*, [1997] O.J.L. C 325/5, online: Europa < http://eur-lex.europa.eu/en/treaties/dat/12002M/pdf/12002M_EN.pdf> (last modified: 24 December 2002). [hereinafter *Treaty of Amsterdam*].

³⁶⁸ European Union, *Public Health: Background Cross-Border Healthcare* (Luxembourg: Publications Office of the European Union, 2009), online: EUROPA < http://ec.europa.eu/health/ph_overview/co_operation/healthcare/cross-border_healthcare_en.htm> (date accessed: 14 January 2009).

³⁶⁹ "EU Reaches Deal on Banning Toxic Pesticides" *EurActiv* (19 December 2008), online: EurActiv
 http://www.euractiv.com/en/environment/eu-reaches-deal-banning-toxic-pesticides/article-178202 (last modified: 22 December 2008).

³⁶² J.J. Richardson, *European Union: Power and Policy-Making* (London: Routledge, 2005).

³⁶³ *Vogel, supra* note 350 at 566.

³⁶⁴ D. Dinan, Ever Closer Union: An Introduction to the European Union, (London: Macmillan, 1999) at 407.

³⁶⁶ *Ibid.* at 408-409.

Evaluation and Authorisation of Chemicals (REACH). In addition, there is a current proposal for a directive on ambient air quality for Europe and for a framework directive on pesticides.³⁷⁰ As a result of the 6th EAP, the Directorates-General of Environment, Health and Research and the Joint Research Centre published the Health Strategy. The strategy's aim is to aid in information gathering and coordinate amongst all levels of the EU in reducing risk.

Both Agenda 21 and the earlier transnational agreements demonstrate that though international recognition of health and environment has been made, these agreements tend to lack any binding or enforceable standards. The relatively new paradigm of environmental health in relation with the varying abilities of developing and developed nations has produced little in effect of bettering westernized nations. These same problems are evident in international doctrines which have focused on children directly.

3.3 Children's Environmental Health: International Agreements

It is well understood that children are not little adults, and, in fact, have a higher rate of susceptibility to harm from exposure to hazardous toxins.³⁷¹ And though international bodies, non-governmental organizations, and even some national governments have begun to recognize the importance separate consideration and analysis of children is in policy, the number of effective international doctrines mandating clear requirements is few and far between. In much of the literature on children's environmental health, praise has been given to those agreements which have made any mention of children whatsoever.³⁷² However, after decades of epidemiological studies indicating the physiological and behavioural differences of children there is sufficient scientific and public support in setting explicit exposure reduction rates. Similar accomplishments have been made at an international level with regard to reducing lead, POPs, and hazardous materials as will be referenced in the following two sections. Therefore, it is reasonable that those agreements which have outlined children's vulnerabilities could have taken it a step further and set forth standards, frameworks, and deadlines.

This section will provide a general overview of some of those doctrines which have highlighted children's environmental health, as well as some of the principles and conventions which are most often affiliated with the field. Transnational agreements which have made an impact on children's environmental health will also be reviewed. It is worth noting that it would be difficult to mandate clear requirements and deadlines on a truly international scale. The current status of children's environmental health is divergent among nations. A glaring contrast in policy protection for children's health differs between that of industrialized and developed nations. A child in Bangladesh is exposed to arsenic contamination in ground water and most likely does not live in an area where sanitation or solid waste

³⁷⁰ Communication from the Commission to the European Parliament, The Council, the European Economic and Social Committee and the Committee of the Regions on the Mid-Term Review of the Sixth Community Environment Action Programme, COM (2007) 225 Final, online: Commission of the European Communities http://eur-lex.europa.eu/LexUriServ.do?uri=COM:2007:0225:FIN:EN:PDF> (last modified: 30 April 2007).

³⁷¹ Landrigan 1999, supra note 171 at 1; Wargo, supra note 26.

³⁷² Landrigan, ibid.; P.J. Landrigan & G. Tamburlini, "Editorial: Children's Health and the Environment: A Transatlantic Dialogue" (2005) 113:10 Environ. Health Perspect. A646 at A646.

disposal is in place.³⁷³ The health effects of these problems for this child, though disproportionately higher than those of Bangladesh adults, are not a pressing issue where civil unrest routinely occurs and basic human rights have not been granted.³⁷⁴ This is in contrast to a child in Norway where the government is actively working towards including children in community planning³⁷⁵, infant mortality rates are extremely low³⁷⁶, and children are clearly identified in policy as a vulnerable subpopulation³⁷⁷. Setting standards at an international level which would require both Bangladesh and Norway to better their environmental health protection is highly unlikely. The standards would have to take into consideration the least progressive nation, therefore eliminating any binding requirements for industrialized nations such as Norway. Nevertheless, this dichotomy between developing and developed nations does not excuse similar nation-states from taking action.

3.3.1 The United Nations

International bodies have been fundamental in bringing children's environmental health to the forefront of consideration. As will be discussed in further detail in this section, this motivation has been in part due to national pressures (both from governmental bodies and non-governmental organizations) for an international discussion. One such international organization that has been effective in bringing awareness to children's environmental health at a global scale is the UN. It is important to stress that this recognition, though useful, has been more effective in developing nations. Organizational bodies within the UN framework, as well as those at a national level, have taken on implementation of basic rights recognized by the UN and the signatory countries. Beginning with the UN Convention on the Rights of the Child (UN CRC), the UN has assisted in educating on the universal basic rights of health and care a child should have. This has enveloped the right to safe drinking water, adequate sanitation, and healthy environmental conditions.³⁷⁸ Nevertheless, the functionality of these rights to require industrialized nations to improve their environmental conditions is not there. The UN has, though, made an impact in increasing awareness

³⁷³ World Health Organization, *Country Health System Profile Bangladesh – Health and Environment* (Geneva: WHO, 2007), online: WHO <http://www.searo.who.int/en/Section313/Section1515_6123.htm> (date accessed: 6 August 2008).

³⁷⁴ U.S., "Background Note: Bangladesh" (Washington, D.C.: U.S. Department of State, 2009), online: U.S. Department of State http://www.state.gov/r/pa/ei/bgn/3452.htm> (date accessed: 3 January 2009).

³⁷⁵ European Union, "Norway – Steps Towards Implementation of Budapest Commitments" (Geneva: WHO/EUROPE European Environment and Health Committee, 2005), online: EEHC ">http://www.euro.who.int/eehc/implementation/20050420_1> (last modified: 10 October 2005).

³⁷⁶ In 2004, 3.2 infants out of 1,000 live births in Norway die within the first year of life. *Highlights on Health in Norway*, (Copenhagen: World Health Organization Regional Office for Europe, 2005), online: WHO Europe < http://www.euro.who.int/document/e88744.pdf> (last modified: 2005); *The Environment and Health for Children and their Mothers*, (Copenhagen: World Health Organization Regional Office for Europe, 2005), online: WHO Europe < http://www.who.int/mediacentre/factsheets/fs284/en/> (last modified: February 2005).

³⁷⁷ Norway, *The Norwegian National Environment and Health Action Plan* (Oslo: Norwegian Ministry of Environment and Ministry of Health and Social Affairs, 2001), online: Regjeringen.no < http://www.regjeringen.no/nb/dep/hod/dok/rapporter_planer/rapporter/2001/the-norwegian-national-environment-and-h.html?id=105635> (date accessed:15 January 2009).

³⁷⁸ Office of the United Nations High Commissioner for Human Rights & World Health Organization, *The Right to Health* UN Fact Sheet No. 31, 2008, online: UN http://www.ohchr.org/Documents/Publications/Factsheet31.pdf (last modified: June 2008).

towards remedying the socioeconomic disparities that result in children in developing nations experiencing high levels of environmental exposures.³⁷⁹

The CRC was the result of ten years of efforts by the Working Group on the Question of a Convention on the Rights of the Child.³⁸⁰ While not directly focused on the relationship between children and exposure to environmental hazards, the doctrine has led to legal query by scholars and governments alike on how far these rights extend. This convention built upon the Geneva Declaration of the Rights of the Child of 1924, the United Nations Declaration on the Rights of the Child adopted in 1959, the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights.³⁸¹ Children are highlighted as a subpopulation that "needs special safeguards and care, including appropriate legal protection, before as well as after birth."³⁸² Of particular relevance to children's environmental health is Article 24, which holds that state parties "recognize the right of the child to the enjoyment of the highest attainable standard of health and to the facilities for the treatment of illness and rehabilitation of health".³⁸³ It is within this article that the explicit right to clean water is mentioned.³⁸⁴ While the main objective of this convention was not to promote policy relevant to children's environmental chemical and pollutant exposure, literature on the topic has looked to this doctrine as a relevant starting point.³⁸⁵ Discussion of the CRC stresses that this convention was a manifestation of a changing social environment where children were to be protected.³⁸⁶ For some nation-states, the CRC merely reaffirmed rights already assumed under domestic law. The Finnish Child Custody and Rights of Access Act passed in 1983 and the Norwegian Children's Act of 1981 are just two examples of domestic legislation which not only enforces the basic rights of the child (nutrition, freedom from poverty, health care), but also identifies the ability of children to actively participate in decision-making.³⁸⁷ However, other nations, such as the UK, have been criticized for failing to implement the convention to the fullest extent possible.³⁸⁸ Additionally, many of those authorities with direct

³⁸⁴ *Ibid*.

³⁸⁸ *Ibid*. at 97.

³⁷⁹ Critics hold that this awareness has not resulted in the reduction of infant mortality. A. Wagstaff et al., "Child Health: Reaching the Poor" (2004) 94:5 Am. J. Public Health 726 at 726-727.

³⁸⁰ S. Detrick, J. Doek, & N. Cantwell, *The United Nations Convention on the Rights of the Child: A Guide to the "Travaux Préparatoires* (Leiden, The Netherlands: Martinus Nijhoff Publishers, 1992) 1-3.

³⁸¹ Convention on the Rights of the Child, GA Res. 44/25, UN GAOR, online: UN High Commissioner for Human Rights < http://www2.ohchr.org/english/law/crc.htm> (date accessed: 15 July 2008).

³⁸² Ibid.

³⁸³ Ibid.

³⁸⁵ S. Bartlett, *The UN Convention on the Rights of the Child Reporting System and the Physical Environment*, (Stockholm: Save the Children Sweden, 2002), online: Save the Children Sweden <

http://www.childfriendlycities.org/pdf/rbunconvention.pdf> (date accessed: 12 December 2008); A. Davis & L.J. Jones, "Children in the Urban Environment: An Issue for the New Public Health Agenda" (1996) 2:2 Health Place 107 at 111; P.H. Gleick, "The Human Right to Water" (1998) 1:5 Water Policy 487 at 489-490.

³⁸⁶ M. Freeman, "The Future of Children's Rights" (2000) 14:4 Child Society 277; M.A. Freeman & P.E. Veerman, *The Ideologies of Children's Rights* (Leiden, The Netherlands: Martinus Nijhoff Publishers, 1992).

³⁸⁷ B. Franklin ed., *The New Handbook of Children's Rights: Comparative Policy and Practice* (London: Routledge, 2002) at 23.

interaction with children, such as teachers and welfare practitioners, do not appear to be well informed about the CRC.³⁸⁹

3.3.2 The World Health Organization

For developing nations, the recognition of the rights of the child may be a first step in moving towards a more progressive health and environmental policy which takes children into account. Similar projects launched by the UN have aided in strengthening governance and reducing poverty, both of which are essential prior to tackling the hardships of environmental pollution. While relevant to children's environmental health in general, they are less influential in countries such as Canada, the US, and Sweden where these standards have been long ago instituted. International organizations, such as the World Health Organization (WHO) and the Organization for Economic Cooperation and Development (OECD), have had greater success in moving towards a better understanding of the field of children's environmental health. Both organizations have aided in data sharing and in the recognition of knowledge gaps in the field. Interestingly, much of the efforts by both bodies have been in part due to collaboration with the European Union European Environment Agency (EEA).

The WHO has played an important role in bringing awareness to a child's susceptibility to environmental toxins. For the most part, the focus of the WHO has been on morbidity and mortality of children in developing nations, in a great part because of toxic exposures. It has been estimated that as much as thirty-six percent of deaths of children (0-14 years of age) is due to exposure to environmental toxins.³⁹⁰ Many of these deaths are due to respiratory infections, diarrhea, and vector borne disease^{391,392} A high percentage of these deaths occur within developing nations where use of biomass fuels, contaminated water, and poor sanitation are more common. Prioritization of what countries need to be the focus of the WHO necessarily results in concentration on developing nations with high levels of environmental burden of disease and communicable diseases.³⁹³

However, this is not to say that the efforts of the WHO have not been valuable to the increasing awareness and the development of policy within developed nations. The WHO Europe has been able to assist western nations in addressing children's environmental health issues. Research supported by WHO Europe has produced data on the

<http://www.who.int.mediacentre/factsheets/fs272/en/index.html> (last modified: April 2003).

³⁸⁹ *Ibid.* at 112.

³⁹⁰ T.G. Gavidia, J. Pronczuk de Garbino, & P.D. Sly, "Children's Environmental Health: An Under-Recognized Area in Paediatric Health Care" (2009) 9 BMC Pediatr. 10 at 11. A. Prüss-Üstün & C. Corvalán, *Preventing Disease through Healthy Environments* (Geneva: WHO, 2006) at 6.

³⁹¹ Vector borne diseases are those transmitted by mosquitoes. It is estimated that 1.3 million deaths for children under the age of five each year are a result of diarrhoea and 2 million die due to respiratory disease. World Health Organization, *What Happens When Children Live in Unhealthy Environments? Healthy Environments for Children: Facts and Figures* (Geneva: WHO, 2003), online: WHO

³⁹² *Ibid*.

³⁹³ T. Boonyakarnkul, A.P. Kingston, & M.K. Shea, *World Health Organization: Specific Environmental Threats: Sources of Exposure and Health Effects* (Geneva: WHO, 2004), online: WHO

<http://whqlibdoc.who.int/publications/2005/9241562927_section3_eng.pdf> (date accessed: 10 May 2009); D. Briggs, E. Rehfuess, & C. Corvalan, "Global Initiative on Children's Environmental Health Indicators" (Workshop on Environmental Threats to the Health of Children in the Americas, Lima, 9-11 April 2003).

effects of air pollution in general, and more specifically on transport pollution and the effect of particulate matter on children. Research conducted by WHO Europe indicates that though European children are exposed to fewer pollutants than developing nations, there is still need to address pollutant pathways. "Between 1.8% and 6.4% of all deaths among European children up to 4 is caused by outdoor air pollution by fine particulates. Some 4.6% of deaths in the same group are attributed to indoor air pollution by smoke from solid fuel burning. A further 5.3% of deaths in children up to 14 are attributed to dirty water or sanitation."³⁹⁴ In response to these numbers, the WHO Europe, in conjunction with European Union European Environment Agency, has commenced projects that target children's vulnerability to environmental harms.

In 1989, WHO Europe initiated a dialogue on environment and health, producing the European Charter on Environment and Health. This declaration recognized the need for reliable scientific data and effective policy to promote environmental and health action.³⁹⁵ "Specific recommendations [have been] made in areas such as air quality, drinking-water and wastewater, solid waste and radiation. Target Ten in the policy states that, by the year 2015, people in the WHO European Region should live in a safer physical environment, with exposure to contaminants hazardous to health at levels not exceeding internationally agreed standards."³⁹⁶ Further international promotion of environmental health was affirmed in June 1999, at the Third Ministerial Conference on Environment and Health hosted by WHO Europe.³⁹⁷ The Third Ministerial Conference recognized the "special vulnerability of children" and committed to "develop policies and actions to achieve a safe environment in which children can develop to their highest attainable levels of health".³⁹⁸ Thus children's health standards were elevated from that of "internationally agreed standards"³⁹⁹ to that of the "highest attainable level of health".⁴⁰⁰.

Within WHO Europe sits the European Environment and Health Committee (EEHC) which is a coalition of health ministries, environment ministries, non-governmental organizations (NGOs), and intergovernmental organizations. This team of experts and government officials have been tasked with the responsibility of overseeing the implementation of Children's Environment and Health Action Plan for Europe (CEHAPE) objectives. CEHAPE, aimed at policy makers, was adopted by the European Ministers at the Fourth Ministerial Conference on Environment and Health (2004). The purpose of the CEHAPE is to provide a framework for which member states

³⁹⁹ *Ibid*.

⁴⁰⁰ *Ibid*.

³⁹⁴ "WHO Talks Up Scale of Environment-Health Risks" *ENDS Europe* (21 June 2004), online: ENDS Europe < http://www.endseurope.com/index.cfm?go=9540&view=print> (last modified: 21 June 2004).

³⁹⁵ G.H Brundtland, "Environment and Health: Europe's Partnership Can be a Model" (1999) 318:7199 Br. Med. J. 1635 at 1636.

³⁹⁶ WHO Working Group, *Establishing the International Network on Children's Health, Environment and Safety,* WHO Europe, EUR/ICP/EHRO 02 06 02, online: WHO Europe < http://www.euro.who.int/document/e64739.pdf> (date accessed: 15 November 2008).

³⁹⁷ WHO, *Fourth Ministerial Conference on Environment and Health*, WHO Europe EUR/04/5046267/7, online: WHO Europe < http://www.euro.who.int/document/e83338.pdf> (last modified: 25 June 2004).

³⁹⁸ U.S., Environmental Protection Agency, *1997 Declaration of the Environment Leaders of the Eight on Children's Environmental Health* (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency http://yosemite.epa.gov/ochp/ochpWeb.nsf/content/declara.htm> (last modified: 27 November 2009).

can use in analyzing the current state of children's environmental health within their jurisdiction. CEHAPEs are advantageous to children for a few reasons. One, the objectives are clearly defined. Regional priority goals include: (1) ensure safe water and adequate sanitation, (2) ensure protection from injuries and adequate physical activity, (3) ensure clean outdoor and indoor air, and (4) aim chemical-free environments. Also, the objectives are aimed at children. Specifics have been outlined as to how each of these objectives can be met. For instance, in order to reduce chemical exposure the EU aims to ensure that the obligations of the Stockholm Convention on Persistent Organic Pollutants, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade are fulfilled.⁴⁰¹ Secondly, due to the relatively similar state of children's environmental health within the region of WHO Europe and the EU, standards and recommendations are set for industrialized nations. A third reason for the successfulness of the CEHAPE is that there is constant monitoring of progress and failure. Evaluation by country is submitted to the CEHAPE Task Force on a regular basis. Because the CEHAPE requires specific action to be taken by member-states, positive outcomes have resulted. For instance, within the UK government assessed in detail the current status of each priority goal within the nation for future policy development.⁴⁰² Lastly, the project has a target audience of policy makers rather than the science community. The EEHC and the WHO Europe have been fundamental in "facilitating, promoting and coordinating" international cooperation.⁴⁰³ The work conducted by the EEHC has incorporated the efforts of non-governmental entities, scientists, and representatives of national health and environment ministries. It is this team of experts and governmental officials that has been tasked with the responsibility of overseeing the implementation of CEHAPE objectives.

⁴⁰¹ WHO 2004, supra note 397.

⁴⁰² U.K., *Children's Environment and Health Action Plan*, (London: Health Protection Agency, 2007), online: HPA http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947328059 (date accessed: 3 June 2009).

⁴⁰³ L. Licari, L. Nemer, & G. Tamburlini, *Children's Health and Environment: Developing Action Plans*, (Geneva: WHO European Office, 2005) at 43.

3.3.3 The Organisation For Economic Co-Operation And Development

Similar to the WHO, the Organisation for Economic Co-Operation and Development has been fundamental in gathering data and fostering meetings with regard to standard setting relevant to children's exposure rates. The OECD actively works towards harmonizing testing and assessment protocols and preventing the repetition of research through data sharing.⁴⁰⁴ As children's environmental health is one focus of the OECD's environmentalsocial interface, the objective is to assist policymakers in making informed decisions pertaining to the health and safety of children.⁴⁰⁵ A portion of their efforts has been utilized to identify environmental health indicators which establish clear links between health impact and environmental hazards.⁴⁰⁶ For instance, the Valuation of Environment-Related Health Impacts program considers values used for monetisation of environment-related health impacts.⁴⁰⁷ Similar studies in the past have imposed adult values on children's health outputs. The OECD, in cooperation with the European Commission's Directorate General for Research, has worked towards producing reports on willingness to pay (WTP) and quality of adjusted life years (QALY) frameworks with focus on children's environmental health.⁴⁰⁸ The hope is that these studies and surveys will be of use in developing future policy within OECD member-states, and in particular the EU. Funded by the European Commission's Directorate General for Research, the OECD hopes to facilitate the gathering of information from the research teams on three objectives: (1) review of epidemiological studies, (2) review of economic studies on willingness to pay to reduce environmental risks to children's health, and (3) evaluation of environment-related health impacts.⁴⁰⁹

While the majority of the efforts by the OECD have been on gathering data and formulating evaluative tools on children's environmental health in general, specific areas of pollution have been targeted by the organization. The OECD 1990 Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals (C(90) 163/Final) aims at reducing negative health outcomes due to chemicals released into the environment.⁴¹⁰

⁴⁰⁶ Environment Directorate Environment Policy Committee, *Children's Environmental Health Indicators: A Survey*, OECD, 2004, ENV/EPOC/WPNEP(2004)16/FINAL, online: OCED http://www.olis.oecd.org/olis/2004doc.nsf/LinkTo/NT0000A14E/\$FILE/JT00189055.PDF (date accessed: 12

(date accessed: 12 December 2008).

⁴⁰⁴ H.B. Koëter & R. Visser, "Work in OECD on Chemical Safety: Approaches for Human Risk Assessment" (2000)38:2 Ind. Health 109 at 110.

⁴⁰⁵ OECD Environment Directorate, *Children's Environmental Health* (Paris: OECD, 2008), online: OECD http://www.oecd.org/document/16/0,3343,en_2649_32495306_35143376_1_1_1_0.0.html (last modified: 14 November 2008).

⁴⁰⁷ Valuation of Environment-Related Health Impacts with a Particular Focus on Children, OECD, online: OECD http://www.olis.oecd.org/olis/2004doc.nsf/LinkTo/NT0000A14E/\$FILE/JT00189055.PDF (date accessed: 2 March 2009).

⁴⁰⁸ *Ibid.*; J. K. Hammitt, *Methodological Review of WTP and QALY Frameworks for Valuing Environmental Health Risks to Children* (OECD, 2005), online: OECD <

 $http://74.125.155.132/scholar?q=cache:7APv4CtMfacJ:scholar.google.com/+hammitt+methodological+review+of+wtp+and+qaly+frameworks+&hl=en&as_sdt=2000> (date accessed: 14 July 2008).$

⁴⁰⁹ Background Reading: Valuation of Environment-Related Health Impacts, (OECD), online: OECD <http://www.oecd.org/document/12/0,3343,en_21571361_36146795_36283596_1_1_1_1_0.0.html> (date accessed: 14 July 2008).

⁴¹⁰ Environment Directorate Environmental Health and Safety Division, *Risk Reduction Monograph No. 1 Lead Background and National Experience with Reducing Risk*, OECD, 1993, OCDE/GD(93)67, online: OCED

Additionally, the 1996 OECD Environment Ministers Declaration on Risk Reduction for Lead is an example of steps member states have taken under this declaration to diminish exposure in both adults and children. This declaration has helped inform legislation in nations as well as industry behaviour.⁴¹¹ Elimination of exposure to lead from products intended for children are specifically outlined within the declaration.⁴¹² However, the declaration relies heavily on voluntary efforts to reduce exposure and production with no set deadlines or requirements to be met.⁴¹³ For instance, though Canada is a signatory to the declaration which mandates reduction in exposure rates, Health Canada's Consumer Product Safety group did not establish a procedure to prohibit consumer exposure to lead until 2004.⁴¹⁴ Alternatively, the OECD's efforts did result in the European Union's Pan- European strategy to phase out leaded petrol by January 1, 2005. Signed at the Fourth Ministerial Conference, motivation for this declaration included the health of the vulnerable populations, such as children.⁴¹⁵ This was particularly effective for Eastern European nations that had not taken the necessary steps to mandate the use of unleaded gasoline. Implementation remains a constant problem.

3.3.4 The Miami Declaration

Although the UN, WHO, and OECD have made headway in bridging knowledge gaps and gathering intellectual and financial resources that aid in reducing children's environmental hazard exposure, their main objectives have not been that of children's environmental health. The policy proposals they have produced do not mandate any specifics to be met, except in those cases where the EU has put in legislation with standard requirements. These organizations have not produced international agreements which focus solely on children's environmental health. Due to the sparse number of international doctrines directly addressing children's environmental health, those that do are often portrayed as successful.⁴¹⁶ While these agreements may lend themselves to bringing awareness to the vulnerabilities that children face when exposed to toxins, they fail to hold signatories accountable or set specific standards. The Miami Declaration is often cited as a landmark agreement in children's environmental health, bringing the topic to

<http://www.oecd.org/dataoecd/23/50/1955919.pdf> (date accessed: 3 June 2009); OECD, Council on the Cooperative Investigation and Risk Reduction of Existing Chemicals, *Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Existing Chemicals*, OECD, 1991, C(90)163/Final, online: OECD <http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C(90)163> (last modified: 31 January 1991).

⁴¹¹ "International Lead Management Center Reducing the Risk of Lead Exposure" *Lead Action News* (18 February 2008), online: Lead Action News http://www.lead.org.au/lanv7n1/L71-9.html> (last modified: 18 February 2008).

⁴¹² Declaration on Risk Reduction for Lead, OECD, 1996 C(96)42/Final, online: OECD < http://webdomino1.oecd.org/horizontal/oecdacts.nsf/linkto/C(96)42> (last modified: 19 February 1996).

⁴¹³ "Reducing the Risk of Lead Exposure" *Lead Action News* (26 January 2009), online: Lead Action News < http://www.lead.org.au/lanv7n1/L71-9.html> (last modified: 26 January 2009).

⁴¹⁴ W. Bell & K. O'Grady, "Lead Poisoning in Children" (2004) 171:5 C.M.A.J., online: CMAJ <http://www.cmaj.ca/cgi/content/full/171/5/429> (last modified: 31 August 2004).

⁴¹⁵ United Nations Economic Commission for Europe, *Pan-European Strategy to Phase Out Leaded Petrol*, UN ECE, 1998, online: UN Bibliographic Information System
">http://unbisnet.un.org:8080/ipac20/ipac.jsp?session=1208WBJ503217.56241&profile=bib&uri=full=3100001~!440418~!6&ri=1&aspect=alpha&menu=search&source=~!horizon#focus>">http://unbisnet.un.org:8080/ipac20/ipac.jsp?session=1208WBJ503217.56241&profile=bib&uri=full=3100001~!440418~!6&ri=1&aspect=alpha&menu=search&source=~!horizon#focus>">http://unbisnet.un.org:8080/ipac20/ipac.jsp?session=1208WBJ503217.56241&profile=bib&uri=full=3100001~!440418~!6&ri=1&aspect=alpha&menu=search&source=~!horizon#focus>">http://unbisnet.un.org:8080/ipac20/ipac.jsp?session=1208WBJ503217.56241&profile=bib&uri=full=3100001~!440418~!6&ri=1&aspect=alpha&menu=search&source=~!horizon#focus>">http://unbisnet.un.org:8080/ipac20/ipac.jsp?session=1208WBJ503217.56241&profile=bib&uri=full=3100001~!440418~!6&ri=1&aspect=alpha&menu=search&source=~!horizon#focus>">http://unbisnet.un.org:8080/ipac20/ipac.jsp?session=1208WBJ503217.56241&profile=bib&uri=full=3100001~!440418~!6&ri=1&aspect=alpha&menu=search&source=~!horizon#focus>">http://unbisnet.un.org:8080/ipac20/ipac.jsp?session=1208WBJ503217.56241&profile=bib&uri=full=3100001~!440418~!6&ri=1&aspect=alpha&menu=search&source=~!horizon#focus>">http://unbisnet.un.org:8080/ipac20/ipac.jsp?session=1208WBJ503217.56241&profile=bib&uri=full=3100001~!4404404"
CEMT/CM(99)25/FINAL.

⁴¹⁶ Sharpe, supra note 56 at 96.

the forefront of policy dialogue in developed nations (G-8 nations).⁴¹⁷ The efforts set forth in the declaration have been reaffirmed in the Banff Ministerial Statement on the World Summit on Sustainable Development in 2002. However, the Miami Declaration was a product of pressures by the US to bring attention to children's environmental health, an effort which decreased in urgency with the following change of presidential administration. Similarly, the efforts to bring attention to children's environmental health in the North American context, under the pretext of NAFTA, failed to hold countries accountable to specific standards. The following portion of this section will review these two agreements and their ineffectiveness in changing children's environmental health.

The 1997 Declaration of the Environment Leaders of the Eight on Children's Environmental Health has provided an international forum on children's environmental health. A multitude of events led up to the Miami Declaration, including the 1990 EPA and International Life Sciences Institute symposia on *Similarities and Differences Between Children and Adults: Implications for Risk Assessment*⁴¹⁸ and efforts to recognize children's vulnerabilities in the US policy *Food Quality Protection Act* in 1996. ⁴¹⁹ Prompted by the US EPA and President Clinton, this meeting of the G8 countries (Canada, France, Germany, Italy, Japan, the Russian Federation, the United Kingdom, the United States of America, and the European Union) outlined topics of focus, including lead reduction, providing microbiologically safe drinking water, undertaking research on air quality effects on children, eliminating environmental tobacco smoke exposure, gathering inventory on research concerning endocrine disrupting chemicals, and considering the impact of global climate change on children's health.⁴²⁰ While this doctrine is legally non-binding, it has served as a motivational tool for nation-states for research and, to a lesser degree, relevant policy.

Signatories of the declaration pledged "to establish national policies that take into account the specific exposure pathways and dose-response characteristics of children when conducting environmental risk assessments and setting protective standards."⁴²¹ Each nation-state has made efforts to address some if not all of the issues outlined in the doctrine. The commitments made by the countries are helpful in highlighting the vulnerabilities of children, but fail to set standards or guidelines, or resolve issues surrounding knowledge gaps. Each nation-state has made legislation citing the Miami Declaration, but the policy differs in consideration of children's health. Canada has focused on developing climate change human health impact assessment guidelines, while Germany committed to reducing carbon dioxide emissions by twenty-five percent of the 1990 levels by the year 2005.⁴²² This illustrates that the science and the policy- making process may result in different outcomes though agreement has been made at an international level that action needs to be taken.

⁴¹⁷ *Ibid*.

⁴¹⁸ This was one of the first conferences on children's environmental health.

⁴¹⁹Sharpe, supra note 56 at 96.

⁴²⁰ 1997 Declaration of the Environment Leaders, supra note 398.

⁴²¹*Ibid*.

⁴²² Canada, *Status Report on Implementation of the 1997 Declaration of the Environment Leaders of the Eight on Children's Environmental Health* (Ottawa: Government of Canada, 2002), online: EPA http://yosemite.epa.gov/ochp/ochpWeb.nsf/content/G8report.htm/%File/G8report.pdf> (last modified: April 2002).

The Miami Declaration has instigated consultation at an international level on children's environment health; however, it lacks clear requirements of compliance. Some of the objectives of the declaration have merit, such as the request made that the International Organization on the Management of Chemicals and the US EPA to create an inventory on international research on endocrine disrupting chemicals. However, the nations not only aren't required to meet certain goals by predetermined deadlines, but follow-up on the issue is left to the devices of the nations with vested interests in the field. The topic of environment and health first appeared on the G8 agenda in 1996.⁴²³ The 1997 Miami Declaration focused on environment and health in relation to children, with follow-up discussion at the 2002 Banff G8 meeting. Additional consideration of the topic of children's environmental health by the G8 ministers of environment has not been acted upon. Though progress has been made in the area of children's environmental health following the Miami Declaration, much of this would have taken place regardless of the agreement. At the time the US administration was highly supportive of improving children's health outcomes due to hazardous exposure and it is likely efforts taken by the US EPA in conjunction with Canada and Mexico to improve waterways would have occurred.⁴²⁴ Although the reduction of lead exposure is held out as a sign of progress in the 2002 review report, this was a recognized issue of concern long before the G8 meeting.⁴²⁵

The review of progress to date on the Miami Declaration conducted in 2002 illustrates that all G8 nations still had not yet explicitly considered children as a component of the risk assessment for water standards.⁴²⁶ The application of efforts to reduce exposure to endocrine disrupting chemicals has illustrated how the vague terminology of the Miami Declaration can result in differing outcomes. The G8 ministers of the environment pledged to develop "pollution prevention strategies, as major sources and environmental fates of endocrine disrupting chemicals are identified".⁴²⁷ Relevant policy in Europe has banned the use of phthalates not only in toys but cosmetics, whereas Canada has done so for toys only, and the US EPA for none of the above.⁴²⁸

<http://yosemite.epa.gov/opa/admpress.nsf/8d49f7ad4bbcf4ef852573590040b7f6/29c1e0120c6153e38525701a0052e 3cc!OpenDocument> (last modified: 4 April 1998).

⁴²⁵ Environment Ministers' Meeting, supra note 422.

⁴²⁶ *Ibid*.

⁴²⁷1997 Declaration of the Environment Leaders, supra note 398.

⁴²³ "G7 Environment Ministers' Meeting" (G7 Meeting, Cabourg, France, 9-10 May 1996), online: U of T G8 Information Centre http://www.g8.utoronto.ca/environment/1996cabourg/summary_index.html (date accessed: 3 June 2009).

⁴²⁴ C. Browner, "G-8 Environment Ministerial Follow up Report from Miami Meeting" (Leeds Castle, England, 4 April 1998), online: EPA

⁴²⁸ Sharpe, supra note 56 at 93; Canada, Chemical Substances Canada, Phthalates, (Ottawa: Chemical Substances Canada, 2007), online: Chemical Substances Canada http://www.chemicalsubstanceschimiques.gc.ca/interest-interet/phthalates_e.html (last modified: 20 April 2007); J. Walsh, "EPA Should Pursue Cumulative Risk Assessment of Phthalates and Other Chemicals" Press Release from the National Academies (18 December 2008), online: National Academies < http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12528> (last modified: 18 December 2008).

3.4 Regional Agreements: Europe

While the Miami Declaration may be heralded as a success in bringing awareness to the issue of children's environmental health⁴²⁹, regional agreements have made a larger impact on actual exposure rates. Regional agreements have been used specifically for the protection of children's health. Preventative measures with specific consideration of children's environmental health have been employed to a great extent in Europe by the European Union and Nordic Committee of Senior Officials for Social and Health Affairs. The European Union's Science, Children, Awareness, Legislation and Evaluation (SCALE)⁴³⁰ project focuses on children's vulnerabilities with concentration on childhood respiratory diseases, neurodevelopmental disorders, cancer, and endocrine disrupting effects.⁴³¹ Not only are children highlighted in this project, but it incorporates the monitoring of pollutant levels and childhood health indicators.⁴³² Information gathered from this project led to the development of the European Environment and Health Action Plan 2004-2010. Criticism has been made regarding the Action Plan's slow progress in developing policy based on research outcomes from SCALE. What makes this situation different from that of the Miami Declaration, though, is the willingness of EU officials to remedy the situation. In 2005, EU Members of Parliament (MEPs) voted in favour of a report⁴³³ which provided on evaluation of the strategy and took necessary legislative action to reduce exposure to phthalates, chlorinated solvents, mercury, cadmium, and some pesticides.⁴³⁴

While the efforts by the EU are legislatively binding on member states, there are examples of voluntary transnational agreements which impact children's environmental health. The Nordic Council of Ministers, formed by Denmark, Finland, Norway, and Sweden, developed a working group to address children's environmental health issues. For instance, air pollution has been a topic of discussion where children's health has been specifically outlined for consideration in areas such as the distance between schools and major traffic.⁴³⁵ Simple ideas, such as use of green space, have been addressed. In August, 2005, the Council of Ministers adopted the Odense Declaration which recommended that daycare centers in Nordic countries be no further than five miles from green spaces which they could utilize.⁴³⁶ To follow-up on this declaration, the Council has commissioned a pilot study to review the policy

⁴³¹ *Ibid*.

⁴³² *Ibid*.

⁴²⁹ Sharpe, supra note 56 at 93.

⁴³⁰ E.C., *Communication "A European Environment and Health Strategy"* [2003] COM (2003) 338 final, online: EurActiv < http://www.euractiv.com/en/environment/environment-health-strategy-scale/article-117480#> (last modified: 11 June 2003). [hereinafter *Com*(2003) 338 final].

⁴³³ The EU ministers voted to ban the use of phthalates in children's toys in 2004. Efforts have been taken by the EU to eliminate export of mercury and decrease use and emissions by 2011. Cadmium in consumer batteries has been partially banned, with exceptions for power tools. Additionally, 110 active substance found in pesticides have been removed from the market by the end of 2003.

⁴³⁴ "Industry Deplores MEP Vote on Environment and Health Plan" *EurActiv News* (24 November 2006), online: EurActiv News < http://www.euractiv.com/en/environment/industry-deplores-mep-vote-environment-health-plan/article-135911> (last modified: 24 November 2006).

⁴³⁵ S. Herfelt, *Nordic Synergy: The Day-Care Environment and Children's Health* (Copenhagen: Nordic Council, 2007), online: Nordic Council http://norden.org/pub/miljo/sk/ANP2007720.pdf (date accessed:15 January 2009).

instruments needed to address the effect of local particle pollution and chemicals substances on children's environmental health.⁴³⁷

3.5 Regional Agreements: North America

Regional agreements addressing children's environmental health are also present in North America. Although the relationship between human health and the environment has been evolving in both Europe and North America, the method by which this topic has been approached differs. Within the United States, a great deal of the success children's environmental health has had at a national level has been linked to President Clinton. The United States was fundamental in motivating international symposiums and declarations on the topic of children's environmental health, mostly due to the EPA administration, President Clinton, and Vice President Gore.⁴³⁸ The Miami Declaration and the follow-up meeting, the World Summit on Sustainable Development (Johannesburg, 2002), elevated the awareness of the vulnerability of children to exposures. However, what has been of value to regional responsiveness has been the NAAEC. A parallel treaty to the North American Free Trade Agreement, this regional declaration was signed by Canada, Mexico, and the United States and came into effect on January 1, 1994.⁴³⁹ The NAEEC is overseen by the Commission for Environmental Cooperation (CEC) which consists of the Council, Joint Public Advisory Committee (JPAC) and the Secretariat. The CEC's Expert Advisory Board on Children's Health was created to provide the CEC Council with advice and recommendations on "issues related to environmental threats to children's health in North America".⁴⁴⁰

Concern surrounding the NAFTA's perceived ineffectual ability to address environmental issues, as well as environmental issues that had arisen under the General Agreement on Tariffs and Trade (GATT)⁴⁴¹, led to the drafting of the NAAEC. The agreement has been frowned upon for its reliance on litigation rather than cooperation⁴⁴², as well as for its failure to address local polluters (the focus being on specific transboundary issues such as pollution in the Great Lakes).⁴⁴³

⁴³⁷ *Ibid*.

⁴³⁸ Goldman, supra note 6 at 445; Landrigan 1999, supra note 171 at 7.

⁴³⁹ Secretariat of the Commission for Environmental Cooperation, *North American Agreement on Environmental Cooperation between the Government of Canada, the Government of the United Mexican States and the Government of the United States of America,* 1993, online: Commission for Environmental Cooperation < http://www.cec.org/pubs_info_resources/law_treat_agree/naaec/index.cfm?varlan=english>.

⁴⁴⁰ NAFTA, Expert Advisory Board, *Children's Heath and the Environment in North America*, (Commission for Environmental Cooperation, 2008), online: CEC < http://www.cec.org/files/PDF/POLLUTANTS/AdvbdTOR-fin2-eUSC_EN.pdf> (date accessed: 12 December 2008).

⁴⁴¹ J.O. Saunders, "NAFTA and the North American Agreement on Environmental Cooperation: A New Model for International Collaboration on Trade and the Environment" (1994) 5:273 Colo. J. Int. Environ. Law Policy 273 at 274 & 282.

⁴⁴² M. Spalding & J. Audley, "Promising Potential for the US-Mexico Border and for the Future: An Assessment of the BECC" (1997) NADBank Instit.; C. Deere & D.C. Esty, *Greening the Americans: NAFTA's Lessons for Hemispheric Trade*, (Boston: MIT Press, 2002) at 187.

⁴⁴³ G.C. Hufbauer & J.J. Schott, *North American Free Trade: Issues and Recommendations* (New York: NYU Press, 1992) at 131.

Although the NAAEC has been criticized for being weak on requirements⁴⁴⁴, it has been recognized as a collective effort to discuss environmental issues in relation to international trade.⁴⁴⁵ The right to establish protection standards lies with each nation, independently. However, the caveat is that these measures are to be based on "scientific principles" and risk assessment "as appropriate to the circumstances".⁴⁴⁶ The relationship between health and environment is recognized in the agreement and throughout the CEC's publications.

The CEC has been constructive in providing a transboundary forum to discuss children's environmental health. Published in 2006, *Children's Health and the Environment in North America: A First Report on Available Indicators and Measures*, reviews three priority areas: (1)Asthma and Respiratory Disease, (2) Exposure to Lead and Other Toxic Substances, and (3)Waterborne Diseases.⁴⁴⁷ By producing this report, each nation gained an understanding of knowledge gaps and policy needed. Similar reports on chemicals, metals, air pollution, and border traffic (US-Mexican Border) have been published.

Though the CEC has been beneficial in information gathering and bringing awareness to the issues that children face in North America, it has not mandated standards or addressed local pollution. As with other international agreements mentioned earlier, the differing pollution burdens amongst the parties may place an undue burden on Mexico or result in little change in Canada and the US to prevent this hardship. The report recognizes that indicators and data gathering is only a first step and that further action is needed to truly improve the state of health for children in North America. In 2002, Council Resolution 02-06: Cooperative Agenda for Children's Health and Environment in North America was one such measure which strengthens trilateral efforts to reduce exposure rates. Outlined in the agenda is an affirmation to reduce lead exposure in consumer products transferred by cross-border trade, continue to assess cross-border diesel exhaust's impact on childhood health, and integrate children's environmental health into the work of the CEC's Sound Management of Chemicals program.⁴⁴⁸

3.6 Children's Environmental Health: International Agreements Addressing Chemicals and Pesticides

There are a number of international doctrines which address chemicals and pesticides in general. The first section in this chapter outlined how international doctrines pertaining to pollutants, which are not specifically focused on children, can have a positive outcome on their health status. The impact of international doctrines on chemical and pesticide management also do the same; however, they will only be referenced briefly in this section. Rather, the objective is to provide context on international and transnational agreements which focus on children's exposure to chemical toxins and pesticides.

⁴⁴⁴ C.A. Grant, "Transboundary Air Pollution: Can NAFTA and NAAEC Succeed Where International Law has Failed" (1994) 5 Colo. J. Int. Environ. Law Policy 439 at 447-450.

⁴⁴⁵ Saunders, supra note 441 at 279.

⁴⁴⁶ *Ibid.* at 281; *Secretariat of the Commission for Environmental Cooperation, supra* note 439.

⁴⁴⁷ Commission for Environmental Cooperation, supra note 123.

 ⁴⁴⁸ Cooperative Agenda for Children's Health and the Environment in North America, CR 02-06, C/02-00/RES/06/Final, online: CEC < http://www.cec.org/files/pdf/ABOUTUS/ResolutionCEH_en.pdf> (last modified: 19 June 2002).

International agreements such as the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, the Rotterdam Convention, and the Stockholm Convention on Persistent Organic Pollutants are some of the more notable transnational agreements that made strides in reducing transboundary hazardous waste. The Basel Convention was the first global environmental treaty to regulate hazardous waste, acting as a starting point for the following two conventions.⁴⁴⁹ Specifically aimed at preventing the transport of hazardous wastes from developed to developing nations, the Basel convention mandates that "Prior Informed Consent" be applied before shipments of waste are made and that wastes are managed in an environmentally sound manner (ESM).⁴⁵⁰ Building upon these principles, the Rotterdam Convention requires signatories to notify one another of pesticides or chemicals which have been banned due to harmful effects on the environment or health of the population.⁴⁵¹ These doctrines provided a basis for the Stockholm Convention; an agreement which bans twelve persistent organic pollutants which are harmful to human health and the environment.⁴⁵² Though the convention does not specify the consideration of vulnerable groups, one of the motivating factors for the agreement was the presence of POPs in breast milk thereby exposing infants to harmful pollutants.⁴⁵³ The Stockholm Convention does require signatories to include groups involved in the health of children in the implementation plan required under the agreement.⁴⁵⁴

⁴⁵⁰ *Ibid*.

⁴⁴⁹ Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, UNEP (1989), online: Secretariat of the Basel Convention < http://www.basel.int/text/con-e-rev.pdf> (last modified: 22 March 1989); *The Basel Convention at a Glance* (Geneva: Secretariat of the Basel Convention), online: Secretariat of the Basel Convention <http://www.basel.int/convention/bc_glance.pdf> (date accessed: 13 August 2008).

⁴⁵¹ *Rotterdam Convention Overview*, UN EP, online: UNEP < http://www.pic.int/home.php?type=t&id=5&sid=16> (date accessed: 15 January 2009).

⁴⁵² Stockholm Convention on Persistent Organic Pollutants, supra note 211; Good Plant, Stockholm Convention, online: Good Plant http://www.goodplant.info/goodplanet/index.php/eng/Legal-tools/Stockholm-Convention/The-Stockholm-Convention> (date accessed: 14 January 2009); UN EP Chemicals, A Guide to the Stockholm Convention on Persistent Organic Pollutants, UNEP, online: UN < http://www.pops.int/documents/guidance/beg_guide.pdf (last modified: April 2005).

⁴⁵³ *Landrigan 2004, supra* note 12 at 259.

⁴⁵⁴ Good Plant, supra note 452; Stockholm Convention on Persistent Organic Pollutants, supra note 211.

3.6.1 The Codex Alimentarius Commission

Efforts by the WHO and Food and Agriculture Organization of the UN (FAO) to standardize pesticide exposure by food sources has been fostered by the Codex Alimentarius Commission. The objective of the commission is to provide safe food practices and promote fair trade.⁴⁵⁵ With the signing of the GATT Agreement in 1994, the standards set by Codex have been used as "reference texts" by the World Trade Organization (WTO) and in international trade.⁴⁵⁶ Consideration is given of children's vulnerabilities when suggesting standards for processed cereal-based foods for infants and young children.⁴⁵⁷ However, this voluntary agreement has been criticized by Consumers International, as well as the governments of Germany and France for its conclusion that additional safety factors for children, in addition to those currently used, are unjustified.⁴⁵⁸ Controversy amongst nations and NGOs as to the appropriate risk assessment procedures, including whether to expressly consider multiple pesticide exposure pathways, have slowed progress with regards to consideration of childhood exposure to food pesticides.⁴⁵⁹

3.6.2 Cooperative Agenda For Children's Health In North America

In an effort to address the rates of childhood exposure to chemicals and pollutants in North America, the CEC Council adopted the Cooperative Agenda for Children's Health in North America in 2002.⁴⁶⁰ While not mandating standards or requirements, this effort to foster collaboration and gather data on environmentally caused childhood disease has resulted in specific recommendations for Canada, Mexico, and the United States. Highlighting the fact that nearly half a million tons of chemicals "known or suspected to cause cancer" were used in Canada and the US in the year 2002, the report *Toxic Chemicals and Children's Health in North America* calls for greater monitoring, improved scientific knowledge, increased awareness, and implementation of chemical-related disease tracking systems.⁴⁶¹ For instance, the *Action Plan to Enhance the Comparability of Pollutant Release and Transfer Registers in North America* sets forth a framework that aims to harmonize the chemical use monitoring systems of all three countries, particularly requiring Mexico to move from a voluntary reporting system to a mandatory one.⁴⁶² Though similar reports have been conducted at an international level by the WHO, what is unique about this one is that

⁴⁵⁹ *Ibid*.

⁴⁵⁵ FAO & WHO, Food Standards Codex Alimentarius, online: FAO/WHO <

http://www.codexalimentarius.net/web/index_en.jsp> (date accessed: 11 October 2008).

⁴⁵⁶ Consumers International, *Codex Alimentarius for Consumers* (Rome: FAO/Consumers International, 2000), online: FAO < http://www.consumersinternational.org/Shared_ASP_Files/UploadedFiles/D1E13E28-5009-4BCF-9B99-2475BEF47A7D_Doc378.pdf> (date accessed: 3 June 2009).

⁴⁵⁷ Committee on Nutrition and Foods for Special Dietary Uses, "Report of the 25th Session" (UN FAO/WHO, 3-7 November 2003) (ALINORM 03/27/26), online: FAO < ftp://ftp.fao.org/codex/alinorm04/al04_26e.pdf> (date accessed: 3 June 2009).

⁴⁵⁸ K. Racke, "IUPAC Representative Report" (32nd Session, Hague, 1-8 May 2000), online: IUPAC < http://old.iupac.org/standing/on/ccpr/report_000501.pdf> (date accessed: 3 June 2009).

⁴⁶⁰ Cooperative Agenda, supra note 448.

⁴⁶¹ Commission for Environmental Cooperation, *Toxic Chemicals and Children's Health in North America*, (Quebec: Secretariat – Commission for Environmental Cooperation, 2006), online: C.E.C. < http://www.cec.org/files/PDF/POLLUTANTS/CHE Toxics en.pdf> (date accessed: 3 June 2009).

⁴⁶² *Ibid*.

recommendations are specific to each nation-state and based on data from government sources rather than aggregate data on a global scale.

3.7 Conclusion

These previous sections provide an overview of international and regional agreements which may have indirectly impacted on children's environmental health. Though children's vulnerabilities to pollutants may not be the sole focus of many international agreements, those agreements often influence exposure rates. What is unfortunate is that children are not specifically outlined as vulnerable and standards which are set tend to be based on the health of the general population. Additionally, by failing to consider physiological differences of a child prior to implementation, it is difficult to measure whether these agreements have a monumental effect or a negligible consequence on childhood chronic health conditions, morality, and morbidity statistics. Those agreements which have addressed children specifically have accomplished an escalated level of awareness, but fall short of producing standards and deadlines which must be accomplished by signatories. Agreements which consider chemical and pesticide exposure, though they tend to be binding and mandate requirements, have not consistently considered children and infants. Furthermore, what is seen throughout all three sections is that much of the impetus for these global doctrines was present in the 1990s and early 2000s, but has steadily decreased, resulting in little monitoring and evaluation. The result is that pesticide and chemical childhood exposure is left to the governance of nation-states.

4. ADDRESSING CHILDREN'S ENVIRONMENTAL HEALTH AT A NATIONAL AND SUPRANATIONAL LEVEL

4.1 Introduction

Although the topic of children's environmental health has achieved notoriety at an international level, little substantial change has come from this globally. While international doctrines, such as the Stockholm Convention, have had the ability to reduce overall exposure to caustic substances, they have been narrowly focused and only address the most horrible offenders. Because of this, the responsibility to determine how and what substances should be restricted or banned and how to do this remains with federal or regional jurisdictions. This chapter will examine how the differing approaches to regulating toxic substances, specifically pesticides and chemicals, taken by Canada, the United States, and the European Union, have resulted in distinctive standards, the consequence being that those children residing in North America are exposed to more toxins daily than those residing in Europe. The objective of this chapter is to illustrate why the United States' and Canada's use of the risk-based approach in their risk assessment process fails to offer the same protection for children's health as does the EU's hazard-based approach. The reasons for the different levels of protection will be discussed in detail, using the risk assessment of pesticides and chemicals as two case-studies.

Indications of the prevalence and impact environmental pollution can have on children's health were made in chapter two, thereby negating the need to review the epidemiological evidence supporting the assertion that toxic exposure can lead to chronic health conditions and even death. In order to provide context, however, it is important to note that pesticides and chemicals are unavoidable by the general population, including children. More than just agricultural or industrial products, pesticides are used in residential settings including schools, daycares, homes, gardens, and parks and are present on food products. The United States alone used over 102 million pounds of pesticide active substances during the period between years 2000 and 2001.⁴⁶³ The exposures to chemicals are as great a concern as that of pesticides. Of the 85,000 chemicals available worldwide, many are used in large quantities in schools, hospitals, and homes.⁴⁶⁴ Over 2,800 of these chemicals are produced in excess of 500,000 kilograms a year.⁴⁶⁵

In order to control the impact these chemicals and pesticides have on children, Canada, the US, and the EU have put in place legislation that mandates the assessment and management of the use of these substances. This chapter will provide an overview of these pieces of legislation, focusing on the differences in standards that result because of the distinct risk assessment approaches taken. Canada and the US have adopted a risk-based approach to risk assessment with the objective to determine what risks from exposures are considered acceptable. Those substances that pose a

⁴⁶⁵ C.A. Mello-da-Silva & L. Fruchtengarten, "Environmental Chemical Hazards and Child Health" (2005) 81 J. Pediatr. 205, online: J. Pediatr. http://www.scielo.br/scielo.php?pid=S0021-55572005000700011 (let me dified Neurophan 2005)

75572005000700011&script=sci_arttext&tlng=en> (last modified: November 2005).

⁴⁶³ T. Kiely, D. Donaldson, & A. Grube, EPA, *Pesticides Industry Sales and Usage 2000 and 2001 Market* Estimates, (Washington, D.C., EPA, 2004), online: EPA

<http://www.epa.gov/oppbead1/pestsales/01pestsales/market_estimates2001.pdf> (date accessed: 4 October 2009).

⁴⁶⁴ *Wargo, supra* note 26.

risk that is unacceptable, often quantified in rates of chronic health conditions, are restricted to the point that exposure is acceptable. Use of this method relies on science to ensure safety. However, because of the number of unknowns related to toxic exposure and the governments' inability to ensure that the necessary data is collected, the use of science alone fails to protect children's health. This is in contrast to the recently adopted EU hazard-based approach, which aims to avoid risk through the elimination of the substance when the risk is too great. The reason that this approach provides better protection for children's health is that it eliminates substances completely rather than relying on a calculated standard to ensure that children's exposure to a substance does not exceed a safe threshold.

This chapter will be divided into three sections. The first section will provide an overview of the risk assessment approaches taken by each jurisdiction. The second section analyzes the pesticide legislation of each jurisdiction. This section explains why the risk-based approach used by Canada and the United States does not provide for the protection of children's health, whereas the EU hazard-based approach reduces the pesticide exposure children experience. This is particularly bothersome considering pesticide legislation is one of the few examples of environmental policy that has been amended in the US and Canada to account for children's health. Included in this section is a case study of how these policies have affected the standards set for pesticide residues on foodstuffs, resulting in higher intake of residue in Canada and the United States. The third section reviews the different legislative approaches to chemicals taken by each jurisdiction. This section provides a glaring example as to how the risk-based approach fails to protect children from harmful exposure to substances. This is in contrast to the EU's legislation which aims at eliminating caustic chemicals to prevent any chance of exposure.

4.2 The Differences In Risk Assessment: The Risk-Based Approach Versus The Hazard-Based Approach

Each of the jurisdictions utilizes a risk assessment process to review toxins, including pesticides and chemicals.⁴⁶⁶ Having evolved over the course of the last fifty years, this process is one that reviews the effects of exposure to toxins on health. This information is then used to set standards to ensure that use of these pesticides and chemicals is "safe". Though the procedure of assessing substances is very similar among all three jurisdictions, the approach used to interpret the data differs.

4.2.1 General Overview Of The Risk Assessment Process

Although Canada and the US and the EU have taken differing approaches to the risk assessment process, the mechanics of the procedure are still the same. The risk assessment process consists of four steps: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization.⁴⁶⁷ First, the assessing agency aims to determine the harm associated with exposure to the substance, such as injury, disease, or

⁴⁶⁶ Also used for air pollution, water contamination, etc.

⁴⁶⁷ Canada, Pest Management Regulatory Agency, *Science Policy Note: A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*, (Ottawa: PMRA, 2000) at 6; U.S., Environmental Protection Agency, *Standard Operating Procedures (SOPs) for Residential Exposure Assessment*, (Washington, D.C.: EPA, 1997) at 8.

death. Using this data, in the dose-response assessment step an analysis of exposure to specific doses of the substance is used to determine the possible severity of harm. Third, consideration is given to the likelihood of frequent exposure, the possible duration of exposure, and the potential intensity of exposure. Lastly, this data is used to establish the overall health risks associated with the estimated levels of exposure.⁴⁶⁸ Information submitted to the agency from the pesticide registrant applicant used in this four-step process includes toxicological data, animal bioassays, and/or epidemiological studies.⁴⁶⁹

Laboratory animals are exposed to the substance to determine what type of hazards occur at specified levels of exposure. The purpose is to identify the level of exposure to the substance that results in no significant harm. This numerical value, known as the "no observed adverse effect level" (NOAEL), is divided by two uncertainty factors to reduce the possibility of harm. This process is to adjust the NOAEL for any differences between the animals and humans. Each of these uncertainty factors range in value from one to ten. One uncertainty factor is to account for any differences among humans, such as vulnerability to exposure, age differences, weight differences, and genetic variations. The second uncertainty factor is to account for the differences between animals and humans since the studies used for calculation are based on animal laboratory research. This calculation is used to establish a tolerance of exposure. In situations where there is no NOAEL because significant harm is present at every dose of exposure, then a NOAEL is extrapolated from the data. This process, known as the "weight of evidence" approach, is the selection of predictive model by the risk assessor based on all data on the exposure to the substance. The model is used to set a standard that is thought to result in a specified rate of a particular disease, such as cancer. Originally a product of the US EPA, the four-step process has been widely accepted as the global norm in scientific health and environmental assessment. Documented in the 1983 US National Research Council's report Risk Assessment in the Federal Government: Managing the Process⁴⁷⁰, is has become entrenched in the regulatory system of both pesticides and chemicals in the US and Canada. By the mid-1990s the EU had adopted this process as well.⁴⁷¹

4.2.1.1 The Two Approaches To Risk Assessment: Risk- and Hazard-Based

4.2.1.1.1 The Risk-Based Approach

The US and Canada have interpreted the outcomes of the four-step risk assessment process using the risk-based approach. The primary objective of this approach is to control risk in a fashion that is "safe". However, "safe" does not guarantee that no harm will occur. Instead this standard of safe is an "acceptable" level of risk of harm, determined by the government using the data from the risk assessment process.⁴⁷² The belief is that the government

⁴⁶⁸ California, Environmental Protection Agency, *A Guide to Health Risk Assessment*, (Sacramento, CA: Office of Environmental Health Hazard Assessment, 2001), online: CA EPA <http://oehha.ca.gov/pdf/HRSguide2001.pdf> (date accessed: 4 October 2009); U.S., Environmental Protection Agency, *Risk Assessment Process* (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency < http://www.epa.gov/hhrp/risk_process.html> (last modified: 3 September 2009).

⁴⁶⁹ Description of these studies will be provided in the following pesticide section.

⁴⁷⁰ National Research Council 1983, supra note 34.

⁴⁷¹ Lofstedt, supra note 34 at 1330.

⁴⁷² McClenaghan, supra note 36 at 146.

is able to control the amount of exposure by setting tolerances, which results in a probability of a chronic health condition, such as cancer. This method of using the risk assessment process to set standards to control the probability of risk was borne out of a series of legislative and judicial measures in the US.

In the 1950s and 1960s, scientific advancements in toxicology assessment provided government agencies with the ability to evaluate substances for harm. Because of the improved capacity, the US government instituted a "cancer policy"⁴⁷³ in the 1970s that outlined procedural methods for assessing the possibility of cancer from exposure to substances.⁴⁷⁴ At the same time that this "cancer policy" was developed, concerns surrounding the use of inference, when faced with uncertainty in the scientific process, came into question in a number of legal cases. Originally the courts held that the government had the authority to make deductions when faced with scientific uncertainty. Later on, however, the US judicial system narrowed this interpretation of authority to require the government to demonstrate scientific evidence supporting restrictions before any could be made.

In the 1974 case, *Industrial Union Department v. D. Hodgson*⁴⁷⁵ [hereinafter *Hodgson*], the court indicated that the cause-effect relationship of exposure and substance may be surmised made when a government agency is faced with scientific uncertainty. The court affirmed that government agencies have the capacity to make policy judgments when confronting insufficient data as to the effects of substance exposures.⁴⁷⁶ "Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis."⁴⁷⁷

The *Hodgson* case provided the government with the authority to make regulations when lacking scientific evidence to support these standards, nevertheless, this agency capacity was short-lived. In the 1980 case, *Industrial Union Department v. American Petroleum Institute*⁴⁷⁸ [hereinafter *Benzene*], the EPA Secretary's powers were restrained to ensure that he does not have "unprecedented power over American industry".⁴⁷⁹ The regulatory agency⁴⁸⁰ had reduced the standard of exposure to benzene in a workplace setting from ten parts per million (ppm) to one ppm due to uncertainty surrounding the health effects of this substance on those exposed. The court found that this reduction in exposure was inappropriate given that there was "no finding that any of the provisions of the new standard were

⁴⁷⁶ *Ibid.* at 20.

⁴⁷³ National Research Council 1983, supra note 34.

⁴⁷⁴ *McClenaghan, supra* note 147; Even in establishing a cancer policy, the government recognized that there was a great deal of subjectivity in the risk assessment process. The 1983 National Academy of Sciences report, *Risk Assessment in the Federal Government: Managing the Process*, identified at least fifty "inference choices" present in the scientific procedure.

⁴⁷⁵ Industrial Union Department, AFL-CIO, et al., Petitioners v. James D. Hodgson, Secretary, Department of Labor, *Respondent, Environmental Defense Fund, Inc., Intervenor* (1974)499 F.2d 467 (162 U.S.App.D.C. 331), online: OpenJurist < http://openjurist.org/499/f2d/467/industrial-union-department-v-d-hodgson> (date accessed: 30 October 2009).

⁴⁷⁷ *Ibid.* at 26.; J.S. Applegate, "The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control" (1991) 91 Colum. L. Rev. 261 at 268-269.

⁴⁷⁸ Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 638 (S. Ct. 1980). [hereinafter Benzene Case].

⁴⁷⁹ Benzene Case, ibid. at 645.

⁴⁸⁰ The regulatory agency named in the case was the Secretary of Labor as part of the Occupational Safety and Health Administration (OSHA).

'reasonably necessary or appropriate to provide safe or healthful employment and places of employment'''. ⁴⁸¹ The court held that there needed to be "substantial evidence" before such a standard could be valid.⁴⁸²

This decision was a shift away from the *Hodgson* finding that the EPA Secretary had authority to make deductions when faced with scientific uncertainty. Not only did it rein in the authority originally given to government agencies, but also shaped future risk assessment procedures. This case ensured that in future risk assessment the EPA must have the scientific evidence to support any regulatory standards on substance exposure. Rather than interpret evidence when dealing with scientific uncertainty to construe a tolerance level, the government must have the evidence to prove that the standard is reasonable. This is central to the difference between the risk- and hazard-based approaches. The risk-based approach insists that the government have evidence to support the limitation on exposure. As will be discussed later on, this is in contrast to the hazard-based approach that insists that industry have evidence to support removing limitations on exposure.

Not only did the *Benzene* case require that scientific evidence justify the tolerance set, but it also shaped how the government interpreted the results of the four-step risk assessment process. The court held that the chances of risk shall be interpreted as per individual, rather than to the society as a whole.⁴⁸³ The court's statement that " if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it" has been interpreted by the EPA as support for the calculation of risk per individual.⁴⁸⁴ Identified by the agency as the *de minimis* standard⁴⁸⁵, this probability of risk is often set as one-in-a-million and is used throughout the current risk-based approach. This probability of harm eliminates the costs to society of lost days, quality of life, and defines "significant" risk not by disease but by individual chance of having that chronic health condition when exposed to that specific substance.

This case law shaped future risk assessment, including that of pesticides and chemicals. Because of these decisions, the EPA has established that "acceptable risk" is measured by individual risk, quantified, and must meet the *de minimis* standard. These elements of calculating risk define the risk-based approach. In the *Benzene* case it was stated that "legislative history also supports the conclusion that Congress was concerned, not with absolute safety, but with the elimination of significant harm."⁴⁸⁶ As this indicates, the objective of the approach is controlling risk, not

⁴⁸¹ Benzene Case, supra note 478 at 662.

⁴⁸² Ibid. at 653; C.K. Findlay, Pollution Control, Administrative Discretion, and Science: A Journey Through the Maze of Environmental Law (LL.M., University of British Columbia, 1993) [unpublished] at 75.

⁴⁸³ Industrial Union, supra note 481 at 655.

⁴⁸⁴ *Ibid.*; M. Adler, "Risk, Death and Harm: The Normative Foundations of Risk Regulation" (2003) 87:1293 Minn. L. Rev. 1293 at 1432.

⁴⁸⁵ Confirmed in: *Public Citizen, et al, Petitioners, v. Dr. Frank Young, Commissioner, Food and Drug Administration, et al, Respondent*, 831 F.2d 1108 (D.C.Cir. 1987). [hereinafter *Young*]; *Les, et al, Petitioners v. William K. Reilly*, Administrator of the Environmental Protection Agency, et al., Respondent, 968 F.2d 985 (9th Cir. 1992). [hereinafter *Les*].

⁴⁸⁶ Industrial Union, supra note 481 at 646.

eliminating it, in a way that risk is no longer "significant". Moving away from the *Hodgson* decision, the courts have indicated that this process is not to be qualitative, but rather quantitative.⁴⁸⁷

4.2.1.1.2 The Hazard-Based Approach

The EU has utilized a hazard-based approach to interpret the outcomes of the four-step risk assessment process. The purpose of this approach is to achieve a non-toxic environment. It accomplishes this objective through the elimination of toxins when possible. Because the eradication of use of all chemicals is impossible, however, the hazard-based approach aims at removing exposure to the most caustic substances. It does this through a three-step procedure: (1) hazard, (2) exposure, and (3) risk.⁴⁸⁸ Each tier provides the government the ability to restrict or ban the substance based on the hazards associated with it.

In the first tier the substance may be banned because it is associated with a significant hazard, such as cancer. If the hazard associated with this substance is not too great then the product progresses to the second tier where it is compared with similar items already on the market. In this step, the substitution principle is applied. This principle holds that if the product is not more efficient than competitors and is more harmful it will be banned and replaced by a less caustic substance.⁴⁸⁹ If the substance has not yet been banned in tier one or tier two, in the third tier the product's risk is assessed and controlled through regulation.⁴⁹⁰

The use of this three-tier approach by the EU is relatively new. In the past, the EU's authority over the assessment of health and environment was rather limited to issues related to trade and the reduction of trade barriers. Because of this, risk assessment was only a priority insofar as it served to aid trade harmonization.⁴⁹¹ Due to a number of public health and environmental concerns by member states, however, legislative and judicial changes led to a formal adoption of the four-step risk assessment process described earlier.⁴⁹² Rather than interpreting this process in the same fashion as the US and Canada have, the EU has implemented a more cautionary policy.

A series of events led the EU's adoption of the hazard-based approach. Historically, the EU had not developed a formal risk assessment procedure at a supranational level due to the fact that the government's efforts were trade-focused.⁴⁹³ Instead, until the 1990s, the review authority sat with member states. As member states that had embedded the protection of environmental health into their political culture joined the union during the 1990s,

⁴⁸⁷ Though these cases are American jurisprudence, the Canadian risk assessment process has been influenced by them as well. Because of the close trade relationship between the two nations and the joint environment efforts on behalf of both countries, Canada has adopted the same procedural elements of risk assessment as the US.

⁴⁸⁸ Hansen, supra note 38 at 274.

⁴⁸⁹ Sweden's use of the substitution principle does not include efficiency. Sweden, KEMI, *The Substitution Principle* (Stockholm: KEMI, 2007), online: KEMI <</p>

http://www.kemi.se/upload/Trycksaker/Pdf/Rapporter/Report8_07_The_Substitution_Principle.pdf> (date accessed: 10 August 2009).

⁴⁹⁰ *Ibid*.

⁴⁹¹ E. Vos, "EU Food Safety Regulation in the Aftermath of the BSE Crisis" (2000) 23 J. Consum. Policy 227 at 229.

 $^{^{492}}$ Lofstedt, supra note 34 at 1330.

⁴⁹³ *Vos, supra* note 491 at 228.

however, they pressured the EU to do the same.⁴⁹⁴ At the same time, the EU faced an outbreak of disease from ingestion of cow meat contaminated by Bovine Spongiform Encephalopathy (BSE).⁴⁹⁵ Known as "mad cow disease", this degenerative neurological disorder brought attention by member states and the general public to the lack of regulatory authority in the EU.⁴⁹⁶ Though the political focus was originally on food items when this outbreak occurred in 1997, the need for regulatory safety pertaining to other areas, including pesticides and chemicals, was soon recognized.

In the 1999 Amsterdam Treaty, the EU outlined how this newly acquired authority over the regulation of substances should be carried out. A "high level" of health was to be a priority in standard setting.⁴⁹⁷ In achieving this objective, the treaty declared that "scientific facts" should be the basis of assessment.⁴⁹⁸ Though these objectives are similar⁴⁹⁹ to that found in US environmental policy, the interpretation by the European Court of Justice (ECJ) differs from that of the US case law.

Whereas the US judicial system imposed a requirement that the government have evidence supporting any restrictions, the ECJ chose to support the EU's interpretative authority. In similar circumstances to the US *Hodgson* case, the ECJ took the opposite position of the US judicial system and indicated that government shall have the ability to make policy judgments.⁵⁰⁰ Furthermore, the ECJ has held that it is not their role to determine whether or not the assessment is accurate:

"[...] where a Community authority is called upon, in the perform of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to a limited judicial review in the course of which the EC judicature may not substitute its assessment of the facts for the assessment made by the authority concerned. Thus, in such cases, the EC judicature must restrict itself to examining the accuracy of the findings of fact and law made by the authority concerned and to verifying, in particular, that the action taken by that authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion."⁵⁰¹

As a result of these judicial findings, the EU has been able to rely on a risk assessment procedure that includes a way of reasoning that is not solely based on scientific evidence. The EU's Risk Regulatory Framework held that "it is recognized that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk

⁴⁹⁴ Austria, Finland and Sweden have been recognized for pressuring the EU to highten standards for environmental protection. E.C., *Strengthened EU Environment Standards as a Result of the Enlargement with Austria, Finland and Sweden* [1998] IP/98/1107, online: Europa

<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/98/1107&format=PDF&ag> (last modified: 14 December 1998).

⁴⁹⁵ *Vos, supra* note 491 at 227.

⁴⁹⁶ *Ibid*.

⁴⁹⁷ A. Alemanno, "The Role of Experts in Decision-Making and Judicial Review" (Young Researchers Workshop on Science and Law, ISUFI, 31 May – 1 June 2007) at 4. *Treaty of Amsterdam, supra* note 367.

⁴⁹⁸ Alemanno, Ibid. at 5; Vos, supra note 491 at 235.

⁴⁹⁹ Science is to take precedence, though if there is indication of doubt then caution should be taken. This is in contrast to the US position that unless science indicates harm, then no action shall be taken.

⁵⁰⁰ Alemanno, supra 497 at 6.

⁵⁰¹Alemanno, supra note 497 at 19. E.C.J., Commission v. Ceva/Pfizer, Case C-196/03 P [2005], E.C.R. I-06357.

management decision should be based".⁵⁰² This is not the dismissal of scientific fact, rather support for the notion that "scientific knowledge is authoritative, but not exclusively so".⁵⁰³ This cautious approach is a key difference between the risk-based approach and the hazard-based approach. The US and Canada have interpreted scientific fact as authoritative, and when faced with uncertainty, have relied on mathematical adjustments in hopes to avoid subjectivity. In contrast, the EU has recognized that uncertainty cannot be explained away by the calculation of risk alone.

This cautionary approach is based on the EU's precautionary principle⁵⁰⁴. Originating in German environmental policy⁵⁰⁵, this principle has been interpreted by the EU to be the ability to take regulatory action to protect environment, human, animal, and plant health even when scientific evidence does not decisively conclude the action is necessary.⁵⁰⁶ Because the EU has recognized that "acceptable" risk for society is a political responsibility, "[d]ecision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers. Therefore, all these factors have to be taken into consideration."⁵⁰⁷

⁵⁰⁷ Ibid.

⁵⁰² E.C., Council Regulation 1829/2003 on Genetically Modified Food and Feed [2003] O.J.L. 287 at 19.

⁵⁰³ Alemanno, Ibid. at 9; E.C., Commission Communication on the Precautionary Principle COM(2000)1 [2000], online: Europa < http://ec.europa.eu/environment/docum/20001_en.htm> (last modified: 2 February 2000).

⁵⁰⁴ Though all three jurisdictions have publicly embraced the precautionary principle at the *Rio Declaration on Environment and Development*, this concept of caution differs from the principle due to the specific requirements. Rather than merely acting as a theory for shaping future policy, the cautionary approach aims at having procedural requirements that are not negotiable, as will be discussed throughout the rest of this thesis.

⁵⁰⁵ The use of this principle in risk assessment is often controversial as critics argue that the approach is too openended and may allow bias to enter into the process. Although these concerns are valid, within the context of pesticides and chemicals the EU has applied this principle in a fashion that reduces the possibility of subjectivity. First, it sits within the risk assessment process, rather than in the risk management portion of pesticide policy. Second, it has clear procedural tools by which caution can be implemented, such as the substitution principle and the objective to reduce overall exposures whether or not they are independently harmful. Furthermore, one could argue that the mathematical adjustments utilized in a precautionary manner by the US and Canada in the risk-based approach provides an opportunity for bias as well. The use of these procedures in the risk-based approach ensures that industry is favoured over health due to the evidentiary requirement of scientific fact before action. There is also a potential for bias in the process because the US and Canadian governments have legislated that in times that the risk assessor deems appropriate procedural adjustments can be dismissed. This allows the same level of subjectivity as does the hazard-based approach's caution, but the bias is in favour of industry rather than in favour of children's health. G. Conko, "Safety, Risk and the Precautionary Principle: Rethinking Precautionary Approaches to the Regulation of Transgenic Plants" (2003) Transgenic Res. 1 at 2; *Commission Communication on Precautionary Principle, supra* note 503 at 3.

⁵⁰⁶ Commission Communication on Precautionary Principle, supra note 503 at 13.

4.3 Pesticide Legislation: An Example of How Amending The Risk-Based Approach Still Fails To Protect Children In The Same Way The Hazard-Based Approach Does

4.3.1 Pesticide Policy: A Unique Example Of The Risk- And Hazard-Based Approaches

Pesticide regulation policy offers a unique example of how Canada, the US, and the EU have attempted to address some of the childhood health concerns related to toxic exposure. Prompted by the 1993 publication by the US NAS, *Pesticides in the Diets of Infants and Children⁵⁰⁸*, policy in each of the three jurisdictions has been amended to take into consideration children's vulnerabilities in pesticide regulation. This remains one of the few areas of environmental policy that has specifically addressed children's vulnerabilities.

Because children's vulnerabilities and physiology has been incorporated into the risk assessment process in each jurisdiction, pesticide regulation policy provides an example of how amendments alone cannot rectify the problems associated with childhood pesticide exposure. Though the amendments in the US and Canada provided for a better level of health protection for children than prior policy, they are still part of the overarching risk-based approach. This approach, even with amendments, does not offer the same level of protection for children's health as does the EU's hazard-based approach. Canada and the US have attempted to protect children's health by including procedural changes to the risk assessment process that are thought to account for children's health, but they have permitted continued exposure to pesticides that cause cancer and disrupt endocrine function. This is in contrast to the EU's hazard-based approach which eliminates the most caustic of substances, therefore preventing any exposure.⁵⁰⁹

While prior EU pesticide regulatory policy used to resemble the North American policies over food safety, the EU government has made a shift away from this restricted application of their authority. No longer aimed only at consumer safety, the EU's policy on pesticides is one that extends to residential and commercial application.⁵¹⁰ Their current policy purpose is the reduction of overall exposure in a daily setting, not only the monitoring of ingestion of pesticide residue in foodstuffs as is the case in the US and Canada. This demonstrates that pesticide authority offers each jurisdiction an exceptional opportunity to restrict and ban childhood exposure, but Canada and the United States have construed their capacity to regulate in a fashion that fails to utilize this power to its fullest extent possible. As a

⁵⁰⁸ National Research Council, supra note 99.

⁵⁰⁹ Pesticide regulation policy is distinct from other areas of environmental policy because government has the authority to regulate exposure prior to contact. Like consumer products, pesticides are analyzed and registered before market entry, whereas other pollutant regulation policy focuses on the reduction of emissions, not the prohibition of use. This authority to regulate before toxic emissions are produced provides each of the three jurisdictions with the opportunity to make a measureable impact on children's health before quantified harm has occurred. Nevertheless, Canada and the United States have employed this unique authority in limited fashion, only restricting exposure when clear causation of harm was shown prior to market entry. *Science Policy Notice: A Decision Framework, supra* note 467.

⁵¹⁰ The reason behind this restricted definition of authority is found within the risk-based approach. Rather than act cautiously and eliminate the hazard possibilities, the risk-based approach dictates that risk can be controlled. It is difficult to control the amount of pesticides used in residences, agriculture, and industry without banning the products, which is contradictory to the risk-based approach, so the governments have limited their authority to food policy alone.

result, children residing in Canada and the US continue to be exposed to a greater number of pesticides at higher levels.

4.3.1.1 The Impetus For The Amendments To Pesticide Policy: Recognition That Children Were Not Accounted For

Pesticide legislation is one of the few examples of environmental policies that require the consideration of the vulnerabilities of children. Legislative changes made to pesticide policy by Canada, the United States, and the European Union have explicitly included pregnant women, infants, and children in their text. The preamble to the Canadian *Pest Control Products Act*⁵¹¹ (PCPA) states that during the risk assessment process consideration should be given to "the different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, [and] children".⁵¹² Similarly, the US *Food Quality Protection Act*⁵¹³ (FQPA) requires that the EPA take into account the "available information concerning the special susceptibility of infants and children to the pesticide chemical residues".⁵¹⁴ The EU's recently passed pesticide policy, COM (2006) 388 Final, states that "particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children".⁵¹⁵

In order to understand the impetus behind these amendments, it is necessary to provide some background. All three jurisdictions were influenced by the scientific research and legislative process initiated in the US during the 1980s. Prior to the passage of the US FQPA in 1996, pesticide policy in the United States was governed by the "Delaney Clause".⁵¹⁶ A part of the *Federal Food, Drugs, and Cosmetic Act*⁵¹⁷ (FFDCA), this zero-tolerance clause banned the uses of food additives that could cause cancer to man or animal.⁵¹⁸ Though not specifically directed at raw food products, the law applied if the pesticide residues on produce increased when put in processed food products. Because of a rapid improvement in science in the 1980s, the ability to test and find evidence of cancer-causing capacity increased, therefore increasing the number of possible substances that would be banned under this clause.

Due to the number of products that would be restricted under the zero-tolerance rule, the EPA issued a statement asserting that instead of applying the Delaney Clause to pesticide residue they would apply the *de minimis* standard

⁵¹⁵ E.C., *Proposal for a Regulation of the European Parliament and of the Council Concerning the Placing of Plant Protection Products on the Market* [2006] COM(2006) 388 final at 14, online: E.C. < http://ec.europa.eu/food/plant/protection/evaluation/com2006_0388en01.pdf> (last modified: 12 July 2006). [hereinafter COM(2006) 388 final].

⁵¹⁶ Delaney Clause is a 1958 amendment to the *Federal Food*, Drug, and Cosmetic Act of 1938.

⁵¹⁸ *Ibid*.

⁵¹¹ Pest Control Products Act, 2002, S.C. 2002, c.28, online: Department of Justice <

http://laws.justice.gc.ca/PDF/Statute/P/P-9.01.pdf> (date accessed: 10 May 2008). [hereinafter PCPA].

⁵¹² *Ibid.* at preamble.

⁵¹³ Food Quality Protection Act of 1996, P.L. 104-170, 110 Stat. 1489. [hereinafter FQPA].

⁵¹⁴ *Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. §301, amended by through P.L. 110-246 (2008), online: FDA < http://epw.senate.gov/FDA_001.pdf> (date accessed: 12 October 2009) at 68. [hereinafter *FFDCA*].

⁵¹⁷ *FFDCA*, *supra* note 514.

of one-in-a-million risk of cancer.⁵¹⁹ Since the EPA lacked the authority to disregard the Delaney Clause in this instance, the Ninth Circuit Court struck the EPA policy down in the 1992 case *Les v. Reilly* [hereinafter *Les*].⁵²⁰ While this may appear tangential to children's health, it is in fact very relevant to the 1996 amendments that were directly aimed at children's health. The perceived lack of applicability of the Delaney Clause in light of scientific advancements, compounded by a number of food pesticide residue related concerns⁵²¹ and the restrictions placed on the EPA by *Les*, resulted in a complete overhaul of the US pesticide legal framework. The overhaul included amendments to the risk assessment process and the incorporation of the calculation of children's exposures.

Pesticide policy in the United States underwent a transformation. In 1988, Congress amended the pesticide policy at the time, the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA)⁵²². The amendments included the mandate of the re-evaluation of existing pesticides already on the market and strengthened the EPA authority over the registration of pesticide products.⁵²³ This same year, Congress requested that the NAS study "scientific and policy issues concerning pesticides in the diets of infants and children".⁵²⁴ Published in 1993, the report *Pesticides in the Diets of Infants and Children*⁵²⁵ found that the use of the seventy kilogram healthy adult male in the assessment process grovided no real protection for children's health.⁵²⁶ In fact, the NAS found that the EPA risk assessment process did not calculate the differences between children and adults in daily intake of foodstuffs, neglected to consider the cumulative effects of multiple exposures to similar pesticides, and failed to consider the different developmental stages in a child's life. Because of these issues, the report stated that children were likely to take in more pesticide residue than the recommended standards set for the average healthy adult male.⁵²⁷ The suggestions put forth by the committee to remedy these problems included the use of additional safety factors and the use of aggregate and cumulative exposure data, which will be discussed further later in this chapter.⁵²⁸ These recommendations were adopted in full with the passage of the FQPA in 1996 which amended the FFDCA and eliminated the use of the Delaney Clause.⁵²⁹

⁵¹⁹ F.B. Cross, "The Consequences of Consensus: Dangerous Compromises of the Food Quality Protection Act" (1997) 75 Wash. U.L.Q. 1155, online: Wash. U.L.Q. http://lawreview.wustl.edu/inprint/75-3/753-2.html?referer=www.clickfind.com.au (last modified: Fall 1997).

⁵²⁰ *Ibid.; Les, supra* note 485.

⁵²¹ In the 1980s and 1990s, the pesticide aldicarb was linked to a number of food poisoning incidents. This pesticide was used on fruits, nuts, potatoes, and other vegetables. Washing and peeling of this produce did not reduce exposure since the substance was systemic since it was absorbed through the root. This food scare brought attention to the use of pesticides in food products. *Wigle, supra* note 4 at 175-176.

⁵²² Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §121. [hereinafter FIFRA].

⁵²³ U.S., Environmental Protection Agency, *FIFRA Amendments of 1988*, (Washington, D.C.: EPA, 1988), online: EPA <http://www.epa.gov/history/topics/fifra/01.htm> (last modified: 26 October 1988).

⁵²⁴ National Research Council, supra note 99.

⁵²⁵ National Research Council, supra note 99.

⁵²⁶ National Research Council, supra note 99 at 3.

⁵²⁷ *Ibid.* at 7.

⁵²⁸ *Ibid.* at 8.

⁵²⁹ Further discussion of these amendments will be provided in the rest of the section.

An interesting aspect of the NAS report, which was originally aimed at US domestic policy, is that it instigated a conversation on children's environmental health at an international level. Within the US, the report resulted in President Clinton delivering the Executive Order on Children's Environmental Health [hereinafter *The Order*]⁵³⁰. The Order mandated that consideration of children be integrated into environmental standard setting. This set in motion efforts by the EPA, on behalf of the Clinton administration,⁵³¹ to advocate at an international level for greater understanding of children's health in an environmental science context.⁵³² As mentioned in the last chapter, though the discussion at the Environment Leaders' Summit of Eight in Miami, Florida, did not result in mandated requirements by signatories to the 1997 Declaration of the Environment Leaders of the Eight on Children's Environmental Health, it did bring children's health to the forefront of domestic policy elsewhere. The result was that other jurisdictions, such as Canada and the EU, initiated efforts, similar to that of the US, to change pesticide policy in ways that would benefit children's health.

In Canada, legislative amendments like that of the 1996 US pesticide legislation were enacted in 2006. With the objective of preventing "unacceptable risks to people and the environment from the use of pest control products", *Pest Control Products Act* (PCPA) included an additional safety factor and use of aggregate and cumulative data to protect children's health.

In the EU, this publication and international summit prompted further supranational discussion on the impact environmental policy has on children. The EU research on children's health was supported by the WHO Europe, which worked with a large body of scientific researchers, epidemiologists, and paediatricians. The result of this research was an effort to address the discrepancies between adults and children in standard setting. Rather than adopt the same amendments that the US implemented, and that Canada emulated, the EU initiated efforts to revise pesticide policy in general.⁵³³ Over the course of the last fifteen years, the EU has passed legislation that authorized

⁵³² U.S., Environmental Protection Agency, *EPA's Children's Environmental Health Yearbook* (Washington, D.C.: Environmental Protection Agency, 1998), online: EPA

⁵³⁰ U.S., Environmental Protection Agency, *Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks* (Washington, D.C.: Environmental Protection Agency, 1997), online: Environmental Protection Agency < http://yosemite.epa.gov/ochp/ochpweb.nsf/%20content/whatwe_executiv.htm> (last modified: 21 April 1997).

⁵³¹ Administrator Carol M. Browner was appointed by President Clinton in 1993. She has been credited for advocating for children's environmental health. U.S., Environmental Protection Agency, *Carol M. Browner* (Washington, D.C.: Environmental Protection Agency, 1999), online: Environmental Protection Agency < http://www.epa.gov/history/admin/agency/browner.htm> (last modified: February 1999).

<http://yosemite.epa.gov/OCHP/OCHPWEB.nsf/content/pdf5.htm/\$File/ochpyearbook.pdf> (last modified: June 1998).

⁵³³ In addition to the lack of a thorough analysis of the impact adoption of legislation like the FQPA might have on children in Canada, the government was incredibly slow in making these changes. While there are a number of faults with the FQPA risk-based approach, there are even more issues with the prior legislation in both Canada and the US. Beforehand, no mention or consideration of children's health was made; no aggregate or cumulative exposure was integrated into the assessment; and no safety factors were applied when science was not conclusive on the impact exposure would have on children's health. By maintaining the status quo for so long, the Canadian government ensured that children residing in their jurisdiction were protected even less from pesticide exposure than those residing in the US.

By 1988 the US government had recognized the need to re-evaluate older pesticides due to the advancements in science that would allow them to "catch" harmful pesticides that would have been neglected using older methods of

supranational governance over pesticides, established a thematic framework for pesticide regulation, and voted for a "pesticide package" that aims at the elimination of the most toxic pesticides which include consideration of children's health, due to the influence of the NAS report.⁵³⁴

4.3.2 Risk Analysis Under Canada's And The United States' Pesticide Policies

The US and Canada have recently amended pesticide policy. In 1996, the US passed the FQPA, amending the FFDCA and the FIFRA. Under this legislation, pregnant women, infants, and children are to be considered in the four-step risk assessment process. This means that information on childhood behaviour, physiology, and exposure is to be incorporated in calculating the dose that results in the least harm. The purpose behind these amendments is to provide standards which protect children from harmful exposures. In 2002, the Canadian Parliament amended their legislation in much the same way with the passage of the PCPA.⁵³⁵

This section will discuss in detail the problems still present in the FQPA and PCPA due to the fact that the governments' rely on the risk-based approach. The review will be divided into four parts: (1) the dangers of "acceptable" risk, (2) the problems with use of inaccurate data, (3) the use of safety factors to resolve problems of uncertainty, and (4) the errors of permitting use of carcinogenic pesticides.

4.3.1.1 Defining "Acceptable" And "Safe" Risk

In using the risk-based approach to interpret the outcomes of the risk assessment process, the US and Canada have relied on the threshold of "acceptable" risk to set standards. It is this notion that some level of harm is permitted and allowed by society that is central to the risk-based approach. This line of what is and what is not acceptable is used to determine standards of pesticide exposure. The PCPA holds that only "acceptable risk" shall be legal. Likewise, the FQPA states that standards shall be found "safe" if is there is "reasonable certainty of no harm".⁵³⁶

scientific analysis. In 1996, the US government had recognized that children's health was not adequately accounted for under current risk assessment. While the Canadian government rested their decision for legislative change on the same concerns voiced by the US Congress, they failed to act until 2001 when the Pest Management Regulatory Agency (PMRA) initiated a review of older pesticides through internal policy changes. It was not until 2006 that the PCPA was enacted.

⁵³⁴ "Parliament Seals Pesticides Deal Amid Opposition" *EurActiv* (16 January 2009), online: EurActiv <http://www.euractiv.com/en/environment/parliament-seals-pesticides-deal-amid-opposition/article-178470 > (last modified: 16 January 2009).

⁵³⁵ The PCPA was passed in 2002 but was not enacted until 2006. PCPA, supra note 511.

⁵³⁶ FQPA, supra note 513; U.S., Committee on Agriculture, Food Quality Protection Act of 1996 (Washington, D.C.: U.S. Congress, 1996). [hereinafter Committee on Agriculture]; U.S., Committee on Commerce, Food Quality Protection Act of 1996 (Washington, D.C.: U.S. Congress, 1996) at 40. [hereinafter Committee on Commerce].

This standard setting of "acceptable" risk is a product of the US case law, particularly *Benzene*. The US EPA was instructed by the courts that their role was to prevent risk to significant harm, not to eliminate the risk.⁵³⁷ In preventing significant harm, the court recommended that the government agencies use of a quantification of the chance of harm as a measurement by which those exposures which are safe and unsafe be determined. As Congress moved away from the Delaney Clause⁵³⁸, this quantification of risk became the benchmark by which harm was controlled. Labelled as the *de minimis* standard, this quantification of risk is most often set as a one-in-a-million lifetime risk of specific chronic health conditions, such as cancer, when exposed to an individual pesticide. ⁵³⁹

To ensure that these standards of "safe" and "acceptable" risks are met for children's health, both jurisdictions have amended their pesticide policy to include procedural changes which are thought to result in a *de minimis* standard. These measures, adopted from the NAS report recommendations, include the use of an additional safety factor and the calculation of cumulative and aggregate exposures, both of which are discussed later in this chapter. The thought behind the additional safety factor is that dividing the NOAEL by a safety factor of up to ten, the government agency has ensured that the vulnerabilities of children are considered. The purpose of the aggregate and cumulative exposures is that by including the total daily pesticide intake of children to multiple substances in the risk assessment estimates, they will no longer be exposed to "unsafe" levels.

The placement of these procedures in the risk assessment process indicates how the risk-based approach relies on math and science to ensure that exposure is "safe" and risk "acceptable". As will be discussed later on, the problem with this is that there are a great deal of uncertainty in this science and math, therefore making the process unsuitable in controlling the risk accurately. Even if these inherent flaws in the mathematical process were not present, however, there remains the issue with an approach that has deemed harm at some level acceptable.

⁵³⁷ Influenced by the restraints placed on the EPA by the judicial decisions of *Les* and *Benzene*, the US government abandoned the Delaney Clause because the zero-tolerance standard was perceived as too difficult to implement. At the same time that the US government moved away from this zero-tolerance standard, they made an effort to increase the protection of children when setting standards. Because of the NAS report's findings, the US amended the risk assessment process to include consideration of children's daily intake of pesticides when setting standards. Ten years later when the Canadian government amended their legislation, similar amendments were made. The outcome of these amendments is that when setting pesticide standards the PCPA holds that only "acceptable risk" to children shall be permitted and the FQPA states that standards shall be "safe" is there is "reasonable certainty of no harm" to children.

⁵³⁸Committee on Commerce, supra note 536 at 41.

⁵³⁹ Though Canada enacted their amendments nearly a decade after the US had passed the FQPA, much of the parliamentary mandate to the PMRA mirrored that of Congress. As the PCPA had not undergone a thorough revision since 1969, in 2000 Parliament recommended a number of changes be made to it. Included in these suggestions, the Parliamentary committee advocated the adoption of the FQPA's standards of use of an additional safety factor and integration of aggregate and cumulative data as part of the already existing risk assessment process. In assessing cancer-causing pesticides, the PMRA issued a policy note indicating that the EPA's range of one-in-a-million lifetime chance of cancer shall be implemented in the quantitative risk assessment. *Committee on Commerce, supra* note 536 at 41; *Science Policy Note: A Decision Framework, supra* note 467; Canada, Standing Committee on Environment and Sustainable, Development *Key Directions for Change* (Ottawa: Parliament, 2000), online: Parliament

<http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=1031697&Language=E&Mode=1&Parl=36&S es=2&File=6> (date accessed: 7 June 2009).

4.3.1.2 Criticism of the Risk-Based Approach to Protect Children's Health

4.3.1.2.1 Errors In The Risk Assessment Process: The Use Of Inaccurate Or Incomplete Data

This thesis does not contend that risk is acceptable, even when restricted to a probability of disease. Yet, if one were to embrace this concept, it is only reasonable to assume that the risk assessment process would ensure that this level of risk is met and not exceeded. In order to do so, the data needed for the risk assessment process would need to be accurate and current. However, as this section will discuss, neither Canada nor the US have made certain that the information used in computing standards is either correct or up-to-date. Because of this, the risk-based approach fails to provide the protection of controlled risk which it purposes to do.

Both governments have embraced the risk-based approach with the idea that this approach is fact-based.⁵⁴⁰ It is thought that through the calculation of exposure, risk, and hazard, the government has avoided the subjectivity or political judgment that it once was criticized for in case law.⁵⁴¹ As this section will discuss, however, there exists a great deal of subjectivity and unknowns throughout the process, therefore diminishing this mathematical process' accuracy. When Congress and Parliament initiated efforts to consider children's health in the risk assessment process, they did so within the confines of this mathematical process. Yet, because there are even a greater number of unknowns surrounding children's health and pesticide exposure, this computation of risk is very likely to contain error.

The premise of the risk-based approach is that the government is able to accurately predict the harm resulting from exposure through use of scientific information and, therefore, prevent the population from exceeding the level found to cause harm. This is to provide a measure of protection for health and the environment and permit use of pesticide products without excessive restrictions. In theory, this practice should result in the same health outcomes as the hazard-based approach. While the hazard-based approach eliminates exposure to pesticides that cause irreversible chronic health conditions, the risk-based approach should be able to prevent exposure levels from exceeding the level that which would cause chronic health conditions. However, in order for the government to be able to control the risk in a way that will not result in significant harm, the information used for the risk assessment process must be accurate. This is nearly impossible due to the number of scientific uncertainties that surround the effects of toxic exposure on children. This section provides insight as to the problems that the risk-based approach faces when the agencies rely on inaccurate or incomplete data.

One area where error most likely comes into play is that of the use of animal and epidemiological studies. A second area is that of incomplete data sets used to compute aggregate and cumulative exposures. These two topics will be discussed in this part of the chapter.

⁵⁴⁰ *McClenaghan, supra* note 36 at 150; *Committee on Commerce, supra* note 536; U.S., Congressional Research Service Issue Brief for Congress No. 94036, *The Role of Risk Analysis and Risk Management in Environmental Protection* (Washington, D.C.: Congress, 2001), online: NCSE

http://www.ncseonline.org/NLE/CRSrports/Risk/rsk-1.cfm (date accessed: 5 May 2008).

⁵⁴¹ *McClenaghan, supra* note 36.

4.3.3.2.1.1 Data Inaccuracies When Relying On Animal And Epidemiological Studies

The four-step risk assessment process is based on data extrapolated from animal and epidemiological studies. These studies are submitted by applicants to inform the regulatory agencies of the possible negative health outcomes associated with exposure to a specific pesticide product. Animal bioassays are experiments conducted on laboratory animals for a specified amount of time, during which the subjects are exposed to high doses of the active substance of a product. Epidemiological studies examine health outcomes in population groups for a specific length of time, and attempt to determine causational patterns.⁵⁴² While animal and epidemiological studies are the most predictive health outcome tools currently available, there remain a number of concerns associated with the reliability of the data.

Although epidemiological studies are based on human subjects rather than animals, there are a number of problems with the accuracy of these studies when predicting cause-effect relationships. Many of the concerns with epidemiological evidence are specific to children's health because of the inability to conduct clinical studies with pesticides on children. Because of the ethical issues that surround the use of child volunteers, epidemiological studies carried out within the context of children's environmental health tend to be observationally based rather than a case-control study where one group is exposed to a toxin and one is not. As a result, epidemiological studies are likely to result in inexact data as it is nearly impossible to control for confounding factors and to obtain a large enough study population to be statistically significant. In addition to the limited capacity to perform epidemiological studies in this situation, the scientific community favours false negatives over false positives in epidemiological research, preventing the assumption that there is risk when there is not. For this reason, risks may be overlooked.⁵⁴³

Due to the issues associated with epidemiological studies, use of animal bioassays is preferable. However, these studies are not without their own set of problems. Animal studies tend to be conducted on rats and mice in a controlled laboratory environment where subjects are exposed to large isolated doses of an active substance over a specified period of time. Seldom is the environment in which these studies are conducted similar to that of a human child. An isolated high dose of exposure for a limited period of time is not reflective of a child's low dosage of exposure to multiple toxins over the course of a lifetime.⁵⁴⁴ Cumulative exposure to multiple products, and the impact that may have on the development of children, is not factored into these experiments. In addition, the differences in the animal physiology and development from that of a child's may impact the results of the dose exposure. Test animals are often aged six to eight weeks, which is roughly equivalent to five years of age in humans.⁵⁴⁵ A number of developmental differences exist between the pre- and postnatal period and that of early childhood; therefore, animal tests fail to detect harm that may result from neonatal and prenatal life exposure.

⁵⁴² *Cooper, supra* note 5 at 139.

⁵⁴³ N. Garrett, "'Life is the Risk We Cannot Refuse:' A Precautionary Approach to the Toxic Risks We Can" (2005) 17 Geo. Int'l. Envtl. Rev. 517 at 519.

⁵⁴⁴ J. Samet, "Risk Assessment and Child Health" (2004) 113:4 Pediatr. 952.

⁵⁴⁵ Bearer, supra note 15 at 15; L. R. Goldman, "Case Studies of Environmental Risks to Children" (1995) 5:2 Future Child 27 at 31; *National Research Council, supra* note 99 at 128-134.

Furthermore, there are differences in species that may result in different health outcomes because rats have the capacity to detoxify chemicals, a trait that is not present in human genes. ⁵⁴⁶

Canada and the US have instituted two separate uncertainty factors to address the above mentioned uncertainties associated with animal studies. Distinct from that of the additional safety factor integrated into the risk assessment process by the FQPA and PCPA⁵⁴⁷, these factors were introduced into the process to account for the differences between subpopulations as well as the differences between animals and humans. Each of these factors range in value between one and ten and as a result the dose-response value may be divided by any number ranging between one and one thousand.

Although the use of these uncertainty factors does result in a standard lower than that of the NOAEL, there is still some concern as to whether it adequately provides for the inaccuracies that are associated with the animal and epidemiological data. Research conducted by the Swedish EPA (KemI) concluded that these factors are often too low to account for the scientific uncertainty which result from these studies. The inter-species extrapolation is based on the assumption that humans are most likely ten times more sensitive to toxins than animals. This figure is based on estimates of weight. However, KemI finds that if one were to utilize body surface area or caloric intake in addition to the weight sensitivity differences, humans are most likely twelve times more sensitive to toxins than laboratory test animals are. The study found, additionally, that the sensitivity of specific human subpopulations should range between ten and sixteen due to the number of unknowns as to how people absorb, metabolize, and expel toxins.⁵⁴⁸

There is also question as to whether the use of uncertainty factors provides for the unknowns present when assessing cancer-causing pesticides. Because carcinogenic pesticides produce some level of harm in the form of cancer, there is no NOAEL. Instead, a NOAEL is extrapolated from the LOAEL. Uncertainty factors are then applied to this value to account for inter- and intra-species differences. However, if there are inaccuracies in the studies, such as confounding factors, toxicity expulsion by animals, or failure to calculate the impact the substance has on neonatal or prenatal infants, then this qualitative risk of cancer may increase. The length of the study and the animal sample size may affect the outcome as well. "In a typical two-year rodent oncogenicity study utilizing a total of about 600 animals, a cancer occurring at a frequency of 5 in every 1000 would almost certainly go unnoticed. The practical

⁵⁴⁶ M. Sears et al, "Pesticide Assessment: Protecting Public Health on the Home Turf" (2006) 11:4 Paediatr. Child Health 229 at 230.

⁵⁴⁷ The use of the safety factor will be discussed in greater detail later in the thesis. The safety factor is different from that of the uncertainty factors. The uncertainty factors address intra- and inter-species differences, whereas the safety factor addresses scientific uncertainty associated with neonatal and prenatal children.

⁵⁴⁸ Sweden, KEMI, *Human Health Risk Assessment: Proposals for the use of Assessment (Uncertainty) Factors Application to Risk Assessment for Plant Protection Products, Industrial Chemicals and Biocidal Products within the European Union* (Solna, Sweden: The Swedish national Chemicals Inspectorate, 2003) at 16, online: KEMI <http://www.kemi.se/upload/Trycksaker/Pdf/Rapporter/Rapport1_03.pdf> (last modified: January 2003).

implications of this are considerable because a cancer frequency of 5 in 1000 translates into more than 1 million cases of cancer in the current U.S. population."⁵⁴⁹

These difficulties with use of animal bioassays and epidemiological studies are not able to be easily rectified. Because these forms of research are the best available for predicting harm from exposure to a substance, the abandonment of them is unreasonable. They are the basis of the four-step risk assessment process and integral to each jurisdiction's standard setting policy, including that of the EU's. The reason for bringing forth the above concerns is that these errors are not accounted for in the risk-based approach. Even with the recent amendments to the process, such as the additional safety factor, the outcome of the assessment may not result in a precise standard that controls risk appropriately.

The problem is not with the studies, but with the approach. The risk-based approach aims at controlling risk, something that cannot be done accurately. Even with additional mathematical adjustments made through the use of safety factors, the outcome is going to err in a way that results in uncontrolled and unaccounted for exposures. The detriment this has on children's health is unknown, though evidence indicates it is considerable. It is worth noting that the hazard-based approach's method of caution ensures that these inaccuracies are eliminated. The EU government has determined that if there is indication of significant harm, the product should be eliminated. This eliminates the concerns about the precision of animal and epidemiological studies – correct or not, these studies need only to indicate harm, not be used to calculate risk.

In addition to this problematic situation of utilizing animal and epidemiological studies to determine exact standards, the US and Canada have mandated a limited number of toxicological tests be submitted as part of the registration application. The application dossier includes a baseline of studies and secondary tests are "triggered" when baseline test results indicate such tests may be necessary. Since the risk-based approach hinges on accurate data, without a complete data set, the government may not be able to predict harm affiliated with the substance. Under these circumstances the government, therefore, cannot control this risk.

There is no clear indication of what "triggers" a secondary test, such as those for endocrine disruption, immunotoxicity, or developmental neurotoxicity.⁵⁵⁰ There is not a standard by which secondary tests are triggered. No specific level of harm in a baseline test has been defined as a mandate for further studies. This leaves much of the decision of whether to conduct further tests to the applicant and to the interpretation of the reviewer. Because there is so little concrete evidence about how these substances affect child health, there is no way to ensure that the selected "trigger" level is an accurate gauge or that it is consistently applied.

Present evidence on endocrine and immune dysfunction demonstrates just how little is understood about the effects of pesticide exposure on children's health, and therefore how important it is that the EPA and PMRA mandate a full toxicological data set. Recently recognized by the medical community, endocrine and immune dysfunction is

⁵⁴⁹ Pesticides (Pest Control Canada, 2009), online: Pest Control Canada <http://pestcontrolcanada.com/pesticides.htm> (last modified: 25 October 2009).

⁵⁵⁰ *Cooper, supra* note 5 at 336-337.

thought to be linked to relatively low doses of exposure, rather than high doses.⁵⁵¹ As a result, a baseline test of high doses of exposure cannot indicate that there is a need for further testing. Furthermore, there is no clear negative endpoint to justify endocrine or immune dysfunction tests – no clear "trigger" from baseline tests because it is a result of cumulative exposure over a lifespan to a number of toxins.⁵⁵² Often the effects of prenatal and postnatal exposure to endocrine and immune disrupting chemicals will not be evident until adulthood or may not manifest until the following generation, making the use of baseline animal and epidemiological studies unreliable.

4.3.3.2.1.2 Aggregate And Cumulative Data

One of the changes brought about with the amendments to the FQPA and the PCPA⁵⁵³ was the integration of data on cumulative and aggregate exposures to children in the risk assessment process. Aggregate exposure is defined as the total exposure to pesticides through inhalation, skin absorption, and ingestion of pesticides from food, water, and non-occupational environments.⁵⁵⁴ Cumulative exposure is identified as the total exposure to multiple pesticides that have similar chemical toxicity.⁵⁵⁵

As one of the recommendations of the NAS report, the inclusion of aggregate and cumulative exposure in the risk assessment is supposed to provide greater protection for children's health by ensuring that the total amount of pesticide exposure does not exceed the recommended acceptable daily intake (ADI) level. Prior to this requirement, children were consuming pesticides beyond that of standards set for adults because of their collective exposures and unique behaviours. In a survey of 2-year-old children exposed to organophosphate pesticides, it was found that over four percent of the study population were exceeding the tolerance levels per day. That means approximately 140,000 children residing in the US per day where exceeding the permissible intake for an adult of this cancer-causing⁵⁵⁶ pesticide, some of whom were exceeding the limit by ten times the tolerance level.⁵⁵⁷

⁵⁵¹ R. Kavlock et al., "Research Needs for the Risk Assessment of Health and Environmental Effects of Endocrine Disruptors: A Report of the U.S. EPA-Sponsored Workshop" (1996) 104:S4 Environ. Health Perspect., online: EHP <<u>http://www.ehponline.org/members/1996/Suppl-4/kavlock.html</u>> (last modified: August 1996).

⁵⁵² A. Mantovani et al., "Problems in Testing and Risk Assessment of Endocrine Disrupting Chemicals with Regard to Developmental Toxicology" (1999) 39:8 Chemosphere 1293.

⁵⁵³ The FQPA states that the EPA shall assess the risk of pesticide residue exposure by taking in to consideration substances that have a common mechanism of toxicity and ensure that aggregate exposure to pesticide residues do not result in harm. Similar language was adopted by the Canadian government, as the PCPA requires the PMRA to "consider available information on aggregate exposure to the pest control product, namely dietary exposure and exposure from other non-occupational sources, 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".

⁵⁵⁴ Canada, Health Canada, *General Principles for Performing Aggregate Exposure and Risk Assessments* (Ottawa: Health Canada, 2003), online: Health Canada < http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2003-04/index-eng.php > (last modified: 28 July 2003).

⁵⁵⁵ U.S., Environmental Protection Agency, *Aggregate and Cumulative Risk* (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency < http://www.epa.gov/heasd/risk/index.html> (last modified: 27 October 2009).

⁵⁵⁶ Ibid.

⁵⁵⁷ National Academies Press, supra note 99 at 306.

While a valuable improvement in the risk assessment model, the practical aspects of utilizing aggregate and cumulative exposure data have been less remarkable. One of the biggest challenges that the agencies face when considering aggregate and cumulative exposure rates is that they have gathered little data to do so. The information necessary to provide an accurate estimate of how much of a pesticide a child takes in on a daily basis, and how many pesticides are chemically similar, is lacking. In order to make productive use of this total exposure requirement, the agencies would need to have up-to-date information on dietary intake per age group, information on water pesticide contamination, and information on the exposures at schools, homes, daycares, hospitals, parks, and other non-occupational settings frequented by children. Currently neither country has all of this information.

Of the data necessary to accurately gauge childhood exposures, the agencies have the greatest information on dietary intake. In 1994, 1995, 1996, and 1998, the US Department of Agriculture (USDA) surveyed a sample of nearly ten thousand children over the course of twenty-four hours on their daily food consumption. The USDA's *Continuing Survey of Food Intake by Individuals* is used by both the US and Canada⁵⁵⁸ to estimate aggregate and cumulative exposure. While this survey provides some insight as to the consumption of specific foods and juices by children residing in the US, there remains some uncertainty as to whether it is reflective of the typical diet of a child in 2009.⁵⁵⁹ It has been over a decade since the survey was conducted and based on historical trends, it is more than likely that children's diets have changed. By the mid-1990s, children residing in the US had increased their intake of fruit and fruit juices since the 1970s.⁵⁶⁰ In addition to this USDA data increasingly becoming out-dated, there is also some uncertainty as to whether or not it accurately reflected children's intake when conducted. The reliability of this survey in the risk assessment process is questionable because the information is only that of one day and less than two percent of the child population in the US were surveyed.

⁵⁵⁸ The risk-based method relies on an accurate estimate of exposure in order to restrict risk, and because of this it is of crucial that data is gathered on a regular basis if there is to be any attempt to control the risk. Though the US has made efforts, though sadly outdated, to collect information on childhood consumption patterns, the Canadian government has not done so. Canada currently relies on the US monitoring and dietary information for its analysis. The country's most recent dietary intake survey was conducted in 1972 and was used until 1999 when the PMRA began borrowing data from the US dietary surveys. Additionally, because Canada does not have a national body that regulates the compliance of water quality guidelines, the data on the ingestion of pesticides via water in the assessment process is once again borrowed from the US. A fact-based procedure that fails to use country-specific data cannot protect children from exceeding levels of pesticide exposure that would result in harm.

⁵⁵⁹ Conducted from 1994 through 1996, and in 1998, this one-day survey of 16,103 individuals included data from 9,812 children aged infant to nine-years-old. Surveying a fraction of the population at the time. In 1996, the total US population was 263 million. This means only 6% of the population was surveyed on one day's worth of food consumption. U.S., Census Bureau, *1996 Statistical Abstract of the United States* (Washington, D.C.: Census Bureau, 1996), online: Census Bureau http://www.census.gov/prod/2/gen/96statab/96statab.html (last modified: 8 February 1999).

⁵⁶⁰ S. Bowman et al., "Effects of Fast-Food Consumption on Energy Intake and Diet Quality Among Children in a National Household Survey" (2004) 113:1 Pedaitrc. 112 at 112; "Children's Food Consumption Patterns Over Two Decades" (2004) Nutr. Research Nwltr., online: Nutrition Research Newsletter http://findarticles.com/p/articles/mi_m0887/is_8_23/ai_n6175693/ (last modified: August 2004).

Recent data on dietary intake is necessary in order for the risk-based approach to function in a fashion that would provide protection for children's health. The amendments made by the FQPA and PCPA focused on the government's authority to regulate risk associated with food residues. Yet, the legislation mandates that this requirement is to be fulfilled when information permits.⁵⁶¹ Without placing any policy requirements as to how often information must be gathered, or in the case of Canada, that information must be collected in the first place, this amendment to the risk-based approach becomes less effective with each passing year. This diminishes the capacity of the risk-based approach to fulfill its objective of setting safe and acceptable limits on pesticide residues.

In addition to dietary exposure, the government must have data on other pesticide contact to calculate aggregate exposures. The US⁵⁶² keeps track of pesticide usage and sale, however, the EPA does not have reliable data on where the highest concentrations of pesticide use would be found. It does not have accurate data on non-occupational and non-agricultural pesticide application. The only information about personal pesticide use that the EPA has is the amount of active ingredients sold in the country for non-agricultural purposes. This fails to provide any real context as to how many indoor and outdoor pesticides children are exposed to and how many of those exposures are simultaneous. It is estimated that pesticide products are used in over ninety percent of US households, and found in over seventy percent of homes with pregnant women or infants under the age of six months. ⁵⁶³ The impact this amount of pesticide use has on some children has not been accounted for due to the fact that the government has not conducted any basic survey of household pesticides use.

The accuracy of aggregate exposure continues to decrease by the agencies' risk assessment process when the government utilizes information on pesticide use that may not be correct. Estimates by the EPA and PMRA⁵⁶⁴ for water pesticide run-off, soil contamination, and air contamination are based on good agricultural practices (GAP). GAP assumes that agricultural applications of pesticides conform to the label instructions, including the amount and duration applied and the protective clothing used. If farmers were to act in accordance with these requirements, the use of these assumptions in the estimates would be appropriate. Research, however, indicates that farmers often apply more pesticides than necessary, assuming "more is better".⁵⁶⁵ They may also apply mixtures of multiple pesticides concurrently, though not necessarily recommended, thereby changing the chemical potency of each pesticide individually.⁵⁶⁶ Studies indicate that few who use agricultural pesticides read the complete label. One study

⁵⁶¹ *PCPA*, *supra* note 511 at s.7(b)(i); *FQPA*, *supra* note 513 at 2(A)(ii).

⁵⁶² Because Canada is the only OECD country that has failed to formulate a database on national pesticide use the PMRA uses information gathered by the US EPA on residential pesticide exposure in children. Canada relies on a risk-based approach to ensure that children's health is protected from undue harm from pesticides, but in order to fulfil this objective uncertainties and inaccuracies with the risk assessment process must be eliminated to the fullest extent possible. By continuing to use the US data, differences in ethnicity, dietary habits, and availability of produce will not be accounted for, leaving children in Canada more vulnerable to harm.

⁵⁶³ *Wigle, supra note 4* at 177.

⁵⁶⁴As Canada does not have this data they utilize US data for computations.

⁵⁶⁵ Avory, supra note 178 at 238.

⁵⁶⁶ C. Wilson & C. Tisdell, "Why Farmers Continue to Use Pesticides Despite Environmental, Health and Sustainability Costs" (2001) 39 Ecol. Econ. 449 at 450.

found only thirty-eight percent of the interviewees read the label when using the product for the first time.⁵⁶⁷ Although this excessive use of pesticides may appear to be an issue related to occupational exposure, it makes an impact on children's exposure rates as well. The residue on these food products remain, and may be altered due to the multitude of substances used at once. If this data is not integrated into data on dietary and water intake of pesticides, then the use of the aggregate data will be inaccurate. It also makes an impact on the estimates for residential pesticide exposure in children, since those who live near agricultural communities will necessarily be exposed to greater amounts of substances than expected or estimated.

In addition to lacking any real data on exposure routes other than dietary intake, the governments have also excluded parent occupational exposure in the computing of childhood daily intake.⁵⁶⁸ Because children are not exposed to toxins in a workplace on a daily basis considering this area of pesticide exposure seems irrelevant. Yet, recent studies indicate that though children may not be directly exposed to these toxins at a workplace setting, they tend to take in residues transferred from parents who are. Because the risk-based approach does not eliminate those substances which are most caustic from the onset, this exposure via parent transfer should be part of the computation of risk.

The point to be made by this account of Canada's and the US' failures to obtain accurate data is that without this information the risk-based approach fails to control risk. The computation of standards cannot be performed with any precision if the data is lacking. Yet, neither nation has insisted that efforts be made to gather this data. Neither the PCPA nor the FQPA mandate regular surveys of exposure be conducted. Both nations rely on predictive models to estimate intake by children – models based on assumptions that have yet to be proven true.⁵⁶⁹

⁵⁶⁷ *Ibid.* at 454.

⁵⁶⁸ Research has associated an increase in pesticide exposure in children whose parents work in agriculture due to soil transfer from work clothes or across the placenta during pregnancy. Even in circumstances where parents reduce these occupational transfers, evidence indicates that vehicles used for both work and family purposes may transfer measureable pesticide residue to children. Furthermore, proximity to land used for agriculture can greatly affect the intake of pesticides by a child. There is evidence of increased childhood exposure to pesticides from aerial spraying, when a parent works in an agricultural setting. Links have been made between high disease rates and children residing near agriculture, including one study where children within a mile or less of farmland were found to have a decrease in IO in due to an increased exposure to pesticides in comparison to those residing more than a mile from the same area. Additionally, it is believed that children residing near farmlands may have direct contact with pesticides from playing in agricultural fields or areas alongside fields. Children of migrants workers have been found to play in the dirt and work the fields at younger than legal age, therefore increasing their pesticide exposure levels. Under the current regulation the agencies are not required to consider occupational exposure which includes childhood intake from agricultural transfer. C. Lu et al., "Pesticide Exposure of Children in an Agricultural Community: Evidence of Household Proximity to Farmland and Take Home Exposure Pathways" (1999) 84 Environ. Res. 290; D. Koch et al., "Temporal Association of Children's Pesticide Exposure and Agricultural Spraying: Report of a Longitudinal Biological Monitoring Study" (2002) 110:8 Environ. Health Perspect.829; P. Moulton, "Pesticide Exposure, Intelligence and Children: Preliminary Results" (National Pesticide Forum, Washington, D.C., 19 May 2006), online: N.D. Center for Rural Health http://ruralhealth.und.edu/presentations/pdf/natlpesticideforum051906.pdf> (last modified: 19 May 2006); Cooper, supra note 5 at 54.

⁵⁶⁹ U.S., Environmental Protection Agency, *Exposure Assessment Tools and Models* (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency < http://www.epa.gov/oppt/exposure/> (last modified: 22 January 2009).

Once again, the failures of the risk-based approach are magnified by use of incomplete information. Though the use of inaccurate data is not to be permitted under the hazard-based approach, the failsafe put in place through the elimination of a product that poses significant harm lessens these concerns about daily exposure. If there is no standard to be set, then the information on childhood daily intake is not necessary.

Thus far, this section has provided insight as to why the risk-based approach fails to protect children because of the lack of data on daily exposures, as well as a failure on the part of the legislation to incorporate occupational pesticide transfer from parents. Though these points indicate that the necessity of data has been overlooked by the EPA and PMRA, nowhere is this point more relevant than when considering the use of cumulative exposure data. Though the government has been ineffectual in gathering information on dietary and residential intake necessary for aggregate data, it has been even more unproductive in assessing cumulative exposures. Because of this, the problems associated with using a risk-based approach are enlarged with additional opportunities for inaccuracy to seep into the resulting standard.

In order for pesticides to be defined as having a common mechanism of toxicity the same toxic effect must occur in "the same organ or tissue by essentially the same sequence of major biochemical events". ⁵⁷⁰ This means that though two pesticides may have an impact on the same organ or tissue through different biochemical methods, they are not considered cumulatively. This definition is not inclusive of non-active pesticide substances, such as chemicals that may have the same mechanism of toxicity.⁵⁷¹

One of the ways in which the PCPA and FQPA attempt to alleviate the burden of assessing cumulative exposure by both agencies is that there is a caveat that these considerations only need to be given when there is appropriate information available.⁵⁷² However, in most circumstances the necessary information is not available. For example, the EPA has been reviewing the cumulative exposure to pesticides for over a decade, and has only been able to identify four categories of substances that have similar mechanisms of toxicity: (1) organophosphates, (2) N-methyl carbamates, (3) triazines, and (4) chloroacetarilides.⁵⁷³ Because of this impossibly lengthy process of cumulative review, the EPA has very little data on which to act when considering cumulative exposures. Since the legislation provides justification for not having this data during the risk assessment process, it has been left out of many reviews.

⁵⁷⁰ U.S., Environmental Protection Agency, *Organophosphorus Assessment – 2006 Update* (Washington, D.C.: Environmental Protection Agency, 2006), online: EPA http://www.epa.gov/oppsrrd1/cumulative/2006-op/op_cra_main.pdf> (last modified: August 2006).

⁵⁷¹ The fact that additives to the active ingredients, known as inert ingredients, are not included in calculating exposures may result in an intake of substances above the standard set.

⁵⁷² *PCPA, supra* note 511; *FQPA, supra* note 513.

⁵⁷³ U.S., Environmental Protection Agency, *Common Mechanism Groups; Cumulative Exposure and Risk Assessment* (Washington, D.C.: Environmental Protection Agency, 2008), online: Environmental Protection Agency http://www.epa.gov/oppsrd1/cumulative/common_mech_groups.htm> (date accessed: 20 June 2008).

In an effort to remedy some of the above mentioned errors in data, the US and Canada have recently adopted an additional safety factor ranging in value from one to ten. One of the recommendations from the NAS report, the committee thought that the use of an additional safety factor would solve data errs "where there is evidence of development toxicity and when data from toxicity testing relative to children are incomplete".⁵⁷⁴ In both the PCPA and the FQPA this procedural change to the risk assessment process was included as part of the legislative amendments to protect children's health.⁵⁷⁵ In addition to the already existing uncertainty factors to account for inter- and intra-species difference, a factor may be applied "to take into account potential pre- and post-natal toxicity and completeness of the data with respect to the exposure of, and the toxicity to, infants and children".⁵⁷⁶ The thought is that in those instances that the safety factor is used, the infant would be a thousand times (ten for intra- ten for inter-species, and an additional ten for subpopulation vulnerability) more sensitive than the test subject and when faced with uncertainty it is an appropriate precaution.⁵⁷⁷ Both the EPA and the PMRA, however, have the authority to use a value less than ten if the deem appropriate.⁵⁷⁸

There are a number of reasons that this additional safety factor has not been effective in accounting for the scientific uncertainties. One, the factor is still part of an overarching framework that aims at controlling risk. An additional mathematical adjustment does not eliminate the fact that the basis of the risk-based approach is to control risk. For instance, the additional safety factor of ten has been applied to the fungicide pentachloronitrobenzene (PCNB), which is used on a number of vegetable crops, including lettuce, green beans, barley, beans, corn, oats, peas, peanuts, soybeans, sugar beets, wheat, and tomatoes.⁵⁷⁹ Identified by the EPA and the PMRA as a possible carcinogen, the factor was used because of "residual uncertainties in the databases for pre- and/or postnatal toxicity".⁵⁸⁰ Using the hazard-based approach, the EU has banned the product outright.⁵⁸¹ No matter how low of a threshold is set by the US and Canadian governments when using the additional safety factor, they will always exceed that of the EU's prohibition.

A second reason for the failure of the additional safety factor to make a noticeable change for children's health is that the legislation in both jurisdictions provides the agencies the authority to reduce or dismiss the factor. The EPA and PMRA may choose to do so if there is "reliable data" that indicates it will be safe for infants and children to eliminate

⁵⁷⁹ U.S., Environmental Protection Agency, *Reregistration Eligibility Decision for Pentachloronitrobenzene* (Washington, D.C.: Environmental Protection Agency, 2006) 26 online: EPA < http://www.epa.gov/opp00001/reregistration/REDs/pcnb_red.pdf> (last modified: June 2006).

⁵⁸⁰ *Ibid.* at 26.

⁵⁸¹ D.R. Boyd, *The Food We Eat: An International Comparison of Pesticide Regulations* (Vancouver: David Suzuki Foundation, 2006) at 10.

⁵⁷⁴ National Research Council, supra note 99 at 9.

⁵⁷⁵ FQPA, supra note 513; PCPA, supra note 511.

⁵⁷⁶ Committee on Commerce, supra note 536 at 43.

⁵⁷⁷ McClenaghan, supra note 36 at 147.

⁵⁷⁸ PCPA, supra note 511; FQPA, supra note 513.

the additional factor.⁵⁸² Though the agencies have attempted to provide greater guidance as to how one may determine when data is "reliable", the responsibility still rests on the "scientific judgment and principles" of the risk assessor.⁵⁸³ Evidence indicates that interpretation of "reliable" has been less than proactive as of 1999 the EPA "reported that it had made 120 regulatory decisions under the FQPA, and that it had applied the tenfold additional child safety factor in only fifteen of those 120 decisions."⁵⁸⁴

The governments' powers to dismiss the additional safety factor have been often utilized, leaving this amendment rather ineffectual in protecting children's health. The use of this mathematical adjustment has been so narrowly construed that US states New York, Connecticut, Massachusetts, and New Jersey have filed suit against the EPA for failure to honour the obligations set forth in the FQPA.⁵⁸⁵ The states argue that five pesticides in particular, alachlor, chlorothalonil, methomyl, metribuzin, and thiodicarb, are consumed on a regular basis by children and may pose health problems for children, therefore the safety factor should have been applied. Three of these pesticides, alachlor, methomyl, and thiodicarb, have been de-registered in the EU due to their harmful properties.⁵⁸⁶

This reluctance to use the safety factor is reflective of how the risk-based approach aims at taking action when evidence indicates necessary. Use of a safety factor when faced with uncertainty is contrary to this principle - it would be utilizing caution without tangible evidence it is necessary. The risk-based approach sets standards based on evidence of harm. Lack of evidence does not figure into to this equation, therefore leaving the application of the safety factor narrowly defined to be used only when fact indicates increased infant sensitivity to the pesticides.⁵⁸⁷

Another problem with relying on the safety factor to remedy scientific uncertainty is that the decision to apply it rests with the assessor and is therefore subjective.⁵⁸⁸ This subjectivity can make an impact on what cancer-causing pesticides are registered and what standards of exposures are set. In one study of scientific professionals who were all given the same data on 2-4-dichlorophenoxyacetic acid (2, 4-D), thirteen thought that the possibility of the

⁵⁸⁴ V. Watnick, "Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children" (1999) 31 Ariz. St. L.J. 1315 at 1342.

⁵⁸⁵ "States Sue EPA for Failing to Protect Children from Pesticides" *The IPM Institute of North America, Inc.* (15 September 2003), online: IPM http://www.ipminstitute.org/Articles/EPA_Sued.htm> (last modified: 15 September 2003).

⁵⁸⁶ "Bayer Pesticide Plant Explosion Revels Shaky Safety Record" *Beyond Pesticides Daily News Blog* (5 September 2008), online: Beyond Pesticides < http://www.beyondpesticides.org/dailynewsblog/?p=533> (last modified: 5 September 2008).

⁵⁸⁷ E. Groth, "Science, Precaution and Food Safety: How Can We Do Better? A Discussion Paper for the US Codex Delegation" (2000) Consumer Union, online: Consumer Union http://www.consumersunion.org/pub/core food safety/002267.html> (lasted modified: February 2000).

⁵⁸⁸ U.S., Environmental Protection Agency, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment* (Washington, D.C.: Environmental Protection Agency, 2002), online: EPA http://www.epa.gov/pesticides/trac/science/determ.pdf> (last modified: 28 February 2002).

⁵⁸² PCPA, supra note 511; FQPA, supra note 513.

⁵⁸³ U.S., Environmental Protection Agency, *Staff Paper #2 Topic: FQPA Safety Factor (10X)* (Washington, D.C.: Environmental Protection Agency, 1998) (TRAC 5/28-29/98), online: Environmental Protection Agency http://www.epa.gov/oppfead1/trac/10xiss.htm> (last modified: 17 May 1998).

pesticide to cause cancer was strong and five thought it was remote.⁵⁸⁹ This example illustrates how interpretative this fact-based process is.⁵⁹⁰

A final reason as to why use of the safety factor may fail to protect children is there is much debate as to whether this factor does protect children's health or merely reduces exposure rates. It has been argued that in situations where the substance is carcinogenic at all exposure doses, then the use of the safety factor results in no benefit.⁵⁹¹ Other researchers have advocated the use of further toxicological testing rather than utilization of an arbitrary safety factor. If data on "reproduction, multigenerational or developmental studies are conducted there will be no need for an additional 10-fold factor".⁵⁹²

4.3.3.2.3 The Problem With Cancer-Causing Pesticides Being An Acceptable Risk

As mentioned earlier, one of the more problematic issues with the risk-based approach is that use of it asserts that a certain amount of risk is acceptable. Included in this definition of acceptable risk is that of cancer. While a percentage of children will always get cancer, due to genetic predisposition, it is reasonable to mandate that government ensure that this childhood cancer statistic does not increase. The risk-based approach stresses that risk be controlled to a point where it is no longer results in significant harm, not that the risk of cancer due to toxic exposure be eliminated. Defined as the *de minimis* standard, this principle holds that the severity of the disease is not what defines what is significant, instead the number of people who get this disease describes significant harm is the focus of evaluation. Within the last two decades, rates of childhood cancer have risen substantially.⁵⁹³ The National Cancer Institute has found a rise in childhood acute lymphoblastic leukemia (ALL), with 27.4 percent increase from

⁵⁸⁹ M.A. Ibrahim et al., "Weight of the Evidence on the Human Carcinogenicity of 2,4-D" (1991) 96 Environ. Health Perspect. 213 at 220.

⁵⁹⁰ Listed as "not classifiable as to human carcinogenicity" by the EPA and recognized as a safe pesticide by the PMRA, use of the additional safety factor in the 2,4-D evaluation has been removed. It is estimated that over sixteen million pounds of 2,4-D is used annually in the United States and was found present in the urine of sixty-four percent of adults residing in the US. This indicates that the exposure rates are high, even in non-occupational settings. Meanwhile, a number of EU member states and the EU itself have banned use of the pesticide completely.

U.S., Environmental Protection Agency, "Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment" (Washington, D.C.: Environmental Protection Agency, 2002), online: Environmental Protection Agency < http://www.epa.gov/pesticides/trac/science/determ.pdf> (last modified: 28 February 2002).

U.S., Environmental Protection Agency, 2,4-D RED Facts (Washington, D.C.: Environmental Protection Agency, 2005), online: Environmental Protection Agency < http://www.epa.gov/oppsrtd1/REDs/factsheets/24d fs.htm> (last modified: 30 June 2005); Industry Task Force II on 2,4-D Research Data, News Release "Health Canada Finds 2,4-D Used Safely" Can Be (16 May 2008), online: IVMA http://www.ivma.com/documents/industry_task_force_letter.pdf?ID=7305> (last modified: 16 May 2008); "The Next Step-A Province-Wide Ban on Cosmetic Pesticides" Toxic Free! Canada (22 March 2009), online: Toxic Free Canada < http://www.toxicfreecanada.ca/articlefull.asp?uid=62> (last modified: 22 March 2009); "Public Comments Needed Now to Ban the Dangerous Herbicide 2,4-D" Beyond Pesticides Daily News Blog (18 February 2009), online: Beyond Pesticides < http://www.beyondpesticides.org/dailynewsblog/?p=1285> (last modified: 18 February 2009); R.H. Hill et al., "Pesticide Residues in Urine of Adults Living in the United States: Reference Range Concentrations" (1995) 71:2 Environ. Res. 99.

⁵⁹¹ McClenaghan, supra note 36 at 146-147.

⁵⁹² Sweden, KEMI, supra note 548 at 74.

⁵⁹³ Landrigan 2004, supra note 12.

1973 to 1990.⁵⁹⁴ The incidence of brain cancer has also increased by nearly forty percent over the same period.⁵⁹⁵ These numbers equate to thousands of instances of childhood cancer within the US alone.

In the risk assessment process, the governments evaluate carcinogenic pesticides and establish a standard that results in an "acceptable" level of risk of cancer. This "acceptable" level is defined as a "negligible" possibility of getting cancer during a lifetime's period. "Negligible" has been defined as the *de minimis* standard of one-in-a-million chance of getting cancer.⁵⁹⁶ Using animal and epidemiological studies, tolerances are set that are to ensure that the risk of cancer does not exceed this probability. The agencies have the authority to modify this standard of one-in-a-million if the new standard is "at least equally protective of public health" and does not "exceed 10 times the annual risk allowed under a safe tolerance level" and is not "greater than twice the safe lifetime risk".⁵⁹⁷

In determining the standard of exposure that will result in a one-in-a-million risk of cancer, the agencies utilize a "weight of evidence" process.⁵⁹⁸ Because carcinogenic pesticides cause harm at every dose of exposure in epidemiological and animal studies, the government cannot use the same method of standard setting that they do with threshold pesticides. Instead, the agencies review all evidence to arrive at the lowest dose with the lowest health impact, known as a lowest observed adverse effect level (LOAEL). Data on tumour findings in humans and animals, the chemical properties of the substance, its similarities to known carcinogenic pesticides, and epidemiological evidence are pieced together to form a weight of evidence narrative.⁵⁹⁹ This narrative is to provide some insight into the appropriate model to use for determining dose-response curves, and therefore establish a tolerance level that will result in a *de minimis* standard.

Use of the weight-of-evidence approach within the risk-based approach to calculate a specific chance of risk can be problematic for children's health. One issue is that the data used to assess what model should be used for standard setting may not be accurate. Because consideration has already been given to the impact incomplete and inaccurate data can have on standard outcomes, it is not necessary to go over it again. However, because miscalculation of exposures results in much more than skin irritation or respiratory problems it is important to bring up that these issues of data uncertainty exist. Inaccuracy in the risk assessment process may mean an increased risk in cancer which is an often fatal chronic health condition.

⁵⁹⁴ *Ibid*.

⁵⁹⁵ Ibid.

⁵⁹⁶ "[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." *McClenaghan, supra* note 36 at 151.

⁵⁹⁷ In assessing whether or not to modify this *de minimis* standard consideration may be given to any "significant disruption in domestic production of an adequate, wholesome, and economical food supply". *Committee on Commerce, supra* note 536 at 41-42.

⁵⁹⁸ U.S., Environmental Protection Agency, *Evaluating Pesticides for Carcinogenic Potential* (Washington, D.C.: Environmental Protection Agency, 2009), online: EPA < http://www.epa.gov/opp00001/health/cancerfs.htm> (last modified: 9 April 2009).

In addition to the possibility of miscalculation due to data uncertainties, scientific debate surrounds the choice of model used to determine the LOAEL. In a typical risk assessment procedure reviewing non-cancer causing substances, the relationship between the dose and the harm is linear and increasing. With cancer-causing substances, however, this is not always the case. Exposures to relatively low doses of carcinogenic substances for a prolonged period of time have been shown to have a greater impact on the chance of cancer than higher doses.⁶⁰⁰ Though the EPA and PMRA have provided some reference as to the models for dose-response charting available, the selection remains at the discretion of the risk assessor. "The choice of dose/response extrapolation model can make an enormous difference to how risky small doses of the substance appear to be. Two scientifically plausible models for the risk associated with aflatoxin in peanuts or grain may show risk levels differing by a factor of 40,000."⁶⁰¹

Even if the appropriate model was selected, and the data accurate, the use of the risk-based approach still results in a set chance of cancer during one's lifetime. The impact that this life-threatening disease can have on an individual, family, and the general society cannot be underestimated, particularly when considering childhood cancer. To understand the prevalence of childhood exposure to carcinogenic pesticides, one need only consider the use of organophosphates. This group of pesticides provide a clear example of a substance that continues to be used in large quantities, has been linked to negative health outcomes, and yet retains registration status in both Canada and the US. This pesticide has been positively associated with childhood cancers, including leukemia, lymphomas, testicular cancer, and brain tumours.⁶⁰² Over seventeen million pounds of this class of substance was applied in the US in non-agricultural settings, ensuring that most children are exposed to some extent.⁶⁰³ Yet, the risk-based *de minimis* standard maintains that use of this pesticide can continue as long as the risk is one-in-a-million. In fact, in the reevaluation of organophosphates the EPA only applied a three-fold factor despite the health concerns related to these substances and the data uncertainties associated with neurodevelopmental toxicity.⁶⁰⁴

What is interesting about the risk-based approach is that though the courts have mandated that the EPA have the necessary data to prove that an increase in standards is needed, the reverse onus is not present. The EPA has not had to demonstrate that it has the necessary data to lower the safety factor for organophosphates to three rather than apply

⁶⁰⁰ If the dose-response data is charted using a benchmark dose-response curve, the relationship may be expressed in a sigmoidal, U-shaped, or inverted U-shaped. The US has recommended use of this process; however the PMRA has not done the same. U.S., Environmental Protection Agency, *Benchmark Dose Software (BMDS)* (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency < http://www.epa.gov/ncea/bmds/> (last modified: 9 November 2009).

⁶⁰¹ *Pollak, supra* note 42 at 30.

⁶⁰² B. Eskenazi, A. Bradman, & R. Castorina, "Exposures of Children to Organophosphate Pesticides and their Potential Adverse Health Effects" (1999) 107:S3 409 at 411.

⁶⁰³ D. Wessels, D.B. Barr, & P. Mendola, "Use of Biomarkers to Indicate Exposure of Children to Organophosphate Pesticides: Implications for a Longitudinal Study of Children's Environmental Health" (2003) 111:16 Environ. Health Perspect. 1939 at 1939.

⁶⁰⁴ *Cooper, supra* note 5 at 157.

a ten-fold factor.⁶⁰⁵ For instance, the data used to derive a three-fold factor was based on six organophosphates and then applied to all thirty reviewed.⁶⁰⁶ The re-evaluation also failed to take into account a number of exposure routes, such as the large quantities used on farmlands and recreational areas, such as golf courses, that may result in an increased exposure. The calculations of total exposure did not include those uses for public health reasons, such as for black fly control and fire ant extermination.⁶⁰⁷ This lack of data is not reason enough to prohibit the reduction of the safety factor or the elimination of the pesticide completely, however, if this data were lacking and the agencies attempted to increase the standards the courts would find this invalid. The increase of a standard, including that which might prevent cancer, must be based on scientific evidence.⁶⁰⁸

Unfortunately, this mandate put in place by the judiciary is not well understood by the general public. There exists this belief that if a pesticide is registered by the PMRA or EPA, then it is safe for use.⁶⁰⁹ "Acceptable risk" and "reasonable certainty" of no harm often is mistaken by parents and caretakers as "low as can reasonably be achieved", rather than a risk of one-in-a-million of childhood cancer.⁶¹⁰ Because of this, many of the label requirements and safety precautions put in place by the EPA and PMRA to ensure that this probabilistic standard is met are disregarded. In a survey of the schools in the State of New York, it was found that eighty-seven percent of the schools used pesticides and took very few precautions to prevent childhood exposure.⁶¹¹ Pesticides are used indoors in nearly ninety-percent of US households, including those with carcinogenic properties.⁶¹² The idea that this does not make an impact on children is unreasonable considering that scientific evidence available indicates that there is a possibility of harm. In a Canadian study of children, of the six organophosphate insecticide metabolites tested, three were detected in children.⁶¹³ What is unknown is if the person applying the pesticide knew that the actual definition of "acceptable" and "reasonable certainty of no harm" did not equate "safe", but rather a chance of cancer, would have still used the product in the same fashion.

4.3.4 Risk Analysis Under The European Union's Pesticide Policy

Like Canada and the US, the European Union's pesticide framework has undergone amendments recently to ensure that children's health is protected. With the passage of legislation in 1991, the EU gained authority over all pesticide registrations within their jurisdiction, a power that once sat with the federal governments of member states. In 2002,

⁶⁰⁷ *Ibid*.

⁶⁰⁵ Letter from J. Kepner (9 September 2002), online: Beyond Pesticides

<http://www.beyondpesticides.org/watchdog/comments/OP_cumm_risk_10_02.htm> (last modified: 9 September 2002).

⁶⁰⁶ *Ibid*.

⁶⁰⁸ *Hodgson, supra* note 47; *Benzene, supra* note 478.

⁶⁰⁹ *Groth, supra* 587.

⁶¹⁰ *Ibid*.

⁶¹¹ Wigle, supra note 4 at 178.

⁶¹² *Ibid.* at 177.

⁶¹³ *Toxic Nation: Pollution in Canadian Families* (Toronto: Environmental Defence, 2007), online: Environmental Defence < http://www.toxicnation.ca/toxicnation-studies/pollution-in-family> (last modified:5 October 2007).

the European Union initiated the Sixth Environment Action Programme of the European Community (2002-2012) which included environment and health as one of its priority areas.⁶¹⁴ This provided the impetus for the passing of the 2006 *A Thematic Strategy on the Sustainable Use of Pesticides* [hereinafter *The Thematic Strategy*], a framework that aims to "reduce the impacts of pesticides on human health and the environment, and more generally to achieve a more sustainable use of pesticides as well as a significant overall reduction in risks and of the use of pesticides consistent with the necessary level of protection against pests".⁶¹⁵ As a part of this strategy, the EU has recently passed a pesticide package, which includes a regulation and framework directive, with the purpose of moving away from a risk-based approach to that of a hazard-based approach.⁶¹⁶ The new approach eliminates the most toxic of substances, including carcinogenic substances, and registers only those which are least caustic and most effective.

This section will argue that the use of the hazard-based approach is more beneficial for children's health because it relies on caution and eliminates the most caustic exposures. The following section will discuss: (1) the EU's pesticide history that helped shape current policy, (2) the details of the hazard-based approach, (3) the use of caution in pesticide decision-making, and (4) how this framework remedies many of the problems brought forth in the prior section on risk-based approach used by Canada and the US.

4.3.4.1 History: Building On A Long Tradition Of A Non-Toxic Environment In Scandinavian Countries

As mentioned above, pesticide regulatory powers originally sat with member states. Although there was EU pesticide legislation in place as early as the 1970s, the purpose of these policies was limited. These policies focused on consumer safety in specific instances, such as residue limits in infant formula⁶¹⁷, rather than formulated a complete regulatory system. However, in the 1990s there was a shift of authority from the member states to the EU over the registration, sale, usage, and tolerance standards of pesticides. *Directives* 91/414/EEC⁶¹⁸ and 98/8/EC⁶¹⁹

⁶¹⁴ E.C., *European Environment and Health Homepage* (Brussels: European Commission, 2009), online: E.C. < http://ec.europa.eu/environment/health/index_en.htm> (last modified: 9 June 2009).

⁶¹⁵ E.C., Proposal for a Directive of the European Parliament and of the Council Establishing a Framework for Community Action to Achieve a Sustainable Use of Pesticides [2006] COM(2006) 373 final at 3, online < http://ec.europa.eu/prelex/detail_dossier_real.cfm?CL=en&DosId=194492> (last modified: 12 July 2006). [hereinafter COM(2006) 373 final].

⁶¹⁶ Parliament Settles Pesticide Deal, supra note 534.

⁶¹⁷ E.C., *Council Directive 79/117/EEC of 21 December 1978 Prohibiting the Placing on the Market and Use of Plant Protection Products Containing Certain Active Substances* [1978] 79/117/EEC, online: E.C. < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31979L0117:EN:HTML> (last modified: 21 December 1978). [hereinafter *79/117/EEC*].

⁶¹⁸ E.C., *Council Directive 91/414/EEC of 15 July 19991 Concerning the Placing of Plant Protection Products on the Market* [1991] 91/414/EEC, online: E.C. < http://eur-

lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0414:EN:NOT> (last modified: 15 July 1991). [hereinafter 91/414/EEC].

⁶¹⁹ E.C., Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 Concerning the Placing of Biocidal Products on the Market [1998] 98/8/EC, online: E.C. <

http://ec.europa.eu/environment/biocides/pdf/dir_98_8_biocides.pdf> (last modified: 16 February 1998). [hereinafter 98/8/EC].

were adopted in 1991 and 1998 respectively, prohibiting member states from barring pesticides approved by the EU and establishing a supranational registration of pesticides.⁶²⁰

The impetus for the recent transfer of authority from member states to the EU government was neither safety nor health concerns, but rather - similar to the origins of the EU itself - an effort to further trade harmonization. The objective of this policy was to simplify the registration process and eliminate the multi-step process required by a number of nations. This was particularly beneficial to Germany, which has the third largest pesticide manufacturing industry after China and the United States.⁶²¹

One of the influential factors that led the EU to move towards a hazard-based approach, though working towards trade harmonization, was that these efforts coincided with pressures to regulate areas associated with health and the environment.⁶²² In 1992 the EC Treaty was amended to require a "high level" of health and a "high level of protection" for the environment.⁶²³ In addition, during the 1990s member states such as Sweden⁶²⁴, Austria⁶²⁵, Demark⁶²⁶, and the Netherlands⁶²⁷ lobbied the EU in an effort to prevent the reduction of their already high pesticide standards when becoming member states. In fact, when the Swedish government joined the EU in 1995 the accession agreement included the mandate that they would not have to lower their environmental standards for the sake of economic benefits.⁶²⁸

⁶²⁰ Another member state has the authority to refuse registration of a product already approved in another country and by the EU if it can prove that its impact on environment or health differs greatly in its jurisdiction. T.C. Marrs & B. Ballantyne, *Pesticide Toxicology and International Regulation* (West Sussex, England: John Wiley & Sons Ltd., 2004) at 502.

⁶²¹ As well as providing context as to the impetus behind the EU's adoption of pesticide authority, this point of trade harmonization is important to the overall thesis comparison. Within North America, the pesticide industry has played a crucial and influential role in shaping the current policy, including that of the risk-based approach. This has resulted in a procedure that presumes that the product is worthy of registration until evidence indicates otherwise. Because of the trade relationship between the US and Canada is so intertwined, Canada has willingly adopted the US legislation and is in the process of changing tolerance standards to meet that of their southern neighbour. One might draw the conclusion that the EU does not have the same pressures from industry as does the US; therefore the reason for selecting a risk- versus hazard-based approach would be apparent. However, this is not true. Of the five largest pesticide producers, BASF, Bayer, Dow, Monsanto, and Syngenta, three are based within Europe, two of which are in the EU member state of Germany. These corporations have lobbied against the recent modifications to EU pesticide legislation; yet, members of parliament (MEPs) supported the ban on toxic pesticides. This is a clear indication that within the US and Canada there is a possibility for a hazard-based approach to be used. L. Phillips, "MEPs Back Toxic Pesticide Ban Despite Industry Pressure" EU Observer (6 November 2008), online: EUObserver.com <http://euobserver.com/9/27056> (last modified: 6 November 2008); O. Worm & K. Vaupel, The Dirty Portfolios of the Pesticides Industry Product Evaluation & Ranking of Leading Agrochemical Companies – A Report by Greenpeace Germany (Hamburg: Greenpeace, 2008).

⁶²² EU, European Environment Agency, *Children's Health and Environment: A Review of Evidence* (Brussels: European Environment Agency, 2002).

⁶²³ Treaty of Amsterdam, supra note 367 at Art. 152(100(a)).

⁶²⁴ Sweden joined the EU 1995. Strengthened EU Environment Standards, supra note 494.

⁶²⁵ Austria joined the EU 1995.

⁶²⁶ Denmark joined the EU in 1973.

⁶²⁷ The Netherlands was one of the founding members in 1951.

⁶²⁸ Strengthened EU Environment Standards, supra note 494.

The EU pesticide legislation was heavily influenced by these events- the increasing awareness of the importance of addressing environmental health at a supranational level and the pressure by Scandinavian nations to maintain their protective status of the environment - and therefore did not proceed with the same method of assessment as Canada and the United States. Although the EU integrated the four-step risk assessment process into their regulatory policy, they did not rely solely on the risk-based methodology to prevent harm to children. Rather, the EU instituted a "zero-tolerance" approach where the aim of the assessment was to eliminate hazards when possible and mitigate risk when elimination of the hazard was not possible.⁶²⁹ This notion of "zero-tolerance" is borrowed from the Scandinavian environmental framework. The Netherlands, Denmark, and Sweden⁶³⁰ have had a long tradition of environmental advocacy, including a constant objective of a "non-toxic environment". Coinciding with a number of local publications warning of the negative impact pesticide exposure may have, the 1963 publication *Silent Spring⁶³¹* by Rachel Carson caused a number of Scandinavian environmental laws to accomplish this objective.⁶³² These nations have aimed to eliminate unnecessary pesticide use, reduce overall pesticide use by fifty to seventy-five percent, and use less caustic substitutes when available.⁶³³ The Swedish government has gone so far as to entrench this notion of non-toxicity in their *1997 Swedish Environmental Quality Objectives Bill.*⁶³⁴

This description of the history of Scandinavia's environmental policy may not on the surface appear to relate to the EU's efforts to protect children's health from pesticide exposure. This environmental policy, however, is the basis for the EU's recent pesticide policy changes, including the use of the hazard-based approach. The EU could have embraced the North American risk-based approach, but instead the EU has adopted the Scandinavian inspired hazard-based approach whereby the main objective is the elimination of harm, not the mitigation of risk. The influence by the Scandinavian's non-toxic environment policy results in a reduction in overall exposures to children greater than that of the risk-based approach has meant for children's health. It has made a measureable impact in these nations, such as in Sweden, where pesticides are not to be applied near schools, playgrounds, recreational grounds, or hospitals without government authorization.⁶³⁵ Aerial spraying is prohibited in order to reduce the travel of airborne

⁶²⁹ It is worth noting that as the US moved away from a zero-tolerance requirement due to the fact that scientific advancements would eliminate a large number of pesticides, the EU moved towards a zero tolerance approach relying on science to ensure that this can be accomplished.

⁶³⁰ Norway is not a member state of the EU; however that do participate in the European Economic Area (EEA) and the European Free Trade Association (EFTA).

⁶³¹ Silent Spring was published in 1962 within North America. Carson, supra note 18.

 ⁶³² R. E. Löfstedt, "Swedish Chemical Regulation: An Overview and Analysis" (2003) 23 Risk Anal. 411 at 412.
 ⁶³³ *Ibid.*

⁶³⁴ Sweden, *Swedish Environmental Quality Objectives Bill* (1999) 1997/1998:145 Svenska Miljömal.

⁶³⁵ Ibid.

toxins that may be inhaled by children.⁶³⁶ Swedish risk indicators have found that because of these policies, there has been a measureable decrease in health risks, including children's health risks, over the last fifteen years.⁶³⁷

4.3.4.2 Use Of A Three-Tiered Approach

Recent amendments made to the EU legislation⁶³⁸ have indicated that the government intends to use the hazard-based approach, which includes three tiers: (1) hazard elimination (hazard tier), (2) the substitution principle (exposure tier), and (3) risk mitigation (risk tier). The aim is to eliminate the risks from chronic health conditions, particularly cancer, prior to exposure. In order to accomplish this goal, the EU has implemented a principle of caution. This cautionary principle is defined as: "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."⁶³⁹ This is in contrast to the US and Canadian approach that proposes that there is an acceptable level of harm that comes with use of these pesticides, and therefore the aim is to control this risk. While the EU legislative changes are ongoing, their prior pesticide directives indicated that the North American risk-based approach, they were indicative of the caution that would be practiced by means of elimination of harm from the outset.

This section will be divided into three sections which will provide a description of: (1) the three-tiered hazard-based approach, (2) the advantages of using a cautious approach over that of acceptable risk, and (3) how the hazard-based approach rectifies many of the problems discussed in the above risk-based section.

⁶³⁶ *Ibid*.

⁶³⁷ Sweden, Swedish Environmental Objectives Council, *Sweden's Environmental Objectives – for the Sake of Our Children* (Stockholm: Swedish Environmental Objectives Council, 2005) at 28.

⁶³⁸ Com(2006) 388 final, supra note 515.

⁶³⁹ McClenaghan, supra 36 at 160.

⁶⁴⁰ 91/414/EEC, supra note 618; 98/8/EC, supra note 619.

4.3.4.2.1 The Three-Tiers: Hazard, Exposure, And Risk

Prior to the passage of the pesticide package, the EU directives relied on a risk-based approach to control pesticide risk. Recognizing that this procedure of mitigating risk was permitting an undesirable amount of pesticides to enter the environment and that greater attention needed to be given to vulnerable groups, including pregnant women, infants, and children, the EU initiated an overhaul of their pesticide regulatory framework.⁶⁴¹ The government commenced their transition from a risk-based approach to that of a hazard-based approach first with the passage of *Regulation (EC) No 396/2005 of the European Parliament and of the Council on the Maximum Residue Levels of Pesticides on Foods and Feed of Plant and Animal Origin*⁶⁴² [hereinafter *MRL* Regulation] followed by the recent pesticide package which clearly shifts assessment from risk- to hazard-based.

The revision of legislation in the form of the pesticide package was prompted by the 2006 *Thematic Strategy*. The strategy outlined specific objectives: (1) to minimize hazards and risks to health and environment from the use of pesticides, (2) to reduce the levels of harmful active substances including through substitution the most dangerous (including non-chemical) with safer alternatives, and (3) to encourage low-input or pesticide-free crop farming.⁶⁴³ In fulfilling these objectives, the EU Parliament adopted a new pesticide policy framework in January 2009. This new pesticide package includes the adoption of a hazard-based approach over that of a risk-based approach.⁶⁴⁴

These pieces of legislation collectively establish a three-tiered system whereby pesticides are assessed for hazard, exposure, and risk. First and foremost, those substances that are genotoxic, carcinogenic, or toxic to the reproduction system will be eliminated under most circumstances. Similarly, pesticides that are neurotoxic, immunotoxic, or endocrine disrupting will be banned if they pose a significant risk.⁶⁴⁵ These chronic health conditions are known as the "cut-off criteria". Those products which cause these conditions are cut-off from registration, i.e. they will not progress to registration. Products that are not outright eliminated in this first stage are then to be assessed for value.⁶⁴⁶

If a product is not eliminated from the registration process because of the cut-off criteria, then the risk assessment process progresses to the second-tier. During this exposure-based step the substitution principle is applied. Borrowed from Scandinavian countries, this principle maintains that a product should be banned "if a less harmful

⁶⁴¹ COM (2006) 388 final, supra note 515 at 14; COM(2006) 373 final, supra note 615 at 3.

⁶⁴² As a part of this regulation, the EU aimed at limiting children's pesticide exposures via foodstuffs by setting incredibly low standards when faced with scientific uncertainty. E.C., *Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on Maximum Residue Levels of Pesticides in or on Food and Feed of Plant and Animal Origin and Amending Council Directive 91/414/EEC [2005] (EC) No 396/2005, online: E.C. < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:070:0001:0016:en:PDF> (last modified: 23 February 2005). [hereinafter (<i>EC) No 396/2005*].

⁶⁴³ *COM*(2006) 373 final, supra note 615 at 3-4; R. Combes, M. Barratt, & M. Balls, "An Overall Strategy for the Testing of Chemicals for Human Hazard and Risk Assessment under the EU REACH System" (2003) 31 Atla. 7 at 9.

⁶⁴⁴ COM(2006) 373 final, ibid.

⁶⁴⁵ EU Reaches Deal, supra note 369; European Crop Protection Association, Fact Sheet: The Future of European Agriculture (Brussels: ECPA, 2008) (MISC/08/EJ/17647); Com(2006) 388 final, supra note 515.

⁶⁴⁶ Hansen, supra note38 at 273.

pesticide or non-chemical alternative [is] available and able to control pests as effectively".⁶⁴⁷ Though the risk affiliated with a pesticide may be "acceptable", if there is an alternative that offers a "negligible" risk then there is no need for registration of both. If a pesticide product is no more effective in some circumstances than other products already on the market, but is more effective in other circumstances, it is only registered for those specific circumstances.⁶⁴⁸

Those products that are not eliminated because of the cut-off criteria or the substitution principle are then assessed for risk. In this stage the product's dose-response curve is evaluated and the appropriate standards are set. Though this is like that of the US and Canadian risk-based approach, the aim of overall pesticide use reduction influences these decisions in a way that results in lower standards.

While this three-tiered approach is relatively new, the aim of overall reduction and low standards expressed in the 2005 *MRL Regulation* and the 2006 *Thematic Strategy* have already produced positive results in the reduction of childhood pesticide exposure within the EU. Consideration of the review of older pesticides conducted by each agency as part of the pesticide overhaul illustrates this point. The EU de-registered sixty percent of registered substances whereas the US only banned a little over thirty percent.⁶⁴⁹ When reviewing the same products in the EU and North America, there are a number of examples where the EU has banned the product while it has maintained registration status in North America. Amitraz is a substance that has been banned by the EU due to its cancer-causing characteristics while it remains on the market in both Canada and the US for tick and mite control on crops and in household settings (such as on dogs).⁶⁵⁰ Similarly, permethrin has been banned by the EU since 2000,⁶⁵¹ but remains on the market for use on crops, livestock housing, buildings, housing, and, in some circumstances, clothing to combat insects in the US and Canada.⁶⁵² With an estimated two million pounds of this active substance being used in the US, and forty-one percent of this use in residential areas, continued risk to children's health in North America

⁶⁴⁷ H. Nielson, *Danish Pesticide Use Reduction Programme – to Benefit the Environment and the Health* (Copenhagen: Pan-Europe, 2005) at 7.

⁶⁴⁸ This spurs innovation in a way that the risk-based does not, as products have to improve both in capacity and efficacy.

⁶⁴⁹ L. Neumeister, *Pesticide Action Handbook* (Hamburg: Pesticide Action Network, 2003), online: PAN < http://www.pan-germany.org/download/pan_action_handbook.pdf> (date accessed: 14 May 2008).

⁶⁵⁰ California, Environmental Protection Agency, *Amitraz, Risk Characterization Document*, v. 1 (Sacramento: CA EPA, 1995), online: CA EPA http://www.cdpr.ca.gov/docs/risk/rcd/amitraz.pdf> (last modified: 12 December 1995); Canada, Health Canada, *Decision Document: Amitraz* (Ottawa: Health Canada, 1995), online: Health Canada < http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/e95-02/index-eng.php> (last modified: 3 May 1995).

⁶⁵¹ E.C., Directorate General for Agriculture, *Review Report for the Active Substance Permethrin* (Brussels: Directorate General for Agriculture, 2000), online: Europa

<http://ec.europa.eu/food/fs/sfp/ph_ps/pro/eva/existing/list1-23_en.pdf> (last modified: 13 July 2000).

⁶⁵² U.S., Environmental Protection Agency, *Permethrin Facts (Reregistration Eligibility Decision (RED) Fact Sheet* (Washington, D.C.: Environmental Protection Agency, 2006), online: Environmental Protection Agency < http://www.epa.gov/oppsrrd1/REDs/factsheets/permethrin_fs.htm> (last modified: June 2006).

by this endocrine disrupting product is likely.⁶⁵³ In a comparison of forty substances registered in each jurisdiction in no circumstance were either the US or Canadian MRLs lower (stronger) than the EU.⁶⁵⁴

4.3.4.2.2 Use Of Caution

Whereas Canada and the US have determined that exposures shall be regulated in a fashion that provides acceptable risk, the EU has utilized a different standard. Central to the three-tier hazard-based approach is a principle of caution, one that holds that harm shall be prevented rather than controlled. The premise of this concept is that it is prudent to eliminate harm rather than try to control it, particularly due to the number of uncertainties that surround the risk assessment process. Because of this, there are specific chronic health conditions that, no matter how controlled, should not be permitted.

Like the precautionary principle, this cautionary approach aims formulating preventative policy when there is indication of possible harm to environment or human health.⁶⁵⁵ Whereas the precautionary principle has been viewed as highly subjective because it lacks tangible procedures by which it can be implemented, the use of caution in the EU risk assessment process has concrete measures, and in doing so the risk assessor has no more arbitrary capacity than that found in the risk-based approach.

This standard of caution is found throughout the three-tier approach. The elimination of possibly carcinogenic pesticides is an example of caution, where the government has found it is better to prevent exposure to these substances whatsoever - better to be safe than sorry. The use of the substitution principle is an example of caution. The government has found it is better to eliminate the use of the more caustic of products for those less so. Even in the risk-based tier there is caution, where the government has chosen to apply the lowest possible standard when faced with scientific uncertainty.

There are few key elements of this cautious approach which set it apart from the notion of "acceptable risk" embraced by the US and Canada. First, there is a presumption of harm. The pesticide is assumed to be harmful to health and the environment until toxicological tests demonstrate otherwise. Second, there is a prioritization of health over that of market interests, meaning that when faced with scientific uncertainty health takes precedence over concerns of restricting innovation. Third, though science and mathematical adjustments are part of the process, there is a realization that subjectivity is inherent in the process no matter the amendments. Because of this, there is an overlay of caution through procedural differences and reliance on qualitative "weight of evidence" over that of a quantitative risk assessment process.⁶⁵⁶

The first distinction, a presumption of harm, is central in understanding how the hazard-based approach results in different standards and tolerances than the risk-based approach.⁶⁵⁷ From the outset, the risk-based approach indicates

⁶⁵³ *Ibid*.

⁶⁵⁴ *Boyd, supra* note 581 at 17.

⁶⁵⁵ Conko, supra note 507 at 2.

⁶⁵⁶ McClenaghan, supra note 36 at 22.

⁶⁵⁷ *Ibid*.

that toxicological tests will be used to determine what, if any, restrictions need to be placed on the pesticide product. If evidence does not indicate that restrictions are needed, then none are put in place. Action is not taken unless scientific evidence can demonstrate that it is necessary. As discussed earlier, even in circumstances where evidence indicates there is probable harm, this is not sufficient for regulatory action.⁶⁵⁸ The hazard-based approach assumes that the product is harmful, which is a logical conclusion, considering that it is formulated to kill pests. Working backwards, the hazard-based approach relies on science to illustrate that this harm is not detrimental to human health. If it is found not to cause a severe chronic health condition, then it is reviewed for its benefits over other products on the market. If it is more harmful and is no more effective than products already registered, then there is no reason to continue with the registration process. Only if the product does not pose a significant risk to human health and is more effective will it undergo a review to set standards and MRLs.⁶⁵⁹

Another element of this cautious framework is the prioritization of health over industry interests. The directive on MRLs states that "public health should be given priority over the interests of crop protection".⁶⁶⁰ The recently passed regulation states that "the objective of protecting human or animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health or any unacceptable influence on the environment".⁶⁶¹ Building on this, the amendments include a number of requirements which ensure that health have priority. Aerial spraying is banned, thereby decreasing inhalation of pesticides by children residing nearby agricultural areas. Compulsory inspection of pesticide application equipments has been instituted, therefore ensuring the most efficient use of, and least exposure to, the substances.⁶⁶² Priority for registration and use is to be given to the low-risk pesticides, including integrated pest management (IPM), when possible.⁶⁶³

This prioritization of health over industry is in contrast with the US and Canadian legislations which hold that restrictions shall "avoid a significant disruption in domestic production of a safe, economical, and wholesome food supply". Both the PMRA and the EPA have been instructed to consider in prohibiting the registration of a product the "effectiveness of alternative pest control methods, the impact of loss of the pesticide on crops, the impact on the national availability and cost of food".⁶⁶⁴ And though the registration of pesticide products that exceed the *de minimis* standard is to only be done in "exceptional situations", such as instances where banning the product would lead to unusually high shortages of animal feed⁶⁶⁵, the use of the one-in-a-million risk itself indicates that health is

⁶⁵⁸ Benzene, supra note 478.

⁶⁵⁹ Parliament Seals Pesticides, supra note 534.

⁶⁶⁰ (EC) No 396/2005, supra note 642 at recital 5.

⁶⁶¹ Com (2006) 388 final, supra note 515 at 15.

⁶⁶² E.U., European Commission, *EU Policy for a Sustainable Use of Pesticides: The Story Behind the Strategy* (Luxembourg: Office for Official Publications of the European Communities, 2007) at 17.

⁶⁶³ Com (2006) 373 final, supra note 615 at 23.

⁶⁶⁴ Committee on Agriculture, supra note 536 at 42.

⁶⁶⁵ Ibid.

not the number one priority. Rather, as the FIFRA and PCPA state, the objective is a weighing of the risks against the economic and social benefits associated with the product's use.⁶⁶⁶ If health were the priority, then only the consideration of the health risks against that of health benefits, such as dangerous infestations, would be given. The inclusion of economic benefits alongside with the notion of acceptable risk indicates that mitigating the risk so the product can be registered is the objective.

While consideration of the consequences of a pesticide ban on food supply provides some indication of the EU's prioritization of health over market interests, it is more apparent when considering non-agricultural pesticides. The amendments to current EU pesticide policy prohibit use of pesticides where children may play. Included in this list are playgrounds, schools, parks, and sports grounds.⁶⁶⁷ Though this still permits the registration of the product, it places restrictions that will protect health more so than limiting intake through MRLs. By banning the application of pesticides in recreation areas, the EU has aided in achieving the reduction of overall exposure. Whereas the US and Canada have narrowly construed their regulatory powers to that of foodstuffs, the EU has broadened theirs to include exposures via residential settings, clearly indicating that health is the priority.

The most prominent illustration of caution found in the EU risk assessment process is the outright ban of those products that may cause significant harm to health. Taking into account all toxicological and epidemiological tests, the EU utilizes the weight-of-evidence approach to determine whether exposure results in significant harm. Though similar to the approach taken to by the US and Canada when evaluating cancer-causing pesticides, rather than utilize this data to select a model of assessment, the EU interprets this information to determine whether or not caution needs to be taken through the banning of specific substances.⁶⁶⁸ This is a clear differentiation between the two processes. The US and Canada use quantitative risk assessment to ensure that there is a risk of cancer per lifetime that is not exceeded. The EU uses a weight-of-evidence approach to assess the probability of harm, and eliminate it rather than control it.⁶⁶⁹

4.3.4.2.3 How The Hazard-Based Approach Resolves The Difficulties With The Risk-Based Approach In Favour Of Children's Health

In the review of the risk-based approach, issues were highlighted that indicated that the approach was flawed both because of accuracy and use of "acceptable" risk as its founding principle. The EU's adoption of the hazard-based approach remedies many of the problems surrounding these issues. Although the EU utilizes the same four-step risk assessment process, including the animal and epidemiological studies, the procedural differences and use of caution have resolved many of the problems discussed earlier.

One of the problems with the risk-based approach is that it relies on science and mathematical models to estimate harm and set standards which result in "acceptable" risk. Earlier discussion on animal bioassays and epidemiological studies indicated that this presumption that the process was fact-based and therefore accurate is highly flawed, in part

⁶⁶⁶ *Ibid.* at 37.

⁶⁶⁷ *EU Policy, supra* note 665 at 17.

⁶⁶⁸ *McClenaghan, supra* note 36 at 162.

⁶⁶⁹ Ibid.

due to the quality of the studies themselves. While these same tests are used for the EU's risk assessment, the difference in interpretation results in more protective standards for children's health.

There are a few reasons why the EU's standards are stronger (lower) than the US's and Canada's though the basis of these tolerances are the same toxicological tests. First, the EU approaches the analysis with the assumption that harm is present unless the toxicological data indicates otherwise. This is opposite of the risk-based approach which assumes innocence unless evidence demonstrates harm. Because of this, the EU will more likely eliminate or restrict substances that would not be restricted under the US or Canadian assessment. Second, the EU relies on toxicological tests to trigger the first or second tier of elimination or substitution. Though accuracy of the tests aids in this process, what mistakes are present in the research are less likely to result in harm to children's health. The tests will be used to determine if the product shall be banned – a threshold that does not rely on precise data because the point is not controlling the risk. If anything, these errors will result in undue restrictions on substances because of the presumption of harm.

What is interesting is that though the EU's sole priority is controlling risk, they have mandated a greater number of toxicological studies be submitted with the application than that of the US and Canada.⁶⁷⁰ By requiring more toxicological tests, the EU risk assessor has a better grasp of the impact the substance may make on children's health. It is also to the benefit of the applicant as it may mitigate the presumption of harm, whereas providing greater data in the risk-based approach would do the opposite as the presumption of innocence must be proven wrong before standards are set. Motivation for this requirement is more than merely a better understanding of the product on health. By having greater data on residential non-agricultural pesticides, something the US and Canada do not often subscribe to, the EU can better regulate non-residue pesticides. This enables the government to work towards the reduction of reliance on pesticides for a sustainable future.

One of the problems with use of the risk-based approach to control risk is that in order to do so it must have accurate and complete data, this includes data on children's exposure rates, dietary intake, and pesticide use. This information is greatly lacking in the US and Canadian risk assessment process, particularly in Canada where the government relies on borrowed data from the US. This is troublesome since this information is essential in setting tolerance levels which control risk. Although the EU has established a procedure where they err on the side of caution, resulting in better outcomes for child health, they have also taken it upon themselves to have a better understanding of all exposures necessary for an accurate aggregate exposure calculation. Utilizing a consumption data model Pesticide RIsk Assessment Model (PRIMO), data from fourteen members, forty-one diet sets for different subpopulations, and short- and long-term data, the EU is able to provide a more current estimate of food consumption

⁶⁷⁰ Toxicology studies required for submission are outlined in Annex II of Directive 91/414/EEC. For acute and short-term effects, data on absorption, distribution, excretion, and metabolism in at least one species (usually a rat) is required. Genotoxicity tests are required to provide early identification of substances that may affect cell growth, including carcinogens. In vitro studies for genetic mutation, including gene mutation tests are required. Long-term toxicity tests must be conducted on all active substances using rats as test species. Oral toxicity and carcinogenicity studies of two-year periods are mandated. Reproductive toxicity, multi-generational studies, and neurotoxicity tests are required for all active substances. Other long-term tests that may be compulsory include absorption, distribution, metabolism, and immunotoxicological potential. However, it is a case-by-case determination as to whether these toxicology tests need be submitted.

than that of the models based on the USDA survey of 1998.⁶⁷¹ As a part of the recently passed pesticide package, data on pesticide use and sales will be gathered. A separate regulation on pesticide statistics requires member states to collect information on the quantities of product sold both by distribution chains and directly to professional users, such as farmers.⁶⁷² This data will be standardized and used to compute trends in risks associated with pesticide exposure at a community level.⁶⁷³ The use of PRIMO and pesticide statistics will provide the EU with a better understanding of a child's daily exposure rates than that of the US, and more specifically Canada, where data either has not been updated or gathered.

While this data will assist in estimating more accurately the aggregate exposure a child experiences, the hazard-based approach has mechanisms in place that aid in remedying the problems of inaccuracies that are not remedied by this data. Unlike the risk-based approach, if data is lacking or uncertain, then the assumption is that the pesticide causes harm. Rather than relying on an additional safety factor of ten, the government has utilized a number of procedures when there is uncertainty as to harm. If there is indication that it does not pass the cut-off criteria, then it will be banned. If there are products already on the market that are known to be safer it will be prohibited as well. If the product passes the first two stages of the assessment, however, then the aim will be the lowest standard possibly achievable.

When faced with scientific uncertainty pertaining to childhood exposure to food residues, the EU has utilized a lowest limit of analytical determination (LOD). The LOD is a default tolerance level of 0.01 milligram per kilogram of food that results in a lower threshold than use of the safety factor will in most circumstances.⁶⁷⁴ The LOD is in essence a zero-tolerance level for pesticide residue on food products.⁶⁷⁵ This is a clear difference between that of the North American approach that relies on a mathematical formula to reduce risk in situations where there is harm no matter the exposure rate or where harm is unknown. Furthermore, because application of the safety factor is

⁶⁷¹ One of the largest obstacles the EU faces in setting tolerance levels is that of assimilating a relatively accurate dietary assessment tool. The member states have utilized a variety of individual and population based methods. Individual-based, which is preferable, provides an estimate of what specific age groups consume on a daily basis. The German government has specifically reviewed children's food intake as part of the Health Interview and Examination Survey for Children and Adolescents (KiGGS). A study of 2, 400 individuals between the age of six and seventeen were interviewed directly on food consumption. Parents were interviewed for information on ages too young to respond. Similarly, in the Netherlands, individual data is available on food consumption for children age one and upwards. Population-based methods draw on food production, imports, and exports to assimilate a predicted intake. H. Reich, *EFSA's Role in the Risk Assessment of Pesticide Residues Regulation 396/2005* (Brussels: European Food Safety Authority Pesticide Risk Assessment Peer Review), online: EFSA

<http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/sh_presentation_reich_7thmeet_en,0.pdf?ssbinary=true> (date accessed: 14 October 2009).

⁶⁷² EU Policy for a Sustainable Use, supra note 665 at 18.

⁶⁷³ *Ibid.* at 19.

⁶⁷⁴ E.C., Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions A Thematic Strategy on the Sustainable Use of Pesticides [2006] COM (2006) 372 final, online: E.C. < http://ec.europa.eu/environment/ppps/pdf/com_2006_0372.pdf> (last modified: 12 July 2000). [hereinafter COM (2006) 372].

⁶⁷⁵ Historically applied by the EU for baby foods, studies indicate EU organic agriculture and forty to sixty percent of conventional agriculture already adheres to these limits. *Position Paper on MRL Harmonisation*, (Hamburg: Pesticides Action Network Europe, 2004).

optional, the benefits for children's health that may have come from this change have been greatly minimized.⁶⁷⁶ Consistent use of the LOD may result in lower than necessary MRLs, but because of the uncertainty the EU has determined that a cautious approach to protect children's health is more beneficial than the possible risks.

In a similar vein, the government has put in place a procedure to address scientific uncertainty surrounding cumulative exposure known as ALARA, or "as low as reasonably achievable". ALARA is not a standard, but is "a practice that has as its objective the attainment of dose levels as far below applicable limits as possible."⁶⁷⁷ This standard aims at the reduction of unnecessary pesticides, such as over-application in agricultural settings or use in residential settings. Although the effects of individual pesticides may be known, there is little conclusive data as to the cumulative effects of exposure to doses of multiple substances over the course of a lifetime. As mentioned earlier, the US EPA has only identified four categories⁶⁷⁸ of pesticides with similar mechanisms of toxicity, not because there are only four but because of the limited knowledge and considerable time required for these reviews. However, even less is understood about what impact multiple exposures to substances at repeated *low* doses may have on children's health.⁶⁷⁹ As traditional risk assessment tends to focus on cancer-causing endpoints it may be that endocrine disruption and neurodevelopmental effects from low dose early childhood exposure that occur later in life are unrecognized. It is for this reason that the EU has instituted this notion of reduced overall pesticide use as a cautionary measure.

One of the ways which the US and Canada attempted to remedy their scientific uncertainty was through the use of an additional safety factor. As discussed earlier, this factor may not offer any additional benefit if the data used to compute the original standard was greatly inaccurate. In addition, both governments have been hesitant to use the factor, therefore making it ineffective. Rather than relying on this factor to protect neonatal and prenatal children when faced with scientific uncertainty, the EU has relied on the three-tiered process to eliminate the unknown harm.⁶⁸⁰ By requiring a greater number of tests from the outset, the EU has a better understanding of the impact exposure may make on an infant, and is able to eliminate it through the cut-off criteria or the substitution principle. This will, in turn, reduce exposure to a pesticide more so than use of an additional mathematical adjustment known as a safety factor.

This overlay of a three-tier approach in the risk assessment process not only addresses some of the issues pertaining to safety factors and aggregate data, but eliminates the problematic aim of controlling the risks associated with cancer-causing pesticides, as is the norm in the risk-based approach. Rather than finding a one-in-a-million risk of cancer "acceptable", the EU legislation states that "no harmful effect on human or animal health" shall occur due to

⁶⁷⁶ Watnick, supra note 584.

⁶⁷⁷ As Low As Reasonably Achievable (ALARA), online: Argonne National Laboratory < http://web.ead.anl.gov/uranium/glossacro/dsp_wordpopup.cfm?word_id=183> (date accessed: 9 June 2009).

⁶⁷⁸ The four categories of pesticides found to have common mechanism of toxicity are: Organophosphates, N-methyl Carbamates, Triazines, and Chloroacetanilides. *Common Mechanism Groups, supra* note 573.

⁶⁷⁹ McClenaghan, supra note 36 at 144.

⁶⁸⁰ The EU has only relied on an additional factor in cases of biocidal products that are associated with severe toxicological properties, such as toxicity to reproduction. *98/8/EC, supra* note 619.

pesticide exposure. ⁶⁸¹ In fulfilling this provision, the EU has determined that it will ban substances that are the most caustic.

This approach taken by the EU indicates that rather than adopt the notion that risk is unavoidable, they have instituted a process whereby pesticide risk is removed from children's daily life. As already discussed, the use of the riskbased approach assumes that cancer from exposure is inevitable, and that the government's role is to control the probability of harm from that specific substance. The *de minimis* standard of one-in-one million chance of cancer has been selected as a reasonable level of harm. Yet, when permitting ten substances to have tolerance levels that result in this *de minimis* standard, the result is a risk of ten in a million.⁶⁸² "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."⁶⁸³ It is the recognition of the impact these numbers have on the overall health of the population, and specifically vulnerable subpopulations, which has motivated the ongoing shift towards a hazard-based approach by the EU. In practice, use of the cut-off criteria of toxic substances is estimated to immediately eliminate nearly five percent of active substances currently on the market.⁶⁸⁴ In addition, twenty-two identified substances have already been prohibited for registration renewal.⁶⁸⁵

4.3.5 Case Study: Pesticide Residues In Food Products – An Example Of The Failures Of The Risk-Based Approach

This section provides insight as to how the two methodologies used by each of the jurisdictions results in different standards for food pesticide residues. Each jurisdiction is responsible for regulating the amount of pesticide residue⁶⁸⁶ that remains on produce and foodstuffs, known as maximum residue limits MRLs. The government agencies calculate the MRLs per food, fruit, vegetable, juice, and water using estimated daily intake of specific food groups by children, assessment of pesticide application according to good agricultural practice (GAP), determination of residue chemistry studies, calculation of pesticide accumulation in processed foods, and ingestion of pesticides via water and livestock products.⁶⁸⁷ In addition, the governments take into consideration aggregate and cumulative exposures to multiple pesticides to ensure that daily tolerance levels of a pesticide are not exceeded through ingestion of residue.

⁶⁸¹ 91/414/EEC, supra note 618 at Art.1(b)(iv).

⁶⁸² McClenaghan, supra note 36 at 151.

⁶⁸³ Ibid.

⁶⁸⁴ "EU Moves to Ban More Pesticides" *Pan North America* (26 June 2008), online: Pan North America < http://www.panna.org/resources/panups/panup_20080626> (last modified: 26 June 2008).

⁶⁸⁵ "EU Parliament Pushes for Ban on Toxic Chemicals" *France 24 International News* (13 January 2009), online: France 24 < http://www.france24.com/en/20090113-eu-parliament-supports-ban-dangerous-pesticides-chemicals> (last modified: 13 January 2009).

⁶⁸⁶ MRLs are the concentration of pesticide residue expressed as milligrams of residue per kilogram of food. U.K., Pesticide Residues Committee, *Maximum Residue Levels* (London: Pesticide Residues Committee, 2009), online: PRC < http://www.pesticides.gov.uk/prc.asp?id=956> (date accessed: 15 November 2009).

⁶⁸⁷ P. Chan, "Pesticide Residues in Food Canada's Regulatory Framework" (Regional Symposium on Regulation of Pesticide Residues in Food, Hong Kong, 27-28 March 2009).

Although the section of food-ingestion of pesticide residues offers a useful comparative case study it is also one of the few examples available. Food legislation is one of the only areas where the US and Canada have legislated standards, whereas the EU has broadened their authority to include the prohibition and restrictions of pesticide use in specified residential and agricultural areas. Furthermore, the examination of pesticides in food products is a suitable comparison because there is a great deal of consistency in childhood exposure via food in all three jurisdictions. Pesticide ingestion is the primary source of childhood exposure, as was highlighted in the pivotal NAS report.⁶⁸⁸ Many of the produce and juices consumed by children in the EU area also consumed by children residing in the US and Canada since children tend to have a more produce-based diet than adults, consuming a greater volume for their body weight of apples, bananas, pears, peaches, grapes, oranges, green beans, peas, potatoes, and tomatoes.⁶⁸⁹

4.3.5.1 Food Residue Standards In Canada And The United States: Weaker Than That Of The EU

In a comparison of tolerances set by the EU, Codex⁶⁹⁰, and the US, it was found that the US tolerance levels were the highest (least protective), followed by the Codex, and then the EU.⁶⁹¹ Similarly, a study conducted by the David Suzuki Foundation discovered that both Canada and the United States had the same or weaker MRLs than the EU in all cases. In a comparison of forty MRLs set by Codex, the EU, Australia, the US, and Canada, Canada had the weakest overall, whereas the EU had the strictest in twenty-nine instances.⁶⁹² When comparing the EU, the US and Canadian tolerances for pesticides, the US and Canada were weaker in all but two instances, at which point they were the same.⁶⁹³

These differences clearly indicate that children residing in both Canada and the US are consuming greater amounts of the same pesticides than those living in the EU. To understand what these different MRLs mean to children's health, one can look at a few specific examples of substances linked to childhood illnesses that are permitted on foodstuffs at high rates in Canada and the United States. For instance, the MRLs set for carbaryl for Canada is ten parts per million (ppm) and in the United States ranges from five to twelve ppm depending on the produce. Meanwhile, this endocrine disrupting⁶⁹⁴ insecticide used on fruit crops such as apples and peaches has a MRL ranging between one and three ppm in the EU.⁶⁹⁵ While dietary differences between the regions may account for some of the disparity, it is highly unlikely that the discrepancy is explained merely due to children in Europe consuming less of these crops.

Another example of these divergent MRLs is the standards set by each jurisdiction for the pesticide permethrin, which is often used on leaf lettuce and spinach. In the US and Canada, the MRL is set at 20 parts per million (ppm);

⁶⁸⁸ National Research Council, supra note 99.

⁶⁸⁹ Cooper, supra note 5 at 306.

⁶⁹⁰ See chapter 3 for further discussion on FAO/WHO Codex.

⁶⁹¹ P. Thorbek & K. Hyder, "Relationship Between Physicochemical Properties and Maximum Residue Levels and Tolerances of Crop-Protection Products for Crops set by the USA, European Union and Codex" (2006) 23:8 Food Addit. Contam. 764.

⁶⁹² *Ibid.* at 771.

⁶⁹³ *Boyd, supra* note 581 at 17.

⁶⁹⁴ J.A. Thomas, "Introductory Remarks: The Testes" (1981) 38 Environ. Health Perspect. 3 at 3.

⁶⁹⁵ *Boyd, supra* note 581 at 27.

however in the EU it is set at 0.05 ppm.⁶⁹⁶ Classified by the US EPA as a possible human carcinogen, the risk-based approach taken by Canada and the US has permitted a greater tolerance level of this toxin. As pregnant women are told to increase consumption of spinach because of the health benefits its folic acid offers, these extremely differing MRLs indicate that prenatal children in North America are being exposed to greatly different levels of this substance. Even accounting for dietary differences, these differing MRLs are not defensible, as over 35,000 acres of spinach are grown annually in the US alone⁶⁹⁷.

In one study conducted on US fruit, it was found that children are consuming up to thirty-seven different pesticide residues in apples alone, twenty in peaches, pears, and spinach, and ten in broccoli.⁶⁹⁸ In a 2008 study over fifty pesticide compounds were found on peaches.⁶⁹⁹ Many of these pesticide substances, including carbaryl and permethrin, have already been banned by the EU.⁷⁰⁰ Others, such as the carcinogenic fungicide iprodione, will be banned under the new EU legislation.⁷⁰¹

These are just a few examples of how the risk-based approach results in a higher level of "acceptable" risk. There are a number of reasons, as already discussed, for the weaker standards found in Canada and the US. Both the US and Canada utilize outdated data from the USDA survey regarding childhood daily food intake. The information on non-food exposure rates is greatly lacking. The result may be that the government agencies underestimate other exposures, therefore permitting greater tolerances on food products. These uncertainties in exposure and consumption often have not been remedied by application of a safety factor. Having been used only thirty-eight percent of the time (ranging from the value of two to ten) between the periods of 1996 through 2001⁷⁰² it is safe to assume that this "uncertainty" does not apply to the use of outdated dietary consumption surveys, or in the case of Canada, to lack of reliable data on the usage of pesticides in agriculture. Even in the review of organophosphate pesticides, a class of very toxic insecticides, the safety factor was used only in twenty-six of the forty-nine reviews.⁷⁰³

⁶⁹⁹ M. Eng, "Pesticides in Your Peaches: Tribune and USDA Studies Find Pesticides, Some in Excess of EPA Rules, in the Fragrant Fruit" *Chicago Tribune* (12 August 2009), online: Chicago Tribune < http://www.chicagotribune.com/health/chi-0812-peaches-pesticides_mainaug12,0,2494206.story> (last modified: 12 August 2009).

⁷⁰¹ S.E. Kegley et al., *Iprodione: PAN Pesticide Database*, (San Francisco: Pesticide Action Network, 2009), online: Pesticide Action Network < http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC33033#Toxicity> (date accessed: 14 November 2009); "EU Agrees to Ban 22 Dangerous Substances from Pesticides" *Mother Nature Network*, online: MNN <http://www.mnn.com/food/farms-gardens/stories/eu-agrees-to-ban-22-dangerous-substances-from-pesticides> (date accessed: 23 November 2009).

⁷⁰² P. J. Landrigan, "Children's Health and the Environment: Public Health Issues and Challenges for Risk Assessment" (2004) 112:2 Environ. Health Perspect. 257 at 259.

⁶⁹⁶ *Ibid*. at 15.

⁶⁹⁷ M. LeStrange et al., *Spinach Production in California* (Oakland: University of California), online: University of California http://ucanr.org/freepubs/docs/7212.pdf> (date accessed: 13 October 2009).

⁶⁹⁸ Groth, supra note 199 at 5.

⁷⁰⁰ "EWG Report" *Dr Green* (21 October 2003), online: Dr Green <<u>http://www.drgreene.com/21_1934.html</u>> (last modified: 21 October 2003); *Boyd, supra* note 581 at 16.

Originally developed for chemical warfare⁷⁰⁴, the neurodevelopmental and carcinogenic impact that organophosphates have on foetuses, infants, and children who are exposed over a long term to a low dose is still unknown, yet pregnant women and children are exposed to these toxins through a number of produce sources.⁷⁰⁵

4.3.5.2 Food Residue Standards In The European Union: Greater Protection For Children's Health

Although the transition from a risk-based to a hazard-based risk assessment approach is ongoing, the EU's prior cautionary approach provided greater protection from food ingestion of pesticides by children than the North American approach. The reason for this difference is that the use of the LOD and the presumption of harm led to a system where standards in the EU were more restrictive than those set in Canada and the US. Comparative studies have found that the EU has lower MRLs (more protective) than North America in all cases except for in a limited number where the standards were the same.⁷⁰⁶ For instance, the pesticide propiconazole, used on apricots, peaches, and plums, has a MRL ranging between 0.05 to 0.2 ppm depending on the crop⁷⁰⁷, but this reproductive toxic substance has a MRL in Canada and the US of 1 ppm.⁷⁰⁸ While these differences may seem minute, the impact they may have on a twenty-kilogram child is drastic. A child of that size who consumes a one hundred gram peach would take in five to twenty micrograms (mcg) of propiconazole in the EU or one hundred mcg in the US and Canada, resulting in a difference of eighty mcg or more, just from one peach.

One of the most basic procedural differences in the food standard-setting policy between the EU and North America is the LOD. Prior to the banning⁷⁰⁹ of lindane the EU applied the LOD to the substance's use on pineapples resulting in a MRL below that of the US's of 1ppm formulated using a safety factor of three.⁷¹⁰ Even when the LOD has not

⁷⁰⁷ *Ibid.* at 16.

⁷⁰⁸ *Ibid*.

⁷⁰⁴ A Child-Safe U.S. Chemicals Policy, supra note 101

⁷⁰⁵ Not only is it difficult to assume that these weaker standards are controlling risk due to the fact that their calculations are based on flawed data, but also because of the recent efforts on behalf of Canada and the US to harmonize their MRLs. This standardization of tolerances is an effort to aid in trade under NAFTA. The problem is not that they are attempting to rectify differences between the two nations, but that Canada is willing to adopt the standards set by the US. If the risk-based approach is scientific in nature, and removed from policy, it is contradictory for the PMRA to lower their standards in those areas where they are currently higher. If the objective is to control risk, then this adaption in the name of trade would be irrational. B. Eskenazi et al., "Organophosphate Pesticide Exposure and Neurodevelopment in Young Mexican-American Children" (2007) 115:5 Environ. Health Perspect. 792, online: EHP <htps://www.ncbi.nlm.nih.gov/pmc/articles/PMC1867968/> (last modified: May 2007); *Boyd, supra* note 581 at 30.

⁷⁰⁶ *Ibid.* at 17.

⁷⁰⁹ Lindane was banned in EU in 2000 and withdrawn voluntarily in the US and Canada in 2006; "Lindane Ban Across European Union" *Pesticide News* (September 2000) at 6, online: PAN http://www.panuk.org/pestnews/Issue/pn49/pn49p6.htm> (last modified: September 2000); "Ban Lindane Now!" *PAN North America*, online: PAN http://www.panuk.org/pestnews/Issue/pn49/pn49p6.htm> (last modified: September 2000); "Ban Lindane Now!" *PAN North America*, online: PAN http://www.panuk.org/pestnews/Issue/pn49/pn49p6.htm> (last modified: September 2000); "Ban Lindane Now!" *PAN North America*, online: PAN http://www.panna.org/lindane> (date accessed: 10 November 2009).

⁷¹⁰ Canada's standard is 3ppm and the board has found that the use of additional uncertainty factors unfounded. Canada, Health Canada, *Report of the Lindane Board of Review* (Ottawa: Health Canada, 2005), online: Health Canada < http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_corp-plan/report-lindane-rapport/index-eng.php> (last modified: 18 August 2005); *Boyd, supra* note 581 at 16; "EPA Restricts Use of Lindane" *Beyond Pesticides* (2 August 2002), online: Beyond Pesticides < http://www.beyondpesticides.org/news/daily_news_archive/2002/08_02_02.htm> (last modified: 2 August 2002).

been directly applied, the EU has utilized a more cautious estimate of exposures and risks that resulted in the lower standards, like that of the reproductive toxic and possibly carcinogenic captan.⁷¹¹ This pesticide used on a number of fruit crops has a MRL of two to three ppm in the EU and twenty-five to fifty ppm in the US.⁷¹²

However effective the prior use of LOD and application of conservative estimates might have been in protecting children's health, the recent adoption of the hazard-based approach in pesticide policy will result in even greater reduction of exposure. The cut-off criteria alone will eliminate exposure to some of the most caustic pesticides – pesticides that remain on the market in both the US and Canada. For instance, the pesticide pendimethalin used primarily on corn, potato, and rice crops, has been selected to be banned due to its endocrine disrupting and cancer-causing characteristics, yet remains on the market in both Canada and the United States.⁷¹³ By banning this substance, along with the others, the EU has necessarily provided for a reduced overall pesticide exposure rate for children. Similarly, use of the substitution rule provides for a reduction in exposure to the most caustic of pesticides by children. This method of prohibiting "the use of certain active substances that are intrinsically more hazardous than alternatives"⁷¹⁴ has been successful in reducing pesticide exposure in Scandinavian countries who have aimed at eliminating toxins that have "unacceptable characteristics" such as "persistence, volatility, high acute toxicity, endocrine disruption, neurotoxicity, and carcinogenicity."⁷¹⁵ Application of this principle resulted in the elimination of 2; 4-D, atrazine, and lindane long before other jurisdictions banned or limited use of these pesticides.

4.3.6 Conclusion

The purpose of this section is to provide a clear indication as to how the scientific uncertainty that is prevalent and unavoidable in the risk assessment procedure is not adequately accounted for in a risk-based approach in a way that provides for the protection of children's health. Although the US and Canada have recognized that past risk assessment processes failed to account for children's unique physiological and behavioural differences, the modifications made to the pesticide registration procedure are lacking in any real impact. Examples throughout this section indicate that the use of the new provisions, that of aggregate/cumulative exposures and the application of an additional safety factor, have not been nearly as beneficial in reducing exposure rates as that of the EU hazard-based

⁷¹¹ "Captan", online: EXTONET < http://pmep.cce.cornell.edu/profiles/extoxnet/24d-captan/captan-ext.html> (date accessed: 7 July 2009).

⁷¹² Canada's standard for Lindane is 5ppm; *Boyd, supra* note 581 at 16.

⁷¹³ U.S., Environmental Protection Agency, *Pendimethalin* (Washington, D.C.: Environmental Protection Agency) (CAS No.: 40487-42-1), online: Environmental Protection Agency

<http://www.epa.gov/waste/hazard/wastemin/minimize/factshts/pendmeth.pdf> (date accessed: 14 August 2009); M. Abram, "Pesticides Ban: How it Will Affect your Crops" *Farmers Weekly Interactive* (29 January 2009), online: Farmers Weekly Interactive <http://www.fwi.co.uk/Articles/2009/01/29/114014/pesticides-ban-how-it-will-affect-your-crops.html> (last modified: 29 January 2009).

 ⁷¹⁴ D. Coggon, "Perspective Possible Regulatory Approaches to Comparative Risk Assessment for Pesticides" (2006)
 62 Pest. Manag. Sci. 790 at 790.

⁷¹⁵ D. Boyd, *Unnatural Law – Rethinking Canadian Environmental Law and Policy* (Vancouver: UBC Press, 2003) at 127.

⁷¹⁶ *Ibid.*; U.S., Environmental Protection Agency, *Lindane Voluntary Cancellation and RED Addendum Fact Sheet* (Washington, D.C.: Environmental Protection Agency, 2006), online: Environmental Protection Agency http://www.epa.gov/oppsrd1/REDs/factsheets/lindane_fs_addendum.htm> (last modified: July 2006).

approach. Children in these two jurisdictions continue to be exposed to more types of pesticides at higher quantities. Their intake of pesticides via food sources is greater than that of the EU, even when comparing the same pesticide per jurisdiction.

The recent adoption of the hazard-based approach by the EU eliminates the most harmful substances from the outset, replaces those that are inherently toxic with those that are less so but as efficient, and aims more than mere mitigation of risk. This process by which pesticides, developed with the sole purpose of being toxic, are presumed harmful until proven otherwise reduces the exposure rates of children. The idea behind this approach is not that the amount of specific pesticide exposure to children should be controlled, but rather that the overall aim should be that of a non-toxic environment. This ideal is practical because of the implementation of cut-off criteria, the substitution principle, the ALARA, and the LOD.

Pesticides offer an opportunity for government to regulate and restrict substances prior to sale and use, however, the point to take away from this section is that the risk-based approach does not aim at any more than mitigating the risks, whereas the hazard-based approach intends to eliminate unnecessary harm. For children, this difference can make a noticeable impact on health outcomes, by reducing quality of life from something like asthma or resulting in cancer at an early age. The following section on chemicals provides further insight into the inadequacies associated with the traditional risk-based approach and how children are the unfortunate victims of these policy decisions.

4.4 Chemicals

4.4.1 Introduction

The pesticide review provided an example of how differing approaches to the risk assessment process can result in measureable dissimilarities in substance intake by children, and, therefore result in discrepancies of health outcomes per jurisdiction. Unfortunately, the negative effects of environmental policy on children's health are not isolated to pesticide legislation. In fact, the pesticide framework has been one of the more progressive areas of North American policy in terms of restricting childhood exposure rates. This is because there is a legislative mandate to consider children's vulnerabilities. To understand how prevalent childhood toxic exposures are, this portion of the thesis will provide a review of chemical policy in Canada, the US, and the EU. This section will demonstrate how the risk-based approach has provided insufficient protection for children's health, whereas the hazard-based approach aims at eliminating the most toxic substances and reducing overall use of chemicals.

Often the mention of chemicals and childhood exposure brings forth thoughts affiliated with consumer product safety, specifically that of toys. Recent headlines on the safety of chemicals in baby bottles and in plastic infant toys⁷¹⁷ indicate that childhood exposure to chemicals is a daily occurrence. While these issues are important for the governments to address when legislating on product safety, it neglects a large number of daily exposures to industrial, occupational, and residential chemicals. It is this area of chemical legislation, substances used in daily household goods and used in mass quantities in commercial settings, which will be the center of discussion in this section. That is not to say that consumer product safety is not an area of concern for children's health outcomes, but

⁷¹⁷ W. Chan, *Every Parent's Guide to Safer Toys and a Healthier Home* (Sacramento), online: W. Chan CA State Assembly < http://www.sixwise.com/pdf/ChildrensToysBI.pdf> (date accessed: 14 July 2009).

rather that the topic of general chemical usage has often been overlooked though the over 85,000 substances currently on the market make in tremendous impact on children's health.⁷¹⁸

There are a number of ways in which children come in contact with chemicals on a daily basis. Found in toys, furniture, carpet, electronic equipment, building materials, playground equipment, clothing, and foodstuffs, chemicals surround the general population in Canada, the US, and the EU. Children ingest, inhale, and absorb these chemicals through contact via food, play, dust, air, and water.

To provide some context as to how prevalent this exposure intake to chemicals is, one need only look to recent blood tests conducted in each jurisdiction. An EU survey, which tested fourteen European Union Ministers of Parliament from thirteen different member states, found fifty-five different chemicals, of the one hundred and three tested for, present in blood and urine samples. The median number of chemicals found was thirty-seven, with one minister having up to forty-three different chemicals in his blood at the time.⁷¹⁹ Similarly, in a Canadian family survey forty-six of sixty-eight chemicals tested were detected. Test subjects ranged in age from ten to sixty-six years.⁷²⁰ Twenty-three different types of chemicals were detected in the children volunteers.⁷²¹ Results from US studies also indicate that chemicals are detected in children. In a study of Oregonians, each person tested had anywhere between nine and sixteen of the twenty-nine toxic chemicals for which they were tested.⁷²² In 2004, the first family to undergo body burden testing in the US found that their eighteen-month-old and five-year-old had chemical "exposure levels up to seven times those of their parents".⁷²³

This awareness of the impact chemical exposure has on human health is not new. Persistent organic pollutants were targeted for elimination by a number of nations during the 1970s and at an international level under the 2004 Stockholm Convention⁷²⁴. These chemicals, including PCBs, furons, and dioxins, were used as coolants, plastics, flame retardants, lubricating oils, sealants, adhesives, and water-proofing agents or were by-products of industrial productivity such as iron and steel manufacturing.⁷²⁵ Upon recognition of the negative harm these products had on environment, wildlife, and human health due to their capacity to bioaccumulate, their long half life (persistent), and their ability travel up the food-chain, use was greatly restricted or banned. Although eliminated from use, forty years later these chemicals are still present in measureable levels in both the general population and the environment, clearly indicating the lasting harm that toxins can have to health.

⁷²⁴ Stockholm Convention on Persistent Organic Pollutants, supra note 211.

⁷¹⁸ C.A. Mello-da-Silva, supra note 465.

⁷¹⁹ Bad Blood? A Survey of Chemicals in the Blood of European Ministers (Brussels: World Wildlife Foundation, 2003) at 8.

⁷²⁰ *Toxic Nation, supra* note 614.

⁷²¹ *Ibid*.

⁷²² Oregonians Test Positive for Toxic Chemicals (Portland: EarthShare Oregon), online: EarthShare Oregon http://www.earthshare-oregon.org/our-groups/profiles/oec/pollutioninpeople (date accessed: 14 July 2009).

⁷²³ J. Miller, "Tests Reveal High Chemical Levels in Kids' Bodies" *CNN* (22 October 2007), online: CNN <<u>http://www.cnn.com/2007/TECH/science/10/22/body.burden/index.html</u>> (last modified: 22 October 2007).

⁷²⁵ Canada, Health Canada, *Dioxins and Furans It's Your Health* (Ottawa: Health Canada, 2005), online: HealthCanada http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/environ/dioxin-eng.php (last modified: September 2005).

The negative effects children face due to chemical exposures are not, however, limited to that of the POPs. Recent introduction of PBDEs, used as flame retardants on computers, in televisions, and in furniture, have been linked to endocrine disruption and delayed neurodevelopment.⁷²⁶ Though children are more than likely ingesting and inhaling these chemicals through daily contact of these household items, the chemical has also been used in infant mattresses, cribs, and clothing where young children are inevitably going to have close contact with these toxins.⁷²⁷ Other chemicals of concern are phthalates, which are used in a number of consumer plastics, as well as airborne volatile organic compounds (VOCs) and PAHs which are by-products of industry or ingredients in paints, cleaning supplies, glues, building materials, and furnishings.⁷²⁸ These toxins have been linked to childhood endocrine disruption, cancer, developmental delay, as well as a number of chronic health conditions associated with the liver, kidney, and the central nervous system.⁷²⁹

As was the case with pesticides, current advances in science indicate that governments and scientists have little understanding of the actual impact new chemicals make on health. For instance, the recent debate over whether or not per-flu octanoic acid (PFOA), used in non-stick cookware and all-weather clothing⁷³⁰, causes cancer or disrupts the endocrine system indicates that often development of these substances comes long before the impact they may have is discovered. Originally developed in 1938, it was not until the last decade that independent epidemiological research made a causational link between exposures to this chemical, commonly known as Teflon, and cancer.⁷³¹ Because of this scientific uncertainty, governments aim to provide a risk assessment process before market entry to ensure safety standards are met.

As this section will discuss, the methods by which each jurisdiction provides this chemical assessment differ drastically. Both the US and Canada have relied on a risk-based approach whereby the aim is mitigating the risk. Even more so than in the pesticide framework, the onus is on the government to demonstrate that unacceptable harm occurs due to exposure. Meanwhile, the EU has adopted a hazard-based approach by analyzing all chemicals for

⁷²⁹ *Ibid*.

⁷²⁶ *Chemical Encyclopaedia Polybrominated Diphenyl Ethers (PBDEs)*, (Los Angeles: Healthy Child Healthy World), online: Healthy Child Healthy World http://healthychild.org/issues/chemical-pop/polybrominated_diphenyl_ethers/ (date accessed: 12 July 2009).

⁷²⁷ *PBDE's & Your Children* (Organic Baby Wearhouse), online: Organic Baby Wearhouse http://www.organicbabywearhouse.com/pbdes-and-your-children.html (date accessed: 15 August 2009).

⁷²⁸ U.S., Environmental Protection Agency, *An Introduction to Indoor Air Quality* (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency http://www.epa.gov/iaq/voc.html (last modified: 27 October 2009).

⁷³⁰ *About PFOA*, online: DuPont < http://www2.dupont.com/PFOA/en_US/about_pfoa/> (date accessed: 13 May 2009).

⁷³¹ "It turns out that DuPont [the company who manufactures PFOA] knew of health risks associated with PFOA as far back as 1961, when company researchers discovered that rat livers were enlarged when exposed to very low doses of PFOA. An internal DuPont memo on PFOA and related chemicals advised that 'all of these materials...be handled with extreme care. Contact with the skin should be strictly avoided.'" R. Smith & B. Lourie, *Slow Death By Rubber Duck How the Toxic Chemistry of Everyday Life Affects Our Health* (Toronto: Alfred A. Knopf Canada, 2009) at 79; B. Gavigan, *U.S. Women at Greater Risk from Teflon Chemical*, (Los Angeles: Healthy Child Healthy World, 2009), online: Healthy Child Healthy World <

http://healthychild.org/blog/comments/ucla_study_us_women_at_greater_risk_from_teflon_chemical/> (last modified: 7 February 2009).

toxicity to childhood development with the assumption that the chemical is harmful until the applicant proves otherwise. The following subsections will review the chemical registration process in Canada and the US in contrast with the current policy in the EU.

4.4.2 General Overview Of The Risk Assessment Process

Like the pesticide risk assessment process, the registration process of chemicals includes use of the four-step process. Toxicological data submitted as part of the applicant dossier is analyzed for hazard identification, dose-response assessment, exposure assessment, and risk characterization. Animal bioassays and epidemiological studies are the basis of the process by which the NOAEL and LOAEL are established. Unlike the pesticide registration process, however, standards are not set as to daily exposure rates via food products. Rather, the objective of the process is to establish whether or not the chemicals pose unacceptable threats to the environment and health of the population, and then to set acceptable tolerable daily intake (TDI) per chemical, as will be discussed in further detail in the following subsections.

4.4.3 Risk Analysis Under Canada's And The United States' Chemical Policies

4.4.3.1 Overview Of Legislation

Although Canada and the United States utilize a risk-based approach for assessing the harms affiliated with chemical exposure, the legislation of each country differs slightly in the method by which the analysis of chemicals is triggered. Because of this, a brief overview of the policies will be provided. What is imperative to highlight is though the Canadian legislation has recently been amended and it utilizes different terminology for deciphering what chemicals are permissible for market entry, the outcomes between the two jurisdiction's policies are virtually the same. The reason for this is that the risk assessment is conducted utilizing a risk-based approach; an approach with the objective of acceptable risk.

Before reviewing the chemical regulatory processes set in place by Canada and the US, it is important to emphasize that neither government has the authority to mandate registration of a chemical prior to market entry. This is not only a major difference between chemical and pesticide legislation, but also between the Canadian and US approaches and the EU legislative scheme. The policies put in place by Canada and the US provides the agencies the authority to restrict or prohibit use in specific circumstances, but is not a requirement for a thorough risk assessment for registration prior to sale. Health Canada, Environment Canada, and the US EPA have the ability to put in place pollution prevention plans, but not to restrict the use of the product completely.⁷³²

Within Canada, chemicals are regulated under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). This legislation outlines the assessment of both new and old chemicals to take place before they are listed on the Domestic Substances List (DSL), an inventory of substances that are permitted to be sold in Canada. The assessment process is

 ⁷³² Canadian Environmental Protection Act, 1999 R.S. C. 1999 c.33, online: Department of Justice
 http://laws.justice.gc.ca/en/C-15.31/FullText.html (date accessed: 4 November 2009). [hereinafter CEPA]; Toxic Substances Control Act, 15 U.S.C. § 53 (1976), online: Cornell University Law School

<http://www4.law.cornell.edu/uscode/15/ch53.html> (date accessed: 4 November 2009). [hereinafter TSCA].

conducted by both Environment Canada and Health Canada. Specific data⁷³³ is required to be submitted by the producer or importer of the chemical prior to market entry for each agency's review. This data is used to assess the chemical's toxicity and determine what, if any, restrictions shall be placed on the product prior to listing it on the DSL. Another way by which new products may enter the Canadian market is by being listed on the non-Domestic Substances List (nDSL). This inventory is of substances that have been approved for use by the EPA and on the market in the US for five or more years and therefore are acceptable for use in Canada.⁷³⁴

Since this process of evaluation only applies to new chemicals, the legislation includes an assessment of substances that were already on the market at the time that the first CEPA was passed in 1988. Existing chemicals are defined as those substances that were sold for commercial use in Canada between January 1, 1984 and December 31, 1986. Totalling 23,000 chemicals, these substances had not undergone any risk assessment prior to market entry. With the passage of CEPA 1988, and continued on in the amendments of CEPA 1999, these chemicals have been placed on the DSL for further review.

Chemicals on the DSL are assessed for their ability to: (1) accumulate in living human or non-human tissue, (2) persist in human or non-human organisms or in the environment, and (3) pose great potential for human exposure.⁷³⁵ If a substance meets any of these requirements, further evaluation takes place and one of three outcomes will occur: (1) it is identified as CEPA-toxic, is placed on the List of Toxic Substances⁷³⁶, and use will be restricted, (2) it is placed on the Priority Substances List (PSL) and further evaluation is needed, or (3) it is found not to be inherently toxic and remains on the DSL.⁷³⁷

In the US, chemicals are regulated under the *Toxic Substances Control Act* (TSCA). Like the Canadian legislation, this act differentiates in the assessment process of new and existing chemicals before they are to be placed on the EPA's Chemical Substance Inventory [hereinafter *TSCA Inventory*]. This is a list of substances that may be sold within the US. New chemical applicants are to submit data in their possession for review.⁷³⁸ Substances will either be placed immediately on the TSCA Inventory or be flagged for further evaluation due to: (1) insufficient information to assess health and environmental effects, (2) the substance may appear to pose an unreasonable risk of injury to health or environment, or (3) is thought to be used on substantial quantities and therefore result in

⁷³⁷ Assessing and Managing, supra note 735.

⁷³⁸ Information should be included as part of their premanufacture notice (PMN). U.S., Government Accountability Office, *Chemical Regulation Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals* (Washington, D.C.: GAO, 2007) at 11.

⁷³³ A. Wordsworth, *Within REACH: An Agenda for Improving the Canadian Environmental Protection Act, 1999* (Toronto: C.E.L.A., 2004) at 19.

⁷³⁴ Canada, Environment Canada, *New Substances Program Operational Policies Manual* (Ottawa: Government of Canada, 2009), online: Environment Canada http://www.ec.gc.ca/substances/nsb/eng/c2_e.shtml (last modified: 26 September 2009).

⁷³⁵ Canada, Health Canada, Assessing and Managing the Health Risks of Existing Substances under the Renewed Canadian Environmental Protection Act, 1999 (Ottawa: Health Canada).

⁷³⁶ Canada, Environment Canada, *CEPA Environmental Registry*, *Substances Lists* (Ottawa: Environment Canada, 2008), online: Environment Canada < http://www.ec.gc.ca/CEPARegistry/subs_list/> (last modified: 30 October 2008).

significant or substantial human exposure.⁷³⁹ Upon further review, restrictions on use may be placed on the product before it is listed on the TSCA Inventory.

Passed in 1976, the TSCA was heralded as a progressive piece of policy which provided greater protection for both environment and human health.⁷⁴⁰ However, when drafted, chemicals already on the market were "grandfathered" in, therefore requiring no immediate assessment of their hazards.⁷⁴¹ An estimated 60,000 substances on the market prior to 1976 were placed on the TSCA Inventory.

The EPA has the authority to review chemicals on the TSCA Inventory when there is indication that they pose an "unreasonable risk of injury to human health or the environment or is or will be produced in substantial quantities".⁷⁴² In order to request further information for additional screening, the EPA must be able to demonstrate that: (1) "there is or may be significant or substantial human exposure to the chemical" or (2) "the chemical enters the environment in substantial quantities".⁷⁴³ If these requirements are met, then additional toxicological tests may be required in order to determine if exposure results in "unreasonable risk of injury to health or environment". If this is found, then restrictions may be placed on the substance's use.

4.4.3.2 The Standard Of Safety: Unreasonable And Unacceptable Risk

In the pesticide section, the point was made that the risk-based approach embraces the concept that risk is unavoidable and therefore the aim is to manage it. In both the FQPA and PCPA, the governments have established that this management is to be based on what was deemed as an "acceptable" or a "safe" level of risk. This notion of safe is the determination with "reasonable certainty that no harm will result".⁷⁴⁴ In application, this chance of risk has been a quantification of chronic health conditions, such as a one-in-a-million risk of cancer.

The TSCA applies a standard of "unreasonable risk" as a threshold for chemical regulation, though this is not defined in the act.⁷⁴⁵ Judicial decisions, such as the *Benzene* case, indicate that this standard is the consideration of benefits

http://www.epa.gov/oppt/newchems/index.htm> (last modified: 17 November 2009).

⁷⁴² U.S., Environmental Protection Agency, *Testimony Before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, House of Representatives Chemical Regulation Options for Enhancing the Effectiveness of the Toxic Substances Control Act* (Washington, D.C.: GAO, 26 February 2009) at 6. [hereinafter *Chemical Regulation Options*].

⁷⁴³*Ibid*.

⁷⁴⁴ Committee on Commerce, supra note 536 at 5.

⁷³⁹ U.S., Environmental Protection Agency, *Possible Outcomes of a PMN Review* (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency
http://www.epa.gov/opptintr/newchems/pubs/possible.htm> (last modified: 1 May 2009).

⁷⁴⁰ U.S., Environmental Protection Agency, *New Chemicals Program Policies* (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency <

⁷⁴¹ D. Wallinga, *Chemistry and Better Public Health* (Minneapolis, Minnesota: Institute for Agriculture and Trade Policy, 2008) at 2.

⁷⁴⁵ While chemical risk assessment once again relies on this quantification of risk, the threshold by which this probability of risk is measured is much more lenient. Within the US, the TSCA has reduced the standard of "safe" from that of "reasonable certainty" to that of "an unreasonable risk of injury to health or the environment". This standard of "unreasonable risk" indicates that the quantification of risk involves more than adjusting the exposure rates so that they result in a probability of a chronic health condition.

against that of the risks.⁷⁴⁶ In that case, the EPA's reduction of the benzene standard was found inappropriate considering the lack of substantial evidence that the reduction was necessary. In addition, the court found that the reduced standard would require expenditures that were disproportionate to the health and safety benefits.⁷⁴⁷ The court held that "...the benzene standard is an expensive way of providing some additional protection for a relatively small number of employees."⁷⁴⁸

The CEPA applies a standard of "adverse effects" by which risks are assessed for restrictions or regulation. The act holds that the agencies are charged with assessing whether or not the substance is "toxic" and therefore poses an "unacceptable risk".⁷⁴⁹ Parliament has stated that Ministers are required to determine what level of risk is "unacceptable".⁷⁵⁰

Both the CEPA and TSCA outline specific requirements that must be met before a chemical's risk is considered "unreasonable" or "unacceptable". The CEPA states that a product poses "unacceptable" risk if it is toxic. Substances are toxic if they: (1) present the greatest potential for human exposure, (2) are inherently toxic to humans or to non-human organisms and accumulate in living tissue, or (3) are inherently toxic to humans or to non-human organisms and take a long time to break down in the environment.⁷⁵¹ The TSCA holds that a chemical's risk may be found to be unreasonable if they: (1) there is or may be significant or substantial human exposure to the chemical or (2) it enters or may reasonably be anticipated to enter the environment in substantial quantities.⁷⁵²

The requirement put in place by both the CEPA and TSCA that the chemical's exposure is in substantial quantities weakens the ability to protect health. In practice, this means that the risk assessment process is more than an evaluation of harm at specific doses of exposure. It is also a calculation of the likelihood that many people will be exposed, and the consideration of what economic burdens would be associated with reduction in use of the chemical. For these reasons, this standard of "unreasonable risk" results in a larger exposure rate of chemicals to the general public, including children. In fact, because of these additional caveats, which are not in place in the pesticide quantification of risk, children are more likely to be exposed to greater quantities of toxic chemicals than pesticides assessed under the risk-based approach.

⁷⁵⁰ *Ibid*.

⁷⁴⁶ Applegate, supra note 480 at 268-269.; Benzene, supra note 478.

⁷⁴⁷ Benzene, ibid. at 628.

⁷⁴⁸ Benzene, ibid.

⁷⁴⁹ Canada, House of Commons, "The Canadian Environmental Protection Act, 1999 – Five-Year Review: Closing the Gaps" by B. Mills in *Standing Committee on Environment and Sustainable Development* (2007) at 21. [hereinafter *Five-Year Review*].

⁷⁵¹ Assessing and Managing, supra note 744 at 2.

⁷⁵² U.S., Environmental Protection Agency, *Chemical Regulation Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program* (Washington, D.C.: GAO, 2005) at 8.

4.4.3.3 Burden Of Proof And The Test Rule

The risk assessment process put in place by the CEPA and the TSCA offers little real opportunity for the accurate control of risk, particularly that which is associated with older chemicals. The reason is that the legislation provides a very complex and burdensome route by which the EPA, Health Canada, or Environment Canada can gain the information necessary to assess the risk. And as it has been explained, without the data the risk-based approach becomes inoperable as its accuracy hinges on calculating exposure and hazards.

Over 60,000 substances have been deemed as "existing chemicals" under the TSCA, and 23,000 substances are categorized as such under the CEPA. Many of these substances were developed during or right after WWII, when the government oversight of chemicals that exists did not require a thorough investigation of their health impact.⁷⁵³ Similar to pesticides, with the development of scientific capacity, there was a recognition that little was understood about the risks associated with these substances. Unlike the governments' efforts to rectify this problem with the re-evaluation of older pesticides, however, chemicals that were already on the market at the time of CEPA 1988 and the TSCA have not been re-assessed for risk.

Both pieces of legislation offer an opportunity for the re-evaluation of these substances. What is problematic, however, is that the CEPA and TSCA have an elaborate process by which the government bears the burden of proving harm before further toxicological tests can be required. It is important to emphasize how the risk-based approach is a quantification of harm. Yet, the current chemical review system is one where the risk is not able to be assessed until harm has already occurred. Without evidence of harm from these already used substances, there remains little evidence that indicates further assessment should be conducted. It is a catch twenty-two – the government must have evidence of harm before information can be requested for the risk assessment process. Evidence of harm, however, must come from the quantification of risk. This system undermines the already weak risk-based approach, hindering its ability to control the exposures in order to mitigate the risk.

In order to reassess a chemical under the TSCA, the EPA must demonstrate that the substance poses an unreasonable risk or will be produced in large quantities that may harm humans or the environment. In addition, the government must show that they lack the data to assess the impact of the chemical on health or the environment.⁷⁵⁴ Only when these two requirements are met may the EPA issue a "test rule" which mandates the chemical producer to submit specific toxicological tests. Similarly, the CEPA has established a system whereby producers of older chemicals are required to submit additional information once the Ministries of Health and the Environment have shown that the toxin may be persistent or bioaccumulate and inherently toxic to humans or non-human organisms or pose a great potential for human exposure.⁷⁵⁵ Only when these requirements have been met, may the ministries request more information for a full risk assessment.

⁷⁵³ *Wallinga, supra* note 750 at 2.

⁷⁵⁴ Chemical Regulation Comparison, supra note 738 at 13.

⁷⁵⁵ Only those chemicals that have been flagged as a concern by Environment Canada for bioaccumulation and persistence will be analyzed by Health Canada for inherent toxicity to humans, which may very well prevent the identification of substances that cause cancer or disrupt endocrine function. *Wordsworth, supra* note 742 at 30.

Because of these procedural hurdles, the US and Canadian screening process has been ineffective in preventing further childhood exposure to existing chemicals that are harmful. In both instances, the government must prove that there is likelihood of harm due to exposure, but must prove so without any real toxicological data. By instituting a risk-based approach, both Canada and the United States have indicated that science is the basis for standards and regulations. By placing the onus on the government to generate data through test rules, they have rendered the risk-based approach ineffective. The premise of this procedure is that through scientific evaluation of necessary data, the agencies can predict and therefore restrict unnecessary harm to children. Nonetheless, if the government agencies lack any toxicological information, harm must occur to signal regulatory action is needed. This is an unfortunate aspect of the risk-based approach. The result is reliance on an approach that is supposed to provide "safe" levels of exposure with no real data on risk or harm.

Only two-hundred of the existing chemicals have been reviewed under the TSCA. Similarly, under CEPA only sixty-nine substances have been listed on the Priority Substances Lists, therefore requiring additional toxicological data to be submitted.⁷⁵⁶ Since it is estimated that nearly ninety-two percent of industrial chemicals produced in the US today, in quantities over one million pounds per year, were "grandfathered" in by the TSCA, the impact this lack of real risk assessment makes on children's health cannot be underestimated.⁷⁵⁷

4.4.3.4 Criticism Of The Risk-Based Approach To Protect Children's Health

The risk-based approach is based on the presumption that the government can utilize data on exposure and hazard and compute a standard that will control the amount of risk that results from exposures. In order to do so successfully, a complete data set on harm associated with exposure and the likelihood of exposure must be present. In the pesticide policy, the governments have attempted to remedy some of these scientific uncertainties with the recent amendments. Even with these changes in the risk assessment procedure, children are still exposed to a number of pesticides that cause irreversible harm.

However inadequate the pesticide framework is in providing for the protection of children's health, the chemical policy in both Canada and the US is even more so. As this section will highlight, the lessons learned about the effect pesticide review can have on children's health were not transferred to the study of chemicals. Scientific uncertainty has not been mitigated by safety factors or aggregate exposure. In fact, the uncertainty is even greater in the chemical risk assessment process because little toxicological information is required in the submission process. Even more alarming is that no real risk assessment process has ever been conducted on existing chemicals, which are used in large quantities per day in each nation.

⁷⁵⁶ When the initial review of all older chemicals was completed, a total of 4,300 of the 23,000 chemicals were identified for further review. The government aims at completing the assessment of these 4,300 substances by 2020. Canada, Environment Canada, "Priority Substances List" (Ottawa: Environment Canada, 2005), online: Environment Canada < http://www.ec.gc.ca/ceparegistry/subs_list/Priority.cfm> (last modified: 19 September 2005).

⁷⁵⁷ Wallinga, supra note 750 at 2.

4.4.3.4.1 Failure To Learn Lessons From Pesticide Policies

The 1993 publication by the NAS, *Pesticides in the Diets of Infants and Children*⁷⁵⁸, indicated that the pesticide risk assessment process did not provide adequate protection for children's health. In the report, the NAS warned that children were being exposed to levels of toxicity greater than that of the average healthy male when taking into consideration weight, physical development, and behavioural differences.⁷⁵⁹ These findings provided the impetus for pesticide amendments and policy change in the US, Canada, and the EU.

Unfortunately, the lessons learned by the US and Canada from this research were narrowly applied to pesticide tolerances on food products and nothing more. The vulnerabilities of pregnant women, infants, and children have not been integrated into chemical legislation. There is no requirement that they be considered as they are not mentioned in the legislation. Though pregnant women, infants, and children have been incorporated into the risk assessment process via guidelines, it is only when information is available. This means that the additional safety factor which is present in the pesticide assessment process is not applied in chemical assessment. Therefore, when faced with scientific uncertainty as to the impact the chemical exposure has on the prenatal and neonatal, there is no recommendation that a mathematical adjustment be made to the tolerable daily intake.⁷⁶⁰ Though both governments consider cumulative exposures to chemicals, neither the TSCA and the CEPA has provided that aggregate exposure rates shall be considered in the risk assessment process.

The point to be made here extends beyond the failures to implement an additional safety factor or use of aggregate data in the chemical risk assessment process. The US government commissioned research on the impact pesticide exposure has on children's health, but did not extend this requirement to protect children's health into other areas of environmental pollution. Rather than recognize that there is little understanding on children's health in general, the US Congress focused their attention on pesticides because of specific instances which scared the general public.⁷⁶¹ Because of this narrow focus, it is difficult to interpret respective the legislature's motivation for the pesticide amendments made by the US, and later Canada, as protective of children's health overall.

⁷⁵⁸ National Research Council, supra note 99 at 7.

⁷⁵⁹ Ibid.

⁷⁶⁰ "A Child-Safe U.S. Chemicals Policy" *Children's Environmental Health Network* (March 2005), online: CEHN < http://www.cehn.org/cehn/chemicals%20&%20Vccep/child%20safe%20chemicals%20backgrounder.htm> (last modified: March 2005).

⁷⁶¹ *Supra* note 524.

It has already been established that for the risk-based approach to control the risk associated with exposures, the information in the calculation of the standard must be complete and accurate. One of the problems discussed in the pesticide section was that this data is often lacking due to the use of animal and epidemiological studies and the use of partial data on aggregate and cumulative exposures. These problems have not been rectified in the chemical section. In fact, these weaknesses in the calculation of standards have been magnified in the chemical risk assessment process.

Neither the US nor Canadian agencies direct specific animal bioassay or epidemiological studies be submitted. The only mandatory information is that which is "relevant to identifying hazards to human health and the environment and that is in the person's *possession* [emphasis added]".⁷⁶² As few chemical companies voluntarily conduct toxicological tests, most applicants provide limited information.⁷⁶³ It is estimated that only about fifteen percent of new chemical applications in the US include test data on health and safety.⁷⁶⁴ The remaining eight-five percent without any real toxicological data makes a substantial impact on children's health. It is estimated that the US EPA reviewed over twenty-four thousand new chemical applications between the 1979 and 1994, which would indicate over twenty thousand chemicals were on the market without any real risk assessment.

The data which is submitted, including information on molecular breakdown of the substance, is used to assess the risk. Models are used to screen the chemicals for potential unreasonable risks.⁷⁶⁵ While these models may be useful in detecting possible harm, they "do not always accurately determine the chemicals' properties and the full extent of their adverse effects, especially with regard to their general health effects".⁷⁶⁶

The EPA has advocated that these models are sufficient for the protection of health, including that of children, because they err on the side of caution.⁷⁶⁷ However, in a comparison of EPA findings against that of the EU's based on test data, the EPA's findings varied. "For example, the study concluded that EPA methods are likely to identify those substances that are not readily biodegradable."⁷⁶⁸ Yet, the study found that the EPA's methods "do not appear to work as well in identifying chemicals that readily degrade as determined by the EU's 'ready biodegration' base set test."⁷⁶⁹ In a similar study, it was found that the EPA's models erred in twenty-five percent of the cases compared against actual test data on aquatic toxicity predictions for polymers.⁷⁷⁰

⁷⁶² Wordsworth, supra note 742 at 19.

⁷⁶³ Chemical Regulation Options Exist, supra note 752 at 8.

⁷⁶⁴ Chemical Regulation Comparison, supra note 738 at 12.

⁷⁶⁵ Chemical Regulation Options Exist, supra note 752 at 14.

⁷⁶⁶ *Ibid*.

⁷⁶⁷ Ibid.

⁷⁶⁸ Ibid.

⁷⁶⁹ *Ibid*. at 15.

⁷⁷⁰ *Ibid.*; J. Chun, V. Nabholz, & M. Wilson, "Comparison of Measured Aquatic Toxicity Data with EPA, OPPT SAR Predictions" (Society of Toxicology, San Francisco, March 2001).

By failing to require tests on endocrine disruption carcinogenicity, neurotoxicity, or harm to the reproductive system, it is highly likely that the models used are unsuccessfully in detecting the full impact these chemicals have on these physical systems. This is particularly true with children considering the unknowns pertaining to the vulnerabilities they face as they develop. Evidence indicates that this failure to gather accurate data necessarily impacts the risk assessment process in a way that harms children's health. A recent study by the American Red Cross found 287 industrial chemicals in the cord blood of newborns.⁷⁷¹ Two hundred and seventeen of these chemicals have been identified as animal or human neuro-toxicants.⁷⁷²

While both the US and Canada have attempted to account for childhood developmental stages by using models to estimate the intake of substances from air, water, foods, soil, and consumer products⁷⁷³, the drawback is that these models need only be used when data permits, which is seldom considering no national database or survey on exposure rates per age group exists. The US EPA states that applications may still be submitted if the exposure assessment is of poor quality, for example if there is insufficient information available on exposure, health effects, and interactions of chemical product ingredients.⁷⁷⁴ In such cases, the applicant may provide a qualitative assessment of the chemical compound during which potential for harm and exposure are estimated.⁷⁷⁵ This qualitative assessment is an estimate of potential exposure and the assumed harm. In circumstances where qualitative assessments are submitted, the tolerable daily intakes of chemicals are set on approximations in the adult community and therefore are not necessarily protective of children, or their developmental lifestages.

4.4.3.4.3 The Control Of Risk, Not The Elimination

The chemical risk assessment process provides an exemplary example of how the underlying purpose of the riskbased approach is to control risk, not eliminate it. When faced with an inherently toxic chemical, neither the US nor Canada have legislation in place that provides for the outright ban of use or sale of the substance. Instead, regulatory measures are to be put in place to restrict where and how often the substance may be used, pollution prevention plans may be implemented, or guidelines for use written – all for the adult community.⁷⁷⁶

The Canadian legislation provides that once a full risk assessment has been conducted and the substance is identified as CEPA-toxic, then the substance may be placed on the list of toxic substances, known as the Toxic Substances List

⁷⁷¹ Wallinga, supra note 750 at 3.

⁷⁷² *Ibid*.

⁷⁷³ U.S., Environmental Protection Agency, *A Framework for Assessing Health Risks of Environmental Exposures to Children* (Washington, D.C.: Environmental Protection Agency, 2006) (EPA/600/R-05/093F) at 3-6; Canada, Health Canada, *Children and the Health Risk Assessment of Existing Substances under the Canadian Environmental Protection Act, 1999* (Ottawa: Health Canada, 2008), online: Health Canada < http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/child-enfant-eng.php> (last modified: 22 January 2008).

⁷⁷⁴ U.S., Environmental Protection Agency, *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (Washington, D.C.: Environmental Protection Agency, 2000) (EPA/630/R-00/002) at xi.

⁷⁷⁵ Qualitative assessment "generally occurs in cases where data quality is poor, there are inadequate quantitative data available, data on a similar mixture cannot be classified as 'sufficiently similar' to the mixture of concern, exposures cannot be characterized with confidence, or method-specific assumptions about the toxicological action of the mixture or of its components cannot be met." *Ibid.* at 11.

⁷⁷⁶ Wordsworth, supra note 742 at 36.

(TSL).⁷⁷⁷ As of 2006, eight-five substances have been inventoried on the TSL. However, only two of these substances have been selected for virtual elimination.⁷⁷⁸ Rather, regulatory restrictions have been placed on the remaining substances.

Even in those two instances where virtual elimination has been deemed the appropriate management tool, the result is not the same as actual elimination. "Virtual elimination" is defined as "the ultimate reduction of the quantity or concentration of the substance in the release below the level of quantification specified by the Ministers".⁷⁷⁹ This is not a ban on the substance, but the permitted use of the substance at the "lowest concentration that can be accurately measured using sensitive but routine sampling and analytical methods".⁷⁸⁰ This standard allows the continued use of the substance – a substance that has been identified as inherently toxic because it is persistent and bioaccumulative.⁷⁸¹

The US legislation provides the EPA authority to restrict the use or prohibit the production of a chemical. However, the application of this authority has been greatly limited due to the requirements of substantial evidence prior to regulation. If the EPA can demonstrate that a new chemical will present an unreasonable risk then action can be taken.⁷⁸² The threshold for this "will present", yet, is must more difficult to meet than that of "may present".⁷⁸³ Generally, new chemicals which have been flagged have withdrawn their application, particularly in circumstances where the application is for a new use of an older chemical.⁷⁸⁴

This narrow authority which has been granted to the EPA under the TSCA has been greatly restrained by judicial findings, particularly in the review of existing chemicals. In the 1991 case, *Corrosion Proof Fittings v. EPA*⁷⁸⁵, the US Court of Appeals for the Fifth Circuit found that the EPA "had failed to muster substantial evidence to justify its asbestos ban".⁷⁸⁶ In stating this, the court ensured that the finding of unreasonable risk would not lead to a ban if it was not the "least burdensome" regulation.⁷⁸⁷ This calculation of "least burdensome" is to include a cost-benefit analysis, which provided no additional weight to the cost of life which would result from any exposure to the substance.⁷⁸⁸ The failure to be able to ban asbestos use though the EPA had studied the negative health effects for

⁷⁷⁷ Priority Substances List, supra note 756.

⁷⁷⁸ Canada, Environment Canada, *Virtual Elimination List – Updated as of February 4, 2009* (Ottawa: Environment Canada, 2009), online: Environment Canada http://www.ec.gc.ca/CEPARegistry/subs_list/VEList.cfm (last modified: 4 February 2009).

⁷⁷⁹ *CEPA*, *supra* note 732 at s.65.

⁷⁸⁰ *Ibid.* at s.65.1.

⁷⁸¹ *Ibid.* at 65.4.

⁷⁸² Chemical Regulation Comparison, supra note 738 at 25; TSCA, supra note 732 at s.6.

⁷⁸³ Chemical Regulation Comparison, ibid.

⁷⁸⁴ *Ibid. at 36.*

⁷⁸⁵ Corrosion Proof Fittings v. EPA 947 F.ed 1201 (5th Cir. 1991).

⁷⁸⁶ *Ibid.; Chemical Regulation Comparison, supra* note 738 at 24.

⁷⁸⁷ *CEPA*, *supra* note 738.

⁷⁸⁸ Chemical Regulation Comparison, supra note 738.

ten years and spent over ten million dollars doing so, demonstrates the impossibility to eliminate exposure under the TSCA.⁷⁸⁹ This decision has confirmed that the EPA may only regulate use and control risks, not eliminate hazard.

4.4.4 Risk Analysis By The European Union: A Shift Towards A Hazard-Based Approach

4.4.4.1 Overview Of Legislation

Until recently, the EU's legislative framework on chemicals was very similar to that of the policy in place in the US and Canada. The chemical framework⁷⁹⁰ separated older and new chemicals. The 100,106 existing chemicals, defined as those on the market as of September 1981, were grandfathered in with no thorough risk assessment process.⁷⁹¹ New chemicals, made after that date, had minimal testing requirements.⁷⁹²

In 1998, the EU Council of Environment Ministers initiated a review of chemical policy because of the lack of real data on the impact that these substances had on the environment and health.⁷⁹³ The evaluation led to the recognition that there was no real information on nearly ninety-nine percent of the substances on the market at the time.⁷⁹⁴ Furthermore, the report found that chemical exposure had been linked to reproductive and developmental defects and endocrine disturbances. Although this research was not conclusive, the fact that this cause-effect relationship was a potential problem warrants caution.⁷⁹⁵

In response to these findings, the EU revised their chemical policy. *Regulation (EC) No 1907/2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*⁷⁹⁶[hereinafter REACH] replaced existing regulations. Under REACH all new and existing chemicals will undergo a thorough risk assessment process and will be required to be registered prior to use. This will eliminate differentiation between existing and new chemicals since past regulation grandfathered in older substances.⁷⁹⁷

⁷⁸⁹ "Asbestos Litigation Reform" Reconsidered (Washington, D.C.: Environmental Working Group) at section 5, online: EWG < http://reports.ewg.org/reports/asbestos/facts/fact5.php> (date accessed: 14 October 2009).

 ⁷⁹⁰ E.C., Council Directive 67/548/EEC of 27 June 1967 on the Approximation of Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labelling of Dangerous Substances [1967]
 O.J. 196, online: EurLex < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31967L0548:EN:NOT> (last modified: 27 June 1967). [hereinafter 67/548/EEC]; E.C., Council Directive of 7 June 1988 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Classification, Packaging and Labelling of Dangerous Preparations [1988] 99/379/EEC, online: Europa < http://www.dehp-facts.com/upload/documents/webpage/document32.pdf> (last modified: 7 June 1988). [hereinafter 88/397/EEC].

⁷⁹¹ E.C., *White Paper Strategy for a Future Chemicals Policy* (Brussels: Commission of the European Communities, 2001) at 6. [hereinafter *White Paper*].

⁷⁹² *Ibid*.

⁷⁹³ *Ibid.* at 5.

⁷⁹⁴ *Ibid*.

⁷⁹⁵ *Ibid*. at 4.

⁷⁹⁶ 88/397/EEC, supra note 790.

⁷⁹⁷ Wordsworth, supra note 742 at 35.

All chemical producers, importers, distributors, and users are required to submit data on the hazards, risks, and exposure scenarios of the chemical use as part of their application package.⁷⁹⁸ This data is reviewed for specific properties, including carcinogenicity, mutagenicity, toxicity to reproduction, persistence, bioaccumulation, endocrine disruption, and other serious and irreversible effects on human health.⁷⁹⁹ Substances that indicate that they posses one or more of these properties are identified as "substances of very high concern". These chemicals are placed on the candidate list and need further evaluation and authorization prior to any use. Exemptions from this authorization mandate may be granted by the European Commission if they find other legislative controls are already in place.⁸⁰⁰ The use of these substances may be greatly restricted or banned if found to be risky. Similarly, if a safer and as efficient alternative is found, authorization may not be granted.⁸⁰¹ REACH also provides that restrictions may include outright bans.⁸⁰²

A timeline has been established by which chemicals on the market prior to REACH must meet the submission requirements. The risk evaluation process began in 2008 and will end in 2018. Deadlines have been set based on yearly production, with those with the least production having the earliest deadlines.⁸⁰³

In assessing the risks of all chemicals, the EU has adopted a hazard-based approach. The risk assessment process utilizes a four-step procedure, with an underlying goal of developing a hazard-free environment.⁸⁰⁴ This method of analysis helps in achieving the objectives set forth in the legislation, including the aim "to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances."⁸⁰⁵

⁸⁰⁴ Combes, supra note 643 at 9.

⁷⁹⁸ Note registration need only apply if substance produced in volumes exceeding 1 tonne.

⁷⁹⁹ Wordsworth, supra note 742; E.C., Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation(EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] O.J.L. 396, online: EurLex < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1907:EN:NOT> (last modified: 30 December 2006). [hereinafter REACH].

⁸⁰⁰ Chemical Regulation Comparison of U.S., supra note 378 at 27.

⁸⁰¹ E.C., Environment Directorate General, *Reach in Brief* (Brussels: European Commission, 2007), online: Europa < http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf> (last modified: October 2007) at 13.

⁸⁰² *Ibid*.

⁸⁰³ E.C., Department for Environment, Food, and Rural Affairs, *REACH Implementation Timeline* (April 2008).

⁸⁰⁵ E.C., Environment, *REACH* (Brussels: Europa), online: Europa

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm> (date accessed: 14 November 2009).

4.4.4.2 Standard Of Safety: A High Level Of Human Health Protection

In addition to aiding trade harmonization, one of the motivations for the recent EU chemical policy overhaul has been that of the protection of health. Because research indicated that economic and social costs of chemical related chronic health conditions were substantial, the EU insisted that health protection be enshrined in the new legislation.⁸⁰⁶ Within the opening lines of the regulation, it is stated that the policy shall "ensure a high level of protection of human health".

This "high level of protection" standard is ensured in the legislation with the requirement that all chemicals undergo a registration process and those substances labelled as "very high concern" are restricted or banned.⁸⁰⁷ There are two central differences between the EU standard of safety and that of the US and Canada's "unreasonable risk". The basis of the decision is made on hazard rather than risk.⁸⁰⁸ Consideration is given to the potential to do harm rather than the probability that harm will actually occur given the circumstances of use.⁸⁰⁹ A second difference is that REACH requires that unless evidence proves otherwise, it is prudent to err on the side of caution and assume harm. When faced with scientific uncertainty pertaining to the "magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment."⁸¹⁰

The REACH legislation requires that no chemical be authorized for use if it causes an "unacceptable risk to human health".⁸¹¹ Though this language is very similar to that used in Canadian and American chemical policy, the context by which it is interpreted results in drastically different standards that reduce chemical exposure for children. In using the hazard-based approach, the EU has defined specific hazards which will not be tolerated. If the risk assessment indicates that irreversible chronic health conditions such as cancer are associated with the substance, they will not be used without specific authorization. Chemicals that are persistent and bioaccumulative will also not be used without definite authorization. Authorization is only given if use "presents a negligible risk, or in other cases, that the use is acceptable taking into account socio-economic benefits, lack of 'safer' chemicals for the same task and measures minimising the exposure…".⁸¹²

The standard of a "high level of protection for human health" is also carried out by the use of caution. In practice, this is applied though the use of the substitution principle and by placing the burden of proof on industry rather than government. REACH legislation states that whenever possible, dangerous substances shall be substituted made with less dangerous when available.⁸¹³ In addition, unlike the US and Canadian approach, industry must prove that the

⁸⁰⁶ White Paper, supra note 791 at 5.

⁸⁰⁷ *Ibid.* at 8.

⁸⁰⁸ Coggon, supra note 722 at 790.

⁸⁰⁹ *Ibid*.

⁸¹⁰ White Paper, supra note 791 at 5.

⁸¹¹ *REACH, supra* note 799 at s.73.

⁸¹² White Paper, supra note 791 at 8.

⁸¹³ *REACH, supra* note 799 at s.12.

substances are safe for use and do not cause any of the unacceptable hazards.⁸¹⁴ Though further consideration of this burden of proof will be given in the next section, it is important to note how this onus of proof of "no harm" is the reverse of that of the risk-based approach of "proof of harm by agency".

It is estimated that the use of this safety standard will result in a substantial savings in health-care related costs. In one estimate, it was thought that nearly 200-2,500 million will be saved in the year 2017 from the prevention of adverse health effects.⁸¹⁵ Allergy costs alone cost the EU nearly 29 billion per year. Because it is thought that the increase of asthma, at nearly forty percent since 1970s, is partially related to chemical exposure, the EU government believes that a small reduction in this asthma-related cost will outweigh the costs of the overall strategy.⁸¹⁶

4.4.4.3 Burden Of Proof And Test Requirements

One of the most prominent problems associated with Canadian and US policy is that the government has the responsibility to prove harm. In order to do so, a test rule must be issued which requires the responsible agencies to demonstrate harm prior to obtaining further data for a thorough risk assessment. As a result of this cyclical process, few chemicals, particularly existing chemicals, have been assessed for risk. Therefore, the impact these exposures make on children is unknown.

This problem of burden of proof is addressed directly in the new REACH legislation. No longer is it the responsibility of the government agency to prove probability of risk. The EU places the burden of proof on industry. Industry "should be responsible for all the aspects of the safety of their products and should provide information on use and exposure for the assessments of chemicals."⁸¹⁷ The EU has ensured that this responsibility is fulfilled by requiring information on chemical toxicology, animal and epidemiological studies, and substance exposure estimates before approval is obtained and before.⁸¹⁸

By placing the onus on industry to prove safety up front, the government no longer must undergo an elaborate procedure of requesting data before a thorough risk assessment can take place. The EU is capable of evaluating the risks, hazards, and exposures associated with each chemical, and multiple chemicals, because data is required for all chemicals. Old and new chemicals will be assessed for probability of harm and restricted or banned if found to meet the criteria of a substance "of very high concern".⁸¹⁹ Because the EU has shifted the burden of proof and eliminated

⁸¹⁴ *Ibid*.

⁸¹⁵ F. Pedersen et al., *Report to Directorate General The Impact of REACH on the Environment and Human Health* (Brussels: DHI Water & Environment, 2005) (ENV.C.3/SER/2004/0042r) at 7.

⁸¹⁶ White Paper, supra note 791 at 32.

⁸¹⁷ White Paper, supra note 791 at 8.

⁸¹⁸ This burden of proof has been extended beyond that of those who produce and import chemicals to include downstream users. Defined as anyone other than the importer or manufacturer who uses the substance, "either on its own or in a preparation, in the course of his industrial or professional activities" This definition does not include a distributor or consumer. The reason this is worth mentioning is that by requiring a greater amount of data on exposure rates, the government is more adequately informed, and therefore more capable of assessing childhood risk.

⁸¹⁹ White Paper, supra note 791.

the test rule, they are capable of assessing chemicals in a more informed fashion, which will help protect children's health. Unlike the US and Canadian approach, the EU is able to eliminate the most hazardous chemicals before they enter the market.

4.4.5 How The Hazard-Based Approach Resolves The Difficulties With The Risk-Based Approach In Favour Of Children's Health

4.4.5.1 Lessons Learned

The European Union's efforts to govern chemicals were initiated in the 1960s, with the aim of easing trade and providing consumer protection through use of packaging and labelling requirements.⁸²⁰ Like the evolution of the EU pesticide policy, the government was influenced by the desire by member states and the general public to expand this authority to provide for the protection of health. The EU solidified in the Amsterdam Treaty⁸²¹ with the declaration of a "high level of protection of human beings" in 1997 and initiated efforts to fulfill this objective in practical terms.⁸²²

The 2001 EU White Paper on a *Strategy for a Future Chemicals Policy* [hereinafter *White* Paper] made a number of recommendations that would aid in achieving a "high level of health protection". The overall finding by the European Commission was that "[t]here is a general lack of knowledge about the properties and the uses of existing substances. The risk assessment process is slow and resource-intensive and does not allow the system to work efficiently and effectively."⁸²³ In order to address this concern, the EU drafted the REACH legislation based on a hazard-based approach.

These amendments made to the chemical policy include use of an approach that aims to eliminate hazards, the application of the substitution principle, and the mitigation of risks to the greatest degree possible. The REACH legislation specifically recognizes that pregnant women and children be considered in the risk assessment process. This change to EU chemical policy is in contrast to the lesser efforts by Canada and the US to integrate lessons learned from pesticide policy to other areas of environmental law.

⁸²⁰ Hansen, supra note 38 at 270.

⁸²¹ Treaty of Amsterdam, supra note 367.

⁸²² In 2002, the European Union initiated the Sixth Environment Action Programme of the European Community (2002-2012) which included environment and health as one of its priority areas.

⁸²³ White Paper, supra note 791 at 6.

4.4.5.1 Use Of Accurate And Complete Data

Throughout this thesis the point has been made that the risk assessment process is only as accurate as the data used. Unfortunately, because of inherent uncertainties that surround toxic exposure's impact on children's health, there will never be complete assurance that the standards set are correct. Because of this, the hazard-based approach has integrated procedures of caution that eliminate some of the concern that surrounds this scientific uncertainty. Even with these procedural aspects, such as product elimination and use of the substitution principle, the EU has mandated a greater amount of scientific data than that either the US or Canada who rely solely on the calculation of standards to protect children.

As mentioned earlier, the US and Canada require minimal information for the risk assessment of chemicals and rely on models to estimate exposure, harm, and risk. Similarly, in the past, the EU directives provided limited data submission from new chemical producers. Recognizing that there was a knowledge gap⁸²⁴ about exposure and risk, the EU eliminated this differentiation between the existing and new chemicals and mandated a thorough investigation of risk.⁸²⁵

Under the REACH legislation, registration requirements include the submission of toxicological data on flammability, corrosivity, and mutagenicity if produced in quantities greater than one ton and fewer than ten.⁸²⁶ Chemicals that will be imported or manufactured in quantities greater than ten tons per year will also be required to submit data on carcinogenicity, reproduction toxicity, endocrine toxicity, repeated dose toxicity, and assessment of bioaccumulation, persistence, and toxic properties.⁸²⁷ This data is used to categorize chemicals that require authorization or should be banned.

The mandate of submission of these additional toxicological tests results in a substantial different number of overall tests in contrast with that of the US or Canada. For instance, in a comparison of required tests between the US and the EU the US only required four tests on human health for new chemicals and none for existing.⁸²⁸ The EU required five tests for substances produced in quantities of one ton or more, twelve tests for substances produced in quantities of ten tons or more, fifteen tests for substances produced in quantities of one thousand tons or more.⁸²⁹

⁸²⁴ *Wallinga, supra* note 750 at 3.

⁸²⁵ White Paper, supra note 791 at 6.

⁸²⁶Wordsworth, supra note 742 at 11.

⁸²⁷ Ibid.

⁸²⁸ Chemical Regulation Comparison of U.S., supra note 378 at 21.

⁸²⁹ Ibid.

4.4.5.2 The Elimination Of Risk: A Non-Toxic Environment

One of the more influential aspects, in terms of making a measureable impact on children's health, of the REACH's hazard-based approach is that the government has the authority to ban substances. Unlike either the US or Canada, who have only provided authority to control risk, this option to ban a substance allows the EU to remove harm completely. By eliminating a chemical from use, the EU provides a guarantee that the risks are controlled and that children will not be exposed to the most caustic of substances.

As already discussed, authorizations are required when substances have been identified as dangerous due to specific characteristics. It is estimated that nearly 1,500 of existing chemicals will immediately be placed on the authorization list.⁸³⁰ Permitted of use of these substances will be limited to a five year span for specified conditions. Use will only be granted if industry can demonstrate that the risks can be controlled.⁸³¹ In some cases, however, the government may find that even with "control" the risk is too great and authorization will not be provided.

These chemicals which are considered too dangerous for registration or authorization will be banned completely. Chemicals which are (1) persistent, bioaccumulative, and toxic, (2) very persistent, very bioaccumulative, or (3) carcinogenic or reproductive toxins, will not be authorized for use.⁸³² By 2013, the EU will have determined whether or not to include endocrine disrupting chemicals to this list.⁸³³ It is estimated that nearly forty-two existing substances, covering nine hundred chemicals, will be banned right away.⁸³⁴

These provisions are part of the EU's overall objective of a non-toxic environment.⁸³⁵ Though it is understood that absolute elimination of chemicals is unrealistic, the government has provided an "overlay" on the risk assessment process which will greatly reduce exposure rates.⁸³⁶ The cautious "overlay" requires the risk assessor to as whether the risks are too great and therefore unacceptable and whether there are safer alternatives. This approach "responds to the need for prudence when faced with the consequences of technological progress, whose repercussions are exponential and unknown."⁸³⁷

The results of this cautionary approach differ from that of the risk-based approach. The US and Canada require evidentiary certainty before action can be taken, therefore limiting the ability for either government to restrict use of a substance. In addition, neither country has provided agencies with the authority to ban a substance outright, no matter how much evidence indicates it is caustic. For instance, Canada has only placed two substances on the virtual elimination list. The EPA has had even less success and relies on voluntary measures rather than restrictions for new

⁸³⁰ Wordsworth, supra note 742 at 34.

⁸³¹ Wordsworth, supra note 742 at 34.

⁸³² Chemical Regulation Comparison of U.S., supra note 378 at 27.

⁸³³ *Ibid.* at 28.

⁸³⁴ Wordsworth, supra note 742 at 39.

⁸³⁵ COM (2006) 372, supra note 673.

⁸³⁶ McClenaghan, supra note 36 at 18.

⁸³⁷ D. Vogel, "Risk Regulation in Europe and the US" (2003) 3 Yearb. Eur. Environ. Law at 28.

chemicals. Because of the limitations placed on the US through the judiciary, only five existing chemicals have been restricted.⁸³⁸

It is highly unlikely that the North American continued exposure to chemicals banned in Europe will not negatively affect the health of children residing in the US or Canada. The EU has determined that evidence indicates that there enough uncertainty surrounding the caustic effects of these substances that caution should be taken and exposure eliminated. Meanwhile, the US and Canada rely on a system to control risk, however, they have few mechanisms to do so and limited scientific understanding of the impact exposure has on children's health.

4.4.6 Conclusion

Whereas the pesticide section provided a thorough explanation of how amendments alone cannot remedy the problems associated with the risk-based approach, this section on chemicals illustrates that the risk-based approach often fails to mitigate risks at all, let alone for children. The TSCA and the CEPA provide that scientific evidence must be present before risks can be controlled, yet this data is not required to be submitted. In addition, even when risks are great, neither country offers the option to eliminate the risk completely. Because of this, neither health nor environment is adequately protected.⁸³⁹

The EU's recent adoption of REACH provides greater protection for children's health. By substituting safer alternatives over those that are caustic, the EU provides exposure minimization.⁸⁴⁰ In addition, the elimination of substances which pose a specific potential hazard provides risk avoidance.⁸⁴¹ These aspects of the hazard-based approach ensure that children are exposed to fewer harmful substances.

It is estimated that chemical exposes cause ten to thirty-five percent of childhood asthma cases, two to ten percent of cancers, and five to twenty percent of neurobehavioral disorders.⁸⁴² Yet, there remains a great deal of indifference as to the potential impact chemicals have on children. In a recent study of newborn cord blood, the American Red Cross found two hundred eighty-seven industrial chemicals.⁸⁴³ Because of this, it is important that governments take caution when assessing substances. There remains no doubt that children are exposed to these chemicals, whether they are safe or not.

⁸³⁸ Chemical Regulation Comparison of U.S., supra note 378 at 22.

⁸³⁹ *Ibid*.

⁸⁴⁰ Hansen, supra note 38 at 274.

⁸⁴¹ *Ibid*.

⁸⁴² Wallinga, supra note 750 at 3.

⁸⁴³ *Ibid*.

5. RECOMMENDATIONS AND CONCLUSIONS

5.1 Introduction

The previous chapter provided examples of how using the hazard-based approach to interpret the risk assessment of pesticides and chemicals benefits children's health in a way that the risk-based approach cannot. While it might be easy to suggest that the resolution of this problem should be the adoption of the hazard-based approach by Canada and the United States, the likelihood that this will be done by either country is slight, for reasons discussed in the next section. This chapter will, therefore, offer recommendations of how the risk-based approach may be improved in ways that offer better protection for children's health. The first portion of this chapter will highlight some of the political obstacles that the US and Canada will likely face if they attempt to amend legislation to include the hazard-based approach would be in the best interest of children's health, there are amendments that can be made to the risk-based approach to improve the accuracy of the standards set; therefore presenting a higher level of protection for children's health than is currently offered. It is important to note, however, that no matter the modifications to the risk-based approach, it cannot provide the same level of prevention that the hazard-based approach does.

5.2 Obstacles That The US And Canada Face In Adopting A Hazard-Based Approach

In order for Canada and the US to adopt a hazard-based approach Parliament and Congress would have to initiate procedures to amend the current legislation. The biggest obstacle to this is that the chemical and pesticide industry have substantial influence over members of these legislative bodies, particularly in the US. Implementing the hazard-based approach would take countless hours, dedication, and effort on behalf of members of Congress to amend both the FQPA and the TSCA and of Parliament to amend the PCPA and the CEPA. Part of this effort would require Congressional and Parliamentary representatives to fight the lobbying efforts against policy changes from an \$11 billion pesticide industry and a \$231 billion chemical industry.⁸⁴⁴

The industries' powers to persuade political representatives have played an active role in shaping the current assessment process. Their lobbying efforts, financial contributions to political parties, and investment in employment in regional districts are just a few of the reasons that both nations utilize a risk-based approach. The risk-based approach provides the least restrictions on industry due to the fact that it merely limits exposure to substances rather than banning sale of products. Lobbying by industry is the primary reason why no action has yet been taken by the US Congress to amend the out-dated TSCA. It is also the primary reason why the US Congress adopted the FQPA when prior legislation, which mandated zero tolerance for cancer, was much more likely to lead to banned products. Though the Canadian experience has not had the same level of direct lobbying efforts by industry, the passive pressures by the US government on Parliament ensures that the effect is nearly the same.

⁸⁴⁴ Due Canada's trade relationship with the US, they are indirectly influenced by these lobby efforts as well as directly influenced by lobbying efforts in Ottawa. *Kiely, supra* note 463; U.S., Environmental Protection Agency, *High Production Volume (HPV) Challenge* (Washington, D.C.: Environmental Protection Agency, 2007), online: Environmental Protection Agency < http://www.epa.gov/HPV/pubs/general/hazchem.htm> (last modified: 28 November 2009 2007).

The recent failed attempts to pass chemical legislation in the US demonstrate that there is resistance to change. The latest efforts to make any progress in amending legislation to provide protection for children's health have failed, even though these efforts did not include anything as drastic as a shift from a risk- to a hazard-based approach. In 2003 and again in 2009, the *Kid Safe Chemical Act* (KSCA) was introduced in Congress but was unsuccessful in becoming law. This proposed legislation aimed to place the onus of proof of safety on industry by requiring the submission of toxicological tests for new chemicals.⁸⁴⁵ The KSCA was supported by a critical review of the US chemical policy by the United States Government Accountability Office (US GAO), which made a number of recommendations for amendment of the TSCA.⁸⁴⁶ Despite this publication, no legislative changes have been made.⁸⁴⁷ Similarly, a review of the CEPA conducted by the Canadian Parliament has led to no real reform. Though the Parliamentary Standing Committee on Environment and Sustainable Development found that a complete overhaul was not necessary, it did make a number of recommendations. One such suggestion included the amendment of CEPA to include that "industry has the responsibility of demonstrating, to the satisfaction of the Minister, that the risks of new and existing substances of concern are acceptable."⁸⁴⁸ Three years later no efforts have been made to change the CEPA.

These examples suggest that there will be great difficulty in prompting the modification of the legislation in favour of a hazard-based approach. If Congress and Parliament face this kind of opposition when amending the current risk-based approach, it is highly unlikely that the government will be able to pass legislation adopting a hazard-based approach because it is less industry-friendly. The KSCA merely shifted the onus of proof from government to industry and proposed a review of existing chemicals. Yet, due to the lobbying efforts and the substantial campaign contributions these minor changes, similar to those instituted in pesticide review by the FQPA, failed.⁸⁴⁹

Further evidence of the difficulties that the governments face in amending legislation in favour of a hazard-based approach can be found in the recent passage of pesticide policies. The US government's success in amending their pesticide legislation was a product of self-serving support from the pesticide industry. The government faced pressure from industry to eliminate the Delaney Clause since it would in effect eliminate a number of products found to be carcinogenic. The increasing capacity of scientific research had enabled screening to detect a greater number of substances that cause cancer, therefore increasing the number of products to be banned.⁸⁵⁰ The FQPA provided an

⁸⁵⁰ Consumers Union of U.S., Inc., *Worst First: High-Risk Insecticide Uses, Children's Foods and Safer Alternatives* (Washington, D.C.: Consumers Union of U.S., 1998), online: Consumers Union of U.S. < http://www.consumersunion.org/pdf/worst1st.pdf> (last modified: September 1998).

⁸⁴⁵ *Kid-Safe Chemicals Act* (Washington, D.C.: Environmental Working Group), online: EWG < http://www.ewg.org/files/EWG-Kid-Safe-factsheet.pdf> (date accessed: 15 May 2009).

⁸⁴⁶Chemical Regulation Comparison, supra note 738.

⁸⁴⁷ Chemical Regulation Comparison, supra note 738 at 45.

⁸⁴⁸ Five-Year Review, supra note 749 at 23.

⁸⁴⁹ "The chemical and related manufacturing sector provided \$ 21,027,663 in campaign contributions in the 2000, 2002, and 2004 election cycles. Of this amount \$16, 543,081 was provided to Republications, and \$912,207 was given to George W. Bush." R. Rawlins, "Teething on Toxins: In Search of Regulatory Solutions for Toys and Cosmetics" (2009) 20 Fordham Envtl. Law Rev. 1 at 8.

opportunity for this clause to be abandoned and replaced with the *de minimis* standard.⁸⁵¹ Though this principle still sets limits on industry, it does not eliminate products outright. In riding themselves of the Delaney Clause the US government moved away from a hazard-based approach towards a risk-based approach.

Evidence of how pervasive industry lobbying efforts are was apparent in the political context of the EU's REACH policy. In addition to the EU domestic industry's insistence that the hazard-based approach's bans were unreasonable, the US government lobbied against the proposed changes.⁸⁵² Further, due to pressures from the US chemical industry on US elected governmental officials, the US began efforts to undermine the proposed changes. The Environmental Health Fund found that "[d]ocuments obtained from anonymous sources and through the Freedom of Information Act lay out elements of an ambitious and wide-ranging campaign by the Environmental Protection Agency, State Department, Commerce Department, and the United States Trade Representative to weaken REACH in concert with narrow chemical industry interests."⁸⁵³ If the US is willing to lobby against legislation in another jurisdiction at the behest of industry, it is highly unlikely that similar policy will be adopted in the US.

To counter these industry lobbying efforts, public pressure to abandon use of the risk-based approach would need to be made on members of Congress and of Parliament. Unfortunately, this issue is not on the political radar of most parents and caregivers. In circumstances where environmental health issues are brought to the attention of the public, the focus is usually attached to specific substances, such as the use of the chemical Bisphenol A (BPA) in baby bottles, rather than an overarching change to assessment. ⁸⁵⁴ The success of the ban on BPA in baby bottles was largely due to the public pressure put on Parliament to take action.⁸⁵⁵ Until the general public understands that in the pesticide and chemical legislation "safe" means that certain risks, including cancer, have been found "acceptable", and is outraged enough by that definition to put pressure on the government to change the policy, no real change will take place. Since no group is putting this issue in front of the public, such change is unlikely to occur.

Not only will the US and Canadian governments be required to confront an imposing chemical and pesticide industry, but they will have to alter the nature of the way they view risk. Both governments would have to abandon the notion that all risk is predictable and that risk can be calculated and safe.⁸⁵⁶ It would require the jurisdictions to recognize that the current risk-based approach is subjective, and is shaped by social and cultural factors;⁸⁵⁷ that

⁸⁵¹ *Ibid*.

⁸⁵² J. DiGangi, US Intervention in EU Chemical Policy (Jamaica Plain, MA: Environmental Health Fund, 2003).

⁸⁵³ *Ibid.* at 7.

⁸⁵⁴ Canada, Chemicals Substances, *Government of Canada Protects Families with Bisphenol A Regulations* (Ottawa: Government of Canada, 2009), online: Government of Canada <</p>

http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-2/bisphenol-a/index-eng.php> (last modified: 9 July 2009).

⁸⁵⁵ J. Foulds, "Babies, Parents, and Daycares Rally Against Toxic Baby Bottles" *Environmental Defence* (20 November 2007), online: Environmental Defence <</p>

http://www.environmentaldefence.ca/pressroom/viewnews.php?id=254> (last modified: 20 November 2007).

⁸⁵⁶ Bennett, supra note 30 at 192.

⁸⁵⁷ L. Levidow, S. Carr, & D. Wield, "Genetically Modified Crops in the European Union: Regulatory Conflicts as Precautionary Opportunities" (2000) 3:3 J. Risk Res. 189 at 191.

though the governments have relied on a scientific process, conducted by risk assessors, the interpretation of uncertainty is political, not objective.⁸⁵⁸ Instead, both countries will have to adopt ideologies that are central to the EU policies, specifically: (1) the protection of health and (2) the use of caution. Unless the US and Canada are willing to recognize that scientific uncertainty (and the assessment process must be interpreted with these principles in mind) they will not be motivated to adopt a hazard-based approach.

Though the industry lobbying efforts make it unlikely that either government will change the status quo, it is not probable. The EU is an example of a government which undertook a drastic change from a risk- to hazard-based approach even though this change was opposed by their sizeable and significant chemical and pesticide industries. The EU was able to overcome opposition from the European chemical industry, which makes up 30 percent of the world chemical sales. This is greater than in North America, which accounts for 25 percent of world chemical sales.⁸⁵⁹

5.3 Amendments That Should Be Made If The Use Of The Risk-Based Approach Continues

As it is unlikely that the hazard-based approach will be adopted in Canada and the United States, due to the reasons outlined above, it is necessary to consider modifications that can be made to the current risk-based approach in an effort to provide a greater level of protection for children's health. Even accomplishing such amendments to the risk-based approach, however, will take a great deal of effort from both the general public and government officials. The rest of this section, divided into three parts, will outline certain amendments that should be made in order to protect children's health. The first part will summarize specific amendments that should be made to the pesticide legislation. The second part will highlight amendments that should be made to the chemical legislation. The last part will discuss amendments that should be made to the pesticide and chemical policies, as well as other areas of environmental law.

5.3.1 Amendments To Be Made To The Pesticide Legislation

A number of observations were made in chapter four pertaining to the failure of the risk-based approach to account for children's health in pesticide risk assessments. Though many of these issues cannot be remedied without abandoning the risk-based approach, there are, however, measures that can be taken to improve the pesticide risk assessment process in favour of children's health.

One of the initial concerns outlined in the last chapter was that the risk-based approach relies on inaccurate and incomplete data when predicting risk to children. This section will address some of the changes that must be made to alleviate these data inaccuracies. This includes the use of partial or imprecise animal and epidemiological studies, aggregate data, and cumulative data. The main concern with this is that because of errors that might be present in this data, the overall scientific assessment process may not be accurate. And since the risk-based approach relies on this estimate to predict and control risk, the need for its precision is greater the hazard-based approach that eradicates

⁸⁵⁸ *Ibid.* at 190-191.

⁸⁵⁹ E.C., Enterprise and Industry Directorate-General, *The State of the European Chemicals Industry – A Thoughtstarter for the High Level Group on the Competitiveness of the European Chemicals Industry* (Brussels: European Commission), online: Europa <

http://www.eesc.europa.eu/sections/ccmi/Actuality/Chemicals/Documents/Thoughtstarter_High_level_group_000.pd f> (date accessed: 12 October 2009).

risk. Until these data inaccuracies are recognized, there needs to be the obligation that the safety factor be utilized in a fashion that is actually protective of children's health rather than as an elective exercise.

5.3.1.1 Minimizing The Errors Of Animal And Epidemiological Studies

While it is impossible to guarantee that the errors present in the use of animal bioassays and epidemiological studies are eliminated, there are specific actions that can be taken by the PMRA and the EPA to lessen the gravity of these faults. First, governments need to improve the quality of data used in these studies in order to increase their accuracy. Although use of animal and epidemiological studies is unavoidable, there are opportunities to improve these studies. For one, animal studies should be broadened to include *in utero* and neonatal experimentation to provide a better reflection of an average lifespan, starting from prenatal development.⁸⁶⁰ An additional way that the quality of animal studies can be improved is by the institutionalization of wildlife research. Information on the effect chemicals already on the market have had on animals should be used as interpretative context alongside animal and epidemiological studies.⁸⁶¹

There must also be an improvement in the understanding of the impact toxic chemicals have on children's health in general.⁸⁶² Monitoring of the impact chemicals have on children's health needs to be expanded beyond animal laboratory tests and limited epidemiological studies. Blood, urine, and breast milk sampling are just a few options that provide a better understanding of the impact of chemicals in the body. While the US and Canada both have initiated efforts to conduct this type of study, known as biomonitoring, they have done so in a limited fashion. For instance, the US Center for Disease Control's (CDC) National Health and Nutrition Examination Survey (NHANES) provides a survey of types of exposures. While the largest survey of this type, there has been no mandate by the government to utilize this data in the risk assessment process. This disconnect between the CDC information and the EPA's process results in little measureable positive impact on children. The same is true for the Canadian Health Measures Survey (CHMS) which started in 2007 and aims at reviewing the health of over 5,000 Canadian residents.⁸⁶³ Any value these studies have on estimates of exposure, and therefore the impact of such, is greatly limited due to facts such as, that in the US, the earliest age groups are not tested for anything other than lead, cadmium, and mercury, and that in Canada, the youngest age tested is six years old.⁸⁶⁴

⁸⁶⁰ Landrigan, supra note 12 at 262.

⁸⁶¹ *Ibid*.

⁸⁶² Commission for Environmental Cooperation, supra note 461 at ix.

⁸⁶³ Canada, Health Canada, *Biomonitoring of Environmental Chemicals in the Canadian Health Measures Survey* (Ottawa: Health Canada, 2007), online: Health Canada http://www.hc-sc.gc.ca/ewh-semt/contaminants/health-measures-sante-eng.php (last modified: 7 March 2007); Canada, Statistics Canada, *Canadian Health Measures Survey (CHMS)* (Ottawa: Statistics Canada, 2008), online: Statistics Canada ">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?Function=getSurvey&SDDS=5071&lang=en&db=imdb&adm=8&dis=2>">http://www.statcan.gc.ca/cgibin/imdb/p2SV.pl?

⁸⁶⁴ Canada, Statistics Canada, *Canadian Health Measures Survey* (Ottawa: Statistics Canada, 2004), online: Statistics Canada http://www.statcan.gc.ca/concepts/hs-es/measures-eng.htm (last modified: 19 March 2004); L.L. Needham, D.B. Barr, A.M. Calafat, "Characterizing Children's Exposures: Beyond NHANES" (2004) 26 Neurotoxicol. 547 at 548.

In addition to improving the quality and type of studies, one of the most fundamental changes to the toxicological testing requirements is mandating a greater set of tests. Currently, the majority of long-term tests are only required when basic tests indicate that there may be a need for such tests. This means that tests for neurodevelopmental delay, endocrine disruption, cancer, reproductive disruption, and immune system disruption are often not conducted, particularly because the "trigger" that would cause these tests to be administered is unclear. Because of this, both countries should direct that a greater range of screening tests is necessary and clearly articulate what "triggers" any secondary tests.

Along with increasing the number of tests administered, it is important that the method by which these test results are analyzed be improved. A modification to the risk assessment process that will aid in the accuracy of the risk-based approach is to require the use of the benchmark dose (BMD) in assessing the dose response relationship. Currently, neither the US nor Canada require that animal bioassays be assessed in any way other than determining the lowest dose at which no significant harm occurs in the animal. Once this dose is determined, identified as the NOAEL, the testing is concluded. The BMD provides that all doses be charted, resulting in a predictive curve. Unlike the NOAEL, the BMD curve is to be interpreted as a whole, rather than per dose. The reason that this is advantageous to children's health is that it provides a complete picture – one that indicates what the trend in harm is.⁸⁶⁵ Because the NOAEL approach does not take into consideration the dose-response curve, it cannot identify curves that do not have the assumed linear pattern of increased harm with increased dosage. If the dose-response data for a substance is charted, the relationship may be expressed in a sigmoidal, U-shaped, or inverted U-shaped curve.⁸⁶⁶ The inverted U-shaped curve has already been affiliated with some endocrine-disrupting chemicals, clearly indicating that extremely low doses and extremely high doses of these chemicals are not nearly as insidious as those in between.⁸⁶⁷

In addition to charting dose-response curves using the BMD, it would be valuable for both governments to eliminate the separate standards by which they evaluate the tests for cancer and non-cancer causing substances. Currently, tests are reviewed for carcinogenic capacity and other chronic health conditions. Those substances which cause cancer are controlled to the point that that meet the *de minimis* standard. However, the same standard is not used for toxins that are not deemed to cause cancer. The current system does not provide that one in a million individuals will have non-cancer conditions, such as asthma, hyper- and hypo-thyroidism, or birth defects.⁸⁶⁸

⁸⁶⁵ In a comparison of the BMD approach on the toxicity of carbendazim to the dose-response approach, the NOAEL had less conservative estimates.

⁸⁶⁶ *Wigle, supra* note 4 at 201; C.L. Acerini & I.A. Hughes, "Endocrine Disrupting Chemicals: A New and Emerging Public Health Problem?" (2006) 91 Arch. Dis. Child. 633, online: BMJ

http://www.fetalneonatal.com/cgi/content/full/91/8/633#R39 (date accessed: 14 October 2009).

⁸⁶⁷ P. Palanza, S. Parmigiani, & F.S. Vom Saal, "Effects of Prenatal Exposure to Low Doses of Diethylstilbestrol, o,p'DDT, and Methoxychlor Development in Male and Female Mice" (2001) 40 Horm. Behav. 252 at 252.

⁸⁶⁸ Wigle, supra note 4 at 176-177.

5.3.1.2 Reducing The Problems Associated With The Current Use Of Aggregate And Cumulative Data

Heralded as progressive (by both government and child right advocates) aggregate data and cumulative data were integrated into the risk assessment process as part of the FQPA and PCPA amendments for children's health. These two considerations of exposure, one focussing on total exposure via a number of sources (aggregate) and the second focussing on total exposure to multiple pesticides with similar toxicity (cumulative), were put in place to eliminate the problem of children taking in too many substances at the same time and therefore exceeding the ADI.

Chapter four identified some of the issues associated with the use of aggregate and cumulative data, one of which was the fact that the FQPA and PCPA offered the EPA and the PMRA the opportunity to excuse themselves from using this data if it was not available. This caveat has resulted in little use of either form of data, as no real effort has been made to ensure that this information has been gathered. Unless there is a requirement to gather this data and a legislative mandate that this data be used when available, it will remain an add-on with little positive effect on children's health.⁸⁶⁹ In order to improve the accuracy of the risk-based approach it is essential that this be addressed.

This is most obvious with the use of cumulative data. As mentioned earlier, only four categories of substances have been found to have similar mechanisms of toxicity.⁸⁷⁰ This is not because only these classes of substances have been found to be "cumulative", but because at this point these are all that the EPA, through their research, has determined to have similar mechanisms of toxicity.⁸⁷¹ Because of this, the EPA and the PMRA have seldom had to consider cumulative data in their risk assessment process as they are lacking such data.

Due to the complexity of determining what chemicals are cumulative, it is understandable that the EPA has not done a complete review of all pesticides.⁸⁷² That is not the concern here. The problem is that there is no impetus requiring any deadlines for review be met and no legislative requirement mandating that if deadlines are not met then another safety factor be used. This policy failsafe of use of cumulative data when available has been applied in a fashion that favours the agricultural stakeholder community over children's health.⁸⁷³

Although the slow progress of cumulative data research is problematic, there has at least been some initiative to determine what classes of pesticides are deemed similar in mechanisms of toxicity. This effort, however, is greatly lacking in gathering current information pertaining to aggregate data. The last chapter highlighted the many deficiencies associated with aggregate data, including that of reliance on the USDA's *Continuing Survey of Food*

<http://www.umass.edu/fruitadvisor/fruitnotes/foodqualityprotection2.pdf> (last modified: Winter 2002).

⁸⁶⁹ *Cooper, supra* note 5 at 162-163.

⁸⁷⁰ The four pesticide classes with common mechanisms of toxicity are: 1. Organophosphates, 2. N-methyl carbamates, 3. Triazines, and 4. chloroacetarilides

⁸⁷¹ U.S., Environmental Protection Agency, *Assessing Pesticide Cumulative Risk* (Washington, D.C.: Environmental Protection Agency, 2008), online: Environmental Protection Agency < http://www.epa.gov/oppsrrd1/cumulative/> (date accessed: 16 June 2008).

⁸⁷² R. Spitko, "Food Quality Protection Act: Cumulative Risk Assessment for the Organophosphate Pesticides" (2002) 67 Fruit Notes 16, online: Fruit Notes

Intake by Individuals, reliance on partial data of sale and use of pesticides, dependence on GAP to predict exposures, and failure to incorporate parent-child transfer from occupational settings. All of these data problems could be improved upon, thereby increasing the chance that the risk-based approach is accurate.

The first criticism, that of the US's and Canada's use of the USDA surveys conducted in 1994, 1995, 1996, and 1998, could be addressed simply by utilizing more up-to-date information. The US NHANES is a program of studies conducted by the CDC on an annual basis. A total of 5,000 US residents are polled on a variety of issues, including dietary-related questions.⁸⁷⁴ As a part of the 1999-2000 NHANES survey, a twenty-four hour dietary interview was conducted.⁸⁷⁵ The US government has stated that this survey will be linked with others, such as the National Health Interview Survey (NHIS) and the USDA's survey.⁸⁷⁶ As of 2009 this has yet to be done. There is little apparent reason for this lack of efficiency, especially as this would provide a more current understanding of what children are consuming on a daily basis. More importantly, it is necessary for Canada to conduct a survey that reflects Canadian residents' intakes. Inability to ensure that childhood intake exposures in Canada are the same as in the US's data, which the PMRA is currently using, inherently weakens the accuracy of the risk-based approach.

The failure on the part of both nations to provide a more accurate estimate of childhood exposures to non-food residue pesticides can easily be improved upon by each nation. Although the US has information on the sale and nation-wide usage of pesticides, this does not provide information about where the majority of the substances are being used. Canada has even less information, as it is the only OECD country that has yet to formulate a database on national pesticide use. There are, however, solutions to these problems of estimates of exposure rates. Borrowing from Scandinavian countries and the EU, both nations should require mandatory reporting on the production, importation, exportation, sale and distribution of pesticides.⁸⁷⁷ The governments should also require farms to keep track and submit data on the use of pesticides.⁸⁷⁸ To help ensure that these reports are accurate, Canada and the US should perform surveys of pesticide use and patterns, and monitor pesticide run-off in groundwater.⁸⁷⁹

This data collection will also aid in lessening errors associated with the use of GAP which is used to set standards for agricultural pesticides. The PMRA's and USDA's assessment of GAP includes consideration of soil, water, hands,

⁸⁷⁹ Ibid.

⁸⁷⁴ U.S., Centers for Disease Control and Prevention, *About the National Health and Nutrition Examination Survey* (Washington, D.C.: Centers for Disease Control and Prevention, 2009), online: Centers for Disease Control and Prevention < http://www.cdc.gov/nchs/nhanes/about_nhanes.htm> (last modified: 21 July 2009). [hereinafter *National Health and Nutrition Examination Survey*].

⁸⁷⁵ U.S., Centers for Disease Control and Prevention, *Intake of Calories and Selected Nutrients for the United States Population, 1999-2000* (Washington, D.C.: Centers for Disease Control and Prevention, 2009), online: Centers for Disease Control and Prevention < http://www.cdc.gov/nchs/data/nhanes/databriefs/calories.pdf > (date accessed: 14 October 2009).

⁸⁷⁶ National Health and Nutrition Examination Survey, supra note 874.

⁸⁷⁷ C. Wattiez & S. Williamson, *Pesticide Use Reduction is Working: An Assessment of National Reduction Strategies in Denmark, Sweden, the Netherlands and Norway* (Copenhagen: Pan-Europe, 2003) at 7.

⁸⁷⁸ *Ibid.*

and surfaces.⁸⁸⁰ The objective is to ensure that agricultural practices abide by these standards so that food safety protocols will be met.⁸⁸¹ Unlike the UN FAO's and the EU's definitions⁸⁸², these standards do not incorporate the consideration of environment and health sustainability. The US and Canada should consider including these aspects into the measurement of GAP. In addition, the governments should think about using the Integrated Farm Management (IFM) system in place of GAP. This approach "aims to reduce pesticide use by combining traditional farming methods with using pesticides and fertilisers only when absolutely necessary to keep animals and crops healthy."

While these modifications in data gathering will assist in the accuracy of the assessment process, there still remains the possibility of error when parental occupational exposure is not incorporated into the assessment process. As chapter four highlighted, children often take in pesticides through exposure to a parent's work clothing and vehicles. Children with parents who work in agricultural settings often reside near to those workplaces as well, increasing the chance of intake of occupational pesticides. These considerations have been purposefully left out of the FQPA and PCPA. Though it is difficult to estimate these exposures, as they vary for every child, family, and region, there are methods by which these exposures can be accounted for, even if only partially. The above-mentioned tracking system of the occupational use of pesticides will aid in estimation since it will provide indication as to how much pesticide is used, where, and how close this application is to residential and schools settings. In addition, the requirements put in place by the EU and select member states⁸⁸⁴ that pesticide equipment and protective clothing be inspected periodically will aid in reducing transfer.⁸⁸⁵ Borrowing from Europe, a requirement of occupational and agricultural employee training will help parents to understand the impact these chemicals have on them and their children. For instance, information about changing clothes immediately after application of pesticides and

⁸⁸⁰ On-Farm Food Safety: Guide to Good Agricultural Practices (GAPs) (Ames, Iowa: Iowa State University of Science and Technology), online: Iowa Uni < http://www.extension.iastate.edu/Publications/PM1974A.pdf> (date accessed: 15 October 2009).

⁸⁸¹ Ibid.; Canada, Parliament, Glossary of Agricultural Programs, Acts and Terms-Glossary (Ottawa: Government of Canada), online: Government of Canada

http://www2.parl.gc.ca/Content/LOP/ResearchPublications/prb0617_gloss-e.htm#better (date accessed: 16 October 2009).

⁸⁸² *EurepGap* (Brussels), online: EurepGap <http://www.eurepgap.org/Languages/English/about.html> (date accessed: 16 October 2009).

⁸⁸³ "CWS Agriculture (the UK's largest farming enterprise), turned to agronomists when its retail arm, the Co-Op, decided lindanes should no longer be used. 'That was because of consumer concerns,' said Mr Leake." "Lindane Ban Across European Union" *Pan UK* (September 2000), online: Pan UK < http://www.pan-uk.org/pestnews/Issue/pn49/pn49p6.htm> (last modified: September 2000); U.K. Department for Environment Food and Rural Affairs, "Farming Land Management: Pesticides" (London: DEFRA, 2006), online: DEFRA http://www.defra.gov.uk/foodfarm/landmanage/land-soil/pesticides.htm> (last modified: 1 July 2006).

⁸⁸⁴ Member states with progressive national reduction strategies include Denmark, Sweden, and the Netherlands.

⁸⁸⁵ Wattiez, supra note 877 at 6-7.

prohibiting the mixing of work and child clothing in the clothes wash are examples of health issues that often are not conveyed to those who use the pesticide products.⁸⁸⁶

If the US and Canadian governments work towards filling informational gaps on aggregate and cumulative data, then the estimates of exposure will be more precise. As pointed out a number of times, unless the data is exact, the riskbased approach fails to control risk in a way that protects children. It is for this reason that both nations must dedicate funds and time to improving their calculations of daily pesticide intake.

5.3.1.3 Instituting The Amendments Of The FQPA And PCPA: Use Of The Safety Factor

One of the recommendations made in the NAS report was that the legislation include the adoption of an additional safety factor "to account for developmental risks and incomplete data when considering a pesticide's effect on infants and children, and any special sensitivity and exposure to pesticide chemicals that infants and children may have."⁸⁸⁷ While both Canada and the US included such a measure in the PCPA and the FQPA, use of the factor has been less than effective in fulfilling the objective of accounting for incomplete data.⁸⁸⁸ The reason for the failure of the safety factor is that it has seldom been used. As of 1999, only 15 of 120 decisions included the use of the additional safety factor.⁸⁸⁹ One of the most basic ways to improve the outcomes of the risk-based approach in favour of children's health would be to reverse this trend, instituting the additional safety factor when faced with uncertainty.

Guidelines published by the EPA and the PMRA about when the additional safety factor should be utilized are vague, leaving much of the decision-making regarding the selected value (one through ten) to the risk assessor. Considering one of the objectives of the risk-based approach is to decrease subjectivity, this individual assessment contradicts the overall purpose of the approach. To rectify this situation, the EPA and PMRA need to clarify when and how this safety factor should be applied.⁸⁹⁰

In addition to providing definite instructions with respect to when the safety factor may be applied, the EPA and PMRA should provide similar instructions for when a safety factor may be removed or reduced. One example of a reduction in safety factor can be found in the re-evaluation of 2,4-dichlorophenoxyacetic acid (2,4-D). This pesticide is commonly used in residential settings to combat weeds. Banned in Denmark, Norway, Sweden, and the EU, an additional safety factor of ten was originally instituted in the EPA re-evaluation.⁸⁹¹ Upon further review, however,

⁸⁸⁶ Ibid. at 7; Pesticides (Washington, D.C.: The Mid-Atlantic Center for Children's Health and the Environment, 2008), online: The George Washington University Medical Center <</p>

http://www.gwu.edu/~macche/parents/pesticides.html> (last modified: October 2008).

⁸⁸⁷ U.S., Environmental Protection Agency, *Protecting Children From Pesticides* (Washington, D.C.: Environmental Protection Agency, 2002), online: Environmental Protection Agency <

http://www.epa.gov/opp00001/factsheets/kidpesticide.htm> (last modified: January 2002).

⁸⁸⁸ National Research Council, supra note 99 at 9.

⁸⁸⁹ S. Bayko, "Reforming the Toxic Substances Control Act to Protect America's Most Precious Resource" (2006) 14 Southeastern Envtl. L.J. 245 at 282.

⁸⁹⁰ Landrigan 2004, supra note 12 at 263.

⁸⁹¹ Forty-five (45) of the EU Banned Products also Contained 2,4-D, online: Pesticide Free Yards http://www.pesticidefreeyards.org/PDF%20Files/45%20of%20the%20EU%20banned.pdf> (date accessed: 18 October 2009).

the EPA determined that a lesser factor of one was appropriate.⁸⁹² It is estimated that over 16 million pounds of this pesticide is used annually within the US, and approximately 25 percent of this is for landscaping.⁸⁹³ Epidemiological evidence indicates that exposure to 2,4-D may result in Non-Hodgkin lymphoma, leukemia, sarcoma, and increased incidence of the childhood cancer neuroblastoma.⁸⁹⁴ Other than the indication that the "Agency has no residual concerns for the effects seen in the developmental toxicity studies", little has been offered with regard to why the safety factor was reduced.⁸⁹⁵ Even if this particular decision is defensible, there needs to be a greater level of transparency, as well as specific use of protocols, to ensure that such decisions to reduce or eliminate the safety factor are consistent with one another.

Besides the need for consistency and transparency, it has been recommended that the safety factor be utilized until toxicological issues and incomplete and inaccurate aggregate and cumulative data can be remedied.⁸⁹⁶ Rather than offer the additional factor as an optional failsafe, the governments should mandate its use until they have addressed some of the problems discussed in chapter four and in the above sub-sections. As long as assessors continue to require a minimal amount of toxicological tests for submission and use partial aggregate and cumulative data, it is reasonable to conclude that data uncertainty will continue to be an issue. Because the additional factor was intended to correct any errors with data, it is natural to assume that it should be used more often than not. Currently, however, this is not the case. Requiring the EPA and the PMRA to use the safety factor until these data uncertainties are remedied may serve to motivate efforts to solve these problems and thereby help protect of children's health.

⁸⁹² 2,4-D RED Facts, supra note 595.

⁸⁹³ "Public Comments Needed Now to Ban the Dangerous Herbicide 2,4-D" *Beyond Pesticides Daily News Blog* (18 February 2009), online: Beyond Pesticides http://www.beyondpesticides.org/dailynewsblog/?p=1285 (last modified: 18 February 2009); M. Sears et al., "Pesticide Assessment: Protecting Public Health on the Home Turf" (2006) 11:4 Peds. & Child Health 229 at 229.

⁸⁹⁴ Sears, *ibid.*; M. Sanborn et al., *Pesticides Literature Review* (Toronto: Ontario College of Family Physicians, 2004), online: OCFP <http://www.ocfp.on.ca> (last modified: 23 April 2004); J.L. Daniels, "Residential Pesticide Exposure and Neuroblastoma" (2001) 12:1 Epidemiology 20 at 20.

⁸⁹⁵ 2,4-D RED Facts, supra note 595.

⁸⁹⁶ Landrigan 1999, supra note 171 at 6; Landrigan 2004, supra note 12 at 263.

5.3.2 Amendments To Be Made To The Chemical Legislation

Like the pesticide risk assessment process, the chemical review procedure could be modified to provide a better level of protection for children's health if use of the risk-based approach remains the status quo. A number of issues with the Canadian and American chemical legislation were described in chapter four. Many of these can be alleviated through amendments to the present legislation. The following sections will outline how such changes could be implemented. While these changes may mend some of the problems with the risk-based approach, they will not resolve the overall issue – that the approach controls risk rather than eliminates it.

5.3.2.1 Applying Lessons Learned About Children's Health In Other Areas Of Environmental Law

One of the biggest problems with the current chemical legislation in the US and Canada is that both countries have failed to learn lessons from research done on the negative effects of pesticides on children's health. The NAS report, supported by epidemiological research, clearly indicates that children are not "little adults".⁸⁹⁷ In fact, because of the physiological, biological, and social differences between children and adults, pesticide policy in the US and Canada was amended to provide better protection for this vulnerable group. Unfortunately, neither Parliament nor Congress used this information as the foundation of any amendments to the TSCA or CEPA.

A fundamental change that needs to be made is the specific inclusion of children's health in chemical legislation. In the 2006 *Report of the Standing Committee on Environment and Sustainable Development*, the committee recommended that the CEPA be amended to "make it mandatory to take into account vulnerable populations in the risk assessment process."⁸⁹⁸ The committee found that even if children are already considered in the risk assessment process, there is no reason that "this language not be written into CEPA 1999".⁸⁹⁹ This proposal, supported by a number of non-profit groups who testified on its behalf, has yet to be implemented.⁹⁰⁰ It is not merely enough to recommend that changes be made through guidelines and proposals because there is no accountability. To ensure that children's health is considered in the assessment procedure, it is necessary that the protection of children's health be specified in CEPA like it has been in the PCPA.

The situation is similar within the US. The US Presidential Executive Order 13045, *Protection of Children from Environmental Health Risks and Safety Risks*, holds that government agencies must "make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children".⁹⁰¹ This Executive Order was signed in 1997 with the purpose of ensuring that children were not disproportionately affected by environmental risks. Because this requirement has not been enshrined in the TSCA, however, little protective action has been taken to prevent undue harm to children's health from chemicals. It appears that without legislation

⁸⁹⁷ Landrigan 2004, supra note 12 at 257.

⁸⁹⁸ Five-Year Review, supra note 749 at 27.

⁸⁹⁹ Ibid.

⁹⁰⁰ Ibid.; Canada, Perfluorinated Substances and the Canadian Environmental Protection Act (CEPA), Submission to the Senate Standing Committee for Energy, the Environment and Natural Resources (Ottawa: PollutionWatch, 2007) at 3.

⁹⁰¹ Executive Order 13045, supra note 530.

requiring that children be accounted for in the risk assessment process, neither Canada's nor the US's chemical policy will provide for children's health in a consistent manner.

As a result of the NAS report, pesticide legislation was amended to include the use of an additional safety factor, aggregate data, and cumulative data in the risk assessment. The problems these changes were instituted to remedy are present in the chemical assessment as well, so there is no reason that these same modifications should not be made to the chemical legislation. Currently, estimates of chemical exposure fail to consider the multitude of exposures children experience, including exposures to substances with similar mechanisms of toxicity. As discussed in chapter four, there is a great deal of uncertainty surrounding the impact chemical exposure has on children, making it essential for an additional safety factor to be utilized. Neither Canada nor the US has instituted requirements such as those found in the PCPA and the FQPA in their chemical legislation. There is no reason why Canada and the US should assume that children are protected from exposure to pesticides prior to these amendments. Canada and the US should interpret research, such as the NAS report, with a less narrow scope and apply lessons learned about pesticides or other environmental areas to legislation in different areas, including chemical legislation.

5.3.2.2 Reversing The Onus And Eliminating The Test Rule

In chapter four's review of the North American approach to chemical regulation it was obvious that there is a need to shift the burden of proof of harm from government to industry and eliminate the complex rules which trigger a full evaluation of substances. The current administration have been ineffective in providing the government agencies involved in the review with any real authority to restrict childhood exposures to harmful chemicals. In Canada and the US, the existing legislation requires the government to demonstrate harm to humans before the agency can request that further data be submitted for a full risk assessment. This "catch-22" results in a rather ineffective "test rule". In order to provide a greater level of protection for children's health there is a need to reverse the onus of proof and eliminate the burdensome requirements that must be met before further evaluation of a chemical can take place.

The shift of burden of proof can occur within the confines of the risk-based approach. The pesticide legislation in Canada and the US are clear examples of this. Though the EU's hazard-based approach goes even further with the presumption of guilt, the pesticide risk assessment in North America results in stricter standards than would be produced if it were up to the government to demonstrate harm without the submission of toxicological tests.

Currently, the chemical policies require the government to utilize models to estimate potential harm before further risk assessments may be conducted. While this process provides some insight into the impact exposure may have on children's health, it is often based on inaccurate estimates and incomplete data. The only information provided by the manufacturer is the "anticipated production volume, uses, exposure levels, and release estimates", along with the chemical structure of the substance, so the modeling capacity is decreased if any of these approximations are wrong or change.⁹⁰² To remedy this situation, new chemical applications should be required to submit toxicological tests in

⁹⁰² Currently there is no requirement for industry to resubmit this information if the estimates are not accurate. *Chemical Regulation Comparison, supra* note 738 at 9.

addition to this data, as is mandated under pesticide policy. There is no reason to assume that chemical exposure is less threatening or less common than pesticide exposure, especially as nearly 2,000 new chemical compounds enter the market in the US yearly.⁹⁰³

Without mandating animal bioassays and epidemiological studies as part of the submission package for new chemicals, there will remain a "safety gap".⁹⁰⁴ This is a problem with existing chemicals as well, as the TSCA and the CEPA place the burden of proof of safety on the government, but provides the government with no real authority to obtain the information necessary to prove harm or risk.⁹⁰⁵ The outcome is that few substances have been reviewed for safety, with only an estimated five percent of TSCA-registered chemicals having been examined.⁹⁰⁶

In addition to requiring further information to conduct a thorough risk assessment from the onset, the Canadian legislation should be amended to eliminate the use of the nDSL. This automatic adoption of chemicals that have been on the market in the US for five years does not provide any protection for children's health, particularly since the US TSCA is outdated and therefore the health assessment conducted under that statute may be inaccurate and fail to protect children. It is estimated that approximately 56,000 substances are currently listed on the nDSL; that is 56,000 chemicals which have yet to undergo any risk assessment by the Canadian government.⁹⁰⁷

Even if Parliament and Congress are not willing to amend policy to mandate toxicological data sets, there are other modifications to the process that can be made which would improve the situation for children's health. For one, if each government tracked usage of chemicals and utilized biomonitoring to estimate exposure then the necessity to rely only on the approximations offered by industry would not be necessary.⁹⁰⁸ Biomonitoring of breast milk in Sweden aided the government in recognizing that PCBs, PBDEs, polychlorinated dibenzodiozins (PCDDs), metals, and solvents were contaminating humans, and therefore effecting human health.⁹⁰⁹ Similar efforts by the US and Canadian governments may aid in preventing risks. A second change that can be made to the risk assessment process in remedying this "safety gap" would be to require toxicological tests when models "do not adequately predict toxicity".⁹¹⁰ When there is an indication that the models fail to effectively predict harm, the EPA and the Ministries of Environment and Health could require further tests to provide a conclusive estimate of risk.⁹¹¹ A third option available to the governments is to require that toxicological tests only be submitted prior to the product's availability for purchase. It is estimated that nearly half of the substance applications submitted in the US never make it to the

⁹⁰³ Wallinga, supra note 750 at 2.

⁹⁰⁴ *Ibid*.

⁹⁰⁵ *Ibid*.

⁹⁰⁶ *Ibid*.

⁹⁰⁷ Wordsworth, supra note 742 at 21.

⁹⁰⁸ *Phipps, supra* note 2 at 13.

⁹⁰⁹ Solomon, supra note 212 at 1.

⁹¹⁰ Chemical Regulation Options, supra note 742 at 10.

⁹¹¹ *Ibid*.

marketplace.⁹¹² Because of this, the chemical industry has voiced concern over the expense of toxicological tests on substances that are never sold. To lessen the financial impact toxicological test requirements might have on innovation, the government could require the toxicological tests only when the company is sure a substance will be sold.

If the issue of toxicological test requirements for new chemicals is remedied, both governments still must address the laborious and complicated process by which "test rules" are triggered. The TSCA and the CEPA require that the responsible agency demonstrate that the substance poses an unreasonable risk before further data may be requested from the substance producer. This creates a situation where the responsible agency must show harm without having complete data.

Even in situations where the agency has information indicating harm, the process by which it may be proven is lengthy and expensive. It is estimated that it takes anywhere between two and ten years to gather information and present it in a manner which would guarantee a "test rule" is finalized.⁹¹³ The costs are enormous as well, with issuing one test rule totalling \$234,000.⁹¹⁴ This is not a feasible or an effective way for existing chemicals to be analyzed. The EPA has made statements to this effect, saying that they "could review substantially more chemicals in less time if they had the authority to require chemical companies to conduct testing and provide test data on chemicals once they reach a substantial production volume, assuming EPA had first determined that these data cannot be obtained without testing".⁹¹⁵

It is necessary that both the Canadian and American governments remove this requirement of proof of harm or lack of adequate data prior to requesting further data. There is no reason that industry should not be required to submit these tests in the first place, and even less cause to protect chemical companies from test expenses when there is reason to believe that exposure to a substance may lead to health risks. For this reason, the test rule should be eliminated. Agencies should be given the authority to request toxicological data without first demonstrating harm if the data they have is not conclusive.

⁹¹² *Ibid*.

⁹¹³ *Ibid.* at 7.

⁹¹⁴ Chemical Regulation Comparison, supra note 738 at 14.

⁹¹⁵ Chemical Regulation Options, supra note 742 at 8.

5.3.2.3 Review Existing Chemicals That Were "Grandfathered" In

One of the biggest problems with the chemical assessment process in Canada and in the United States is that there is a differentiation between new and existing chemicals. As mentioned in the last chapter, nearly 60,000 chemicals were grandfathered in under the TSCA and over 20,000 were grandfathered in under CEPA, thereby undergoing little or no risk assessment. Unlike pesticide policy whereby both nations instituted a re-evaluation of existing products, older chemicals have yet to undergo a thorough risk assessment. The TSCA requires the EPA to issue a test rule, prove harm, and then apply the "least burdensome alternative" to restrict or ban an older substance.⁹¹⁶ Similarly, the CEPA requires the government to review the substance with limited data, prove harm, and then request additional toxicological tests.⁹¹⁷

This lack of data on health impacts from existing chemical exposures is one of the reasons the EU amended their prior chemical policy. Because ninety-nine percent of the 100,106 existing chemicals had not undergone toxicological testing, the EU instituted a re-evaluation of all older substances to eliminate this "general lack of knowledge" in a way that will protect human health.⁹¹⁸ Although the approach taken by the EU differs, the risk-based approach should still encompass a review of older substances in order to control the risk from these chemicals. While the CEPA provides the ministries with the opportunity to evaluate older chemicals, the tools with which this is to be done do not allow a thorough assessment. All existing substances were immediately placed on the DSL inventory. From there, the government entities responsible for chemicals are to review the substances for bioaccumulation, persistence, and inherent toxicity. The problem with this scenario is that the government is to perform this review without having the manufacturer submit any further data.

A similar problem is found in the TSCA. Though the legislation allows for the review of existing chemicals, it maintains that before a "test rule" can be made, the EPA must show that there is an unreasonable risk to health or that the substance is produced in substantial quantities. In addition, the EPA must prove that there is significant human exposure to the substance and the substance enters the environment in substantial quantities.⁹¹⁹ Because of these difficulties, the agency's ability to review existing chemicals is effectively limited to substances that have already caused harm.

⁹¹⁶ Chemical Regulation Options, supra note 742 at 13.

⁹¹⁷ Before examining the difficulties that these governments face when trying to evaluate older chemicals due to legislative constraints, it is necessary to emphasize the impact these older chemicals have on children's health. With over 60,000 chemicals grandfathered in under the TSCA and over 20,000 substances grandfathered in under CEPA, the daily interaction that children have with these substances is not to be understated. "Ninety-two percent of industrial chemicals produced today at more than a million pounds per year were grandfathered in by TSCA." The negative health impacts associated with childhood chemical exposures include asthma, cancer, and neurobehavioural disorders. It is estimated that nearly two hundred industrial chemicals have been identified as a cause of neurotoxicity in adults, but thousands of other substances have not yet been evaluated. These same chemicals have not been assessed for their impact on children. There is really no understanding of the effect exposure to these chemicals may have on children's health. *Wallinga, supra* note 750 at 2-3.

⁹¹⁸ White Paper, supra note 791 at 7.

⁹¹⁹ Chemical Regulation Comparison, supra note 738 at 13.

The best solution to these problems would be to mandate a complete re-evaluation of existing substances as has been performed on pesticides.⁹²⁰ It would also be appropriate to require the submission of toxicological data for both new and existing substances in order to provide data for this evaluation. By making these amendments, the US and Canadian governments could abandon their reliance on voluntary measures and act in an anticipatory way to control risk. Currently, the US relies on the High Productive Volume (HPV) Challenge Program for data. As this program is completely voluntary, nearly 200 high-production-volume chemical companies have chosen not to participate.⁹²¹ Likewise, the Canadian government has relied on the voluntary submission of data from industry. It is unlikely that the producers of those substances which are most likely to cause harm will willingly participate in these voluntary measures, making these efforts futile. No company wants to be the agent of its own demise.

5.3.2.4 Revise the Standard by which Chemicals Are Restricted and Banned

If the US and Canada are determined to continue to use the risk-based approach, it is essential that the procedures and the standards by which chemicals are restricted or banned are re-evaluated. Under the current US and Canadian chemical legislation it is nearly impossible for any substances to be banned from use. Though the risk-based approach aims at controlling the risk rather than eliminating it, there are circumstances where no matter how minimal the exposure rates the risks are too great. A well known historical example of this is lead. Though the government originally aimed at limiting exposure, this reduction alone did not eradicate the negative health effects exposure had on children.⁹²² Since similar situations may occur with certain chemical exposures, it is important that the responsible agencies have the authority to ban products from use if necessary.

There are a couple of problems with the current standards used to restrict or ban a chemical in the US or in Canada. Both the lengthy procedure and the narrow definition of what is harmful make it difficult for the government to ban a substance. Also, in circumstances where the government has been able to determine that a chemical would be harmful to human health, the agency has either failed to or been unable to take the most restrictive action to prevent exposure.

The CEPA provides that a substance is CEPA-toxic⁹²³ if it poses a risk to human health, the environment, or the environment upon which life depends.⁹²⁴ If a substance meets these requirements, then it can be placed on the TSL.⁹²⁵ Once placed on the TSL, the Ministers have the option of proposing that the substance be controlled through regulations, pollution prevention plans, codes of practice, or non-regulatory guidelines, or be placed on the virtual elimination list. The virtual elimination list (VEL) is the most restrictive of the choices, and to be placed on this list

⁹²⁰ Though this is similar to the EU's REACH requirement of reassessment, the process differs because the risk-based approach will be used.

⁹²¹ Chemical Regulation Options, supra note 742 at 7.

⁹²² Landrigan 1999, supra note 171 at 2.

⁹²³ See page 116 for further information on CEPA-toxic.

⁹²⁴ CEPA, supra note 513 at S.64; Assessing and Managing the Health, supra note 735.

⁹²⁵ However the Cabinet must agree with this decision before it is finalized.

the substance must be persistent or bioaccumulative *and* inherently toxic to humans or inherently toxic to non-humans.⁹²⁶

As of February 2009, only eighty-five chemicals had been placed on the TSL and, since the government favours non-regulatory instruments, there is no certainty that exposure to these chemicals has been reduced.⁹²⁷ In fact, there is no legislative requirement for the government to take any action once a chemical is found to be toxic.⁹²⁸

The threshold by which a substance is to be placed on the VEL has been narrowly defined, therefore providing little authority to ban a substance. The limits set by which substances are bioaccumulative or persistent are at the upper limits of those standards found in the scientific community or used by the EU. These standards should be lowered to provide a better level of protection for children's health within the risk-based approach.

Even when a substance meets the stringent requirements of persistence, bioaccumulation, and inherent toxicity (PBiT), the substance is not automatically eliminated from use. Rather, a "level of quantification" (LOQ), which is "the lowest concentration [of the substance] that can be accurately measured using sensitive but routine sampling methods", is calculated for the substance using information on health and environment risks and economic matters.⁹²⁹ This arrival at a LOQ should be eliminated if the risk-based approach is to control risk. This subjective process of determining a LOQ undermines the over-all objective of the scientific prediction and mitigation of risk.

Only two chemicals have been placed on the VEL, one of which was never manufactured in Canada and is no longer imported into the country.⁹³⁰ Due to the limited use of this power, in their five year review Parliament found that "this section of the Act can only be described as an abject failure."⁹³¹ The recommendation was put forth that the negotiation of the LOQ should be eliminated.⁹³² It would be productive if the government did away with the LOQ completely and mandated the prohibition of use, production, or importation of these substances.⁹³³

Similar to that of the CEPA, the powers provided to the EPA to regulate and ban chemicals under the TSCA have been just as ineffective. Chemicals may be found toxic under the TSCA if they pose an "unreasonable risk", which can be proven by the EPA if they "find that there is a reasonable basis to conclude that the chemical presents or will

⁹²⁶ Canada, Environment Canada, *Management of Toxic Substances Track 1* (Ottawa: Environment Canada, 2009), online: Environment Canada http://www.ec.gc.ca/toxics/TSMP/en/track1.cfm> (last modified: 2 September 2009).

⁹²⁷ Wordsworth, supra note 742 at 36.

⁹²⁸ Ibid.

⁹²⁹ Wordsworth, supra note 742 at 40.

⁹³⁰ Chemicals currently on the virtual elimination list are Hexachlorobutadiene and Perfluorooctane sulfonate. Canada, Environment Canada, *Virtual Elimination List – Updated as of February 4, 2009* (Ottawa: Environment Canada, 2009), online: Environment Canada http://www.ec.gc.ca/CEPARegistry/subs_list/VEList.cfm> (last modified: 4 February 2009); *Five-Year Review, supra* note 749 at 44.

⁹³¹ *Ibid*.

⁹³² *Ibid*. at 45.

⁹³³ Currently the product may remain on the market for three to four years. *Ibid.* at 45.

present an unreasonable risk of injury to health or the environment".⁹³⁴ If a substance is found toxic then the EPA has the authority to regulate or prohibit use of the substance.

While this appears to provide the EPA the necessary authority to regulate and control risk, the procedural hurdles put in place by both the legislation and judicial interpretations of the EPA powers have made the prohibition tool rather ineffective. The TSCA holds that even when the substance is identified as posing an unreasonable risk, the EPA administrator must consider and publish data on: (1) the effects of the chemical on human health and the magnitude of human exposure to the chemical, (2) the effects of the chemical on the environment and the magnitude of the environment's exposure to the chemical, (3) the benefits of the chemical for various uses and the availability of substitutes for those uses, and (4) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.⁹³⁵ Based on this data, the administrator must select the least burdensome restraint on the chemical's use.

The findings of the asbestos case, *Corrosion Proof Fittings v.* EPA^{936} , placed further restraints on the EPA's authority to ban chemicals through its narrow interpretation of the agency's powers. Following a ten year examination into the impact asbestos makes on health, the EPA "determined that asbestos is a potential carcinogen at all levels of exposures – that is, that it had no known safe exposure level".⁹³⁷ However, because the court found that an outright ban was not the "least burdensome" of actions, the asbestos ban was overturned.⁹³⁸ Since this decision, the EPA has not utilized their powers to ban any chemicals.⁹³⁹

In order to provide an effective control of risk, Congress⁹⁴⁰ needs to revise the TSCA to include a definitive authority that permits the EPA to ban chemicals. The requirement that the "least burdensome" of restraints be used should be eliminated from the legislative language. The EPA's evidentiary burden of proof should be lessened, particularly if the agency maintains the onus of proof without any toxicological data submissions.⁹⁴¹

⁹³⁴ Chemical Regulation Options, supra note 742 at 11.

⁹³⁵ Chemical Regulation Comparison, supra note 738 at 23.

⁹³⁶ Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991). [hereinafter Corrosion Proof].

⁹³⁷ Chemical Regulation Options, supra note 742 at 12.

⁹³⁸ Corrosion Proof, supra note 936.

⁹³⁹ Chemical Regulation Comparison, supra note 738 at 24.

⁹⁴⁰ In 1983, 1988, 1994 Congressional Hearings highlighted limitations – 1988 Director EPA noted that "it is clear to me that the current level of accomplishment of the existing chemicals programs is inadequate". "The Promise and Limits of the United States Toxic Substances Control Act" *Lowell Center for Sustainable Production* (10 October 2003).

⁹⁴¹ Chemical Regulation Options, supra note 742 at 14.

5.3.3 Amendments To Be Made To The Legislation In General

There are a number of issues related to the continued use of the risk-based approach as it applies to both the pesticide assessment and the chemical assessment. The following sub-sections offer recommendations of ways that the risk-based approach could be improved to provide better protection for children's health.

5.3.3.1 Addressing The Knowledge Gap

While the point has been made throughout this thesis that there is a need to increase awareness and add to the understanding of the impact that chemicals and pesticides have on children's health, the importance of this cannot be over emphasized. There are a number of procedural amendments and research-based actions that could be taken by both countries to aid in a more adequate estimate of risk in the assessment process. By increasing research on children's health and requiring a greater number of toxicological tests, the EPA and Ministries of Health and the Environment will be able to reduce the knowledge gap⁹⁴² that currently distorts the accuracy of the assessment process.

As already discussed in this chapter, it is clear that there is a need for Canada and the US to increase the number of toxicological tests required for new applicants. This is especially true for chemical assessments as the basis of the current evaluation as risk modeling based on chemical structure. However, there is more than a call for increased animal bioassays. The governments need to improve the quality of toxicological tests. New models need to be developed and used to better predict the impact chemical exposure has on prenatal and postnatal development, particularly the impact these substances have on the organ, cellular, and molecular levels of development.⁹⁴³ "These new models of developmental toxicity testing need to generate data on organ systems that have not been adequately addressed in the past, for example, the nervous, immune, respiratory, reproductive, cardiovascular, and endocrine systems."⁹⁴⁴

Areas of toxicological testing that need to be included in standard testing practices include that of neurotoxicity, endocrine disruption, reproductive disruption, and immune dysfunction. Though such studies are triggered in some circumstances, it is not that common that the agencies review the harm substances have on these biological systems. The recent realization that endocrine disruptors are making a measureable impact on children's health illustrates how important it is that both governments modify their risk-based approach to mandate consideration of these tests. The fact that specific cause-and-effect toxicological tests are not required perpetuates the current knowledge gap and weakens the accuracy of the risk-based approach. In addition to increasing the number of animal bioassays required for submission, the government needs to support research on the relationship environmental substances have on developmental systems. There also remains a "need for a more comprehensive understanding of the normal physiological processes associated with reproduction and development in those wildlife species studied."⁹⁴⁵

⁹⁴² Wallinga, supra note 750 at 2.

⁹⁴³ Landrigan 2004, supra note 12 at 262.

⁹⁴⁴ Landrigan 2004, supra note 12 at 262; Landrigan 1999, supra note 171 at 1.

⁹⁴⁵ R.L. Cooper & R.J. Kavlock, "Endocrine Disruptors and Reproductive Development: A Weight-of-Evidence Overview" (1997) 152 J. Endocrinol. 159 at164.

Additionally, it is essential that the governments increase their knowledge on the rate of childhood exposures. As already mentioned, up-to-date information surveys on diet, residential exposures, and behaviours need to be conducted. In addition, biomonitoring, longitudinal cohort studies⁹⁴⁶, and breast milk surveys should be integrated into the assessment process. Although the Canadian and US governments have made the initial efforts to gather this type of information, each has failed to maintain its accuracy or require that it be used in standard setting for the risk-based approach. This is in contrast to the EU measures where data from these types of studies have prompted regulatory action.

The US and Canadian governments should also create a national database for tracking disease rates and their relation to socio-economic differences, environmental exposure rates, urban and rural settings, and policy interventions, which will aid in determining the causational relationship between toxins and chronic health conditions.⁹⁴⁷ Not only will this information provide context as to the increased rates of chronic health conditions that may be associated with toxic exposure, but it may provide context as to whether rates are higher in regions where use is greater, such as agricultural settings. In addition, this information will offer a case-control study as in which those areas in North America where pesticide use has been restricted should see a decrease in chronic health conditions associated with exposure over time. For instance, two provinces in Canada, Ontario and Quebec, have made efforts to ban pesticides thought to cause childhood cancers. Similarly, efforts made by US states and cities allow for a type of case-control study. If the disease rates decrease over a span of time in those areas where exposure was eliminated, this may help prove the hypothesis that pesticides cause cancers.

Both governments should increase their efforts to gather data on aggregate and cumulative exposures. This information is essential since it better reflects the impact exposure has on children. It is also important that the governments abandon the notion of substance-by-substance evaluation.⁹⁴⁸ There needs to be an effort to take into consideration that children are constantly exposed to a number of toxins, often at low levels. The assessment needs to be broadened to include more than just similar chemicals or similar pesticides. It should also include other pollutants. A child's body does not differentiate between the classes of toxins, and as many harm the same organs in a body, it is important to take this impact into consideration when setting standards.

These suggested efforts to gather more toxicological data and increase knowledge about children's environmental health are part of a larger scheme that aims at being proactive. Much of the current regulatory efforts by both countries are reactive, particularly when considering the chemical assessment process. In order for the risk-based approach to function properly and actually control risk, it must have the data before exposure has already occurred. For instance, it has been found that the manufacturing and exposure to the chemical perfluorocarbon (PFCs) used to create non-stick coatings for cookware and clothing has tainted the drinking water of Twin Cities, Minnesota.⁹⁴⁹

⁹⁴⁶ *Phipps, supra* note 2 at 46.

⁹⁴⁷ *Ibid.* at 43.

⁹⁴⁸ Perfluorinated Substances, supra note 901 at 2.

⁹⁴⁹ Wallinga, supra note 750 at 3.

Since production and use, this substance has been linked to damage to the heart and brain development.⁹⁵⁰ "As with many other TSCA chemicals, comprehensive toxicity testing of perfluorocarbons lagged behind their commercial use by decades."⁹⁵¹ If the assessment process was one that was preventative, then the EPA would have had a better understanding of the effect these substances have on health before pollution had occurred. There are a number of new toxins for which the health impact remains unknown, such as PBDEs and plasticizers.⁹⁵² It is important that these substances, and others, are evaluated before the harm has progressed to levels similar to that of PCFs and POPs.

5.3.3.2 The US And Canada Should Use The Substitution Rule

The objective of the risk-based approach is to use restrict exposure to a risk that was deemed unacceptable if uncontrolled. The outcome is a risk that is acceptable. One way by which this can be done is through use of the substitution rule. Mentioned in the context of the EU's hazard-based approach, this principle holds that the least caustic toxin should be registered, while those that pose a greater harm are not. The substitution rule not only offers a greater level of protection for children's health, but also instigates the innovation of safer chemicals in a way that the current risk-based approach does not.

Though it is affiliated with the hazard-based approach, the substitution rule can aid in the control of unacceptable risk in the risk-based approach by ridding the exposure to the more caustic and less efficient substances. The legislative language can be amended to provide that the agency may refuse to register a product "where there is a less harmful yet equally effective registered alternative pest control [or chemical] product".⁹⁵³ The definition of "acceptable risks" and "unreasonable risks" should be modified to exclude the continued use of substances that pose a risk but offer no greater technical capacity. There is no reason that "unacceptable risks" under the risk-based approach cannot include substances which are more caustic but no more effective than another substance.

To lessen the concern from the chemical and pesticide industries, the governments could mandate that this rule only apply in specific circumstances. Timelines could be provided whereby the manufacturer of an existing substance already on the market, which is found less effective or less safe than a newer chemical, has a period to phase out continued production and sale of this substance. In addition, the caveats to the rule could include that it is banned from use only in instances where there are safer *and* more efficient substances. The rule could allow the continued registration of a product in specific instances where the competition is as safe, but not for use in other areas where there are safer alternatives – that is, registration for specific uses only.

⁹⁵⁰ U.K., Environment Agency, *PFCs (Perfluorocarbons)* (London: Environment Agency, 2009), online: Environment Agency http://www.environment-agency.gov.uk/business/topics/pollution/39091.aspx (date accessed: 1 November 2009).

⁹⁵¹ Wallinga, supra note 750 at 3.

⁹⁵² P. Cameron & S. Smolka, *Toxic Inheritance More than 300 Pollutants in Breast Milk – Time for a New Chemicals Policy* (Imprimerie Fortemps, Belgium: Friends of the Earth Europe, 2005) at 28.

⁹⁵³ T. McClenaghan & K. Cooper, *Brief to the Senate Committee on Social Affairs, Science and Technology Reviewing Bill C-8, Pest Control Products Act* (Toronto: Canadian Environmental Law Association, 2002) at 7.

The substitution rule could also be used in a limited fashion, only applying to non-essential residential substances.⁹⁵⁴ This would include pesticides for laws, grass, golf courses, recreational areas, schools, daycares, and in homes as well as chemicals that are for home use, such as cleaning supplies.⁹⁵⁵ Because these are the main sources of childhood exposures to chemicals and pesticides, restricting such substances would have a high impact on children's health.⁹⁵⁶

5.3.3.3 Redefining "Acceptable" And "Safe" Risk

The risk-based approach is based on the idea that certain risks are "acceptable" to society. The method by which this terminology of "acceptable" is defined, however, has failed to truly incorporate matters that society would consider in defining this term. For instance, it is highly unlikely that a parent would assess a substance's harm based solely on the likelihood of cancer. Other considerations would come into play, such as the chance of other chronic health conditions, the impact these diseases would make on the family and the household income, and whether they could handle the emotional impact of an ill child. Yet, none of these issues have been incorporated into the risk-based approach. If the approach is to accurately assess "acceptable risks" it is necessary that the current definition be broadened. An amendment should be made to the risk-based approach to include a cost-benefit assessment.

In order to truly determine what risks are "acceptable", the governments should include the costs of illness, the costs to government, the costs to the ecosystem, and the costs to businesses as well as the benefits associated with each of these groups.⁹⁵⁷ This cost-benefit analysis would take into consideration the costs of illness (COI) and the WTP for these standards.

⁹⁵⁴ Specific guidelines should be developed to ensure that this rule is not used subjectively. Though this should be performed no matter the approach, it is especially important in the risk-based approach as it is based on the notion that science and objectivity are key.

⁹⁵⁵ Along these same lines, Canadian provinces Ontario and Quebec have instituted a provincial ban on the use and sale of specific cosmetic pesticides. Both provinces have banned pesticides for use on "lawns, vegetable and ornamental gardens, patios, driveways, cemeteries, and in parks and schools yards". This outright ban of non-essential pesticides is in many ways a hybrid of the two approaches. For all other pesticides, the risk is controlled, but those pesticides that are merely cosmetic are eliminated completely. If this approach were to be integrated into the federal risk-based approach by Canada and the US, industry would have to focus their innovative capacity on industrial and agricultural products – an area where the purchaser has greater expertise as to the value of the item.

⁹⁵⁶ One of the problems with the continued use of the risk-based approach is that it is does not promote innovation of better or of safer toxic substances. Currently, each new substance is evaluated independently, with no consideration given to whether it reduces the harms associated with products currently on the market. This failure to provide for innovation, both in a technical sense and in a way that results in less harm, results in a less protective approach.

The EU recognized that their prior system, like that of the US and Canadian approach, offered no incentive to be innovative in a way that would produce safer chemicals. Because of this, when amending their legislation, the EU aimed at stimulating innovation and tied this objective to the development of safer chemicals. The EU government intends to ensure that their current chemical sector grows, but so that this goal no longer contradicts the protection of health, they have put in place the substitution rule. The idea is that the safer and more efficient substance will be registered, whereas those that offer nothing new will not be certified. *White Paper, supra* note 791 at 32.

⁹⁵⁷ Wallinga, supra note 750 at 3.

The costs and benefits of the policy on children's health would be based on the net cost/benefit to society.⁹⁵⁸ This would include the financial costs of medical treatment and the value of time lost.⁹⁵⁹ These costs/benefits would need to be assessed with children in mind, which is different than an assessment of adults. For example, adult estimates of time lost would be based on productivity lost, however, when children are ill the time lost includes that of the child and a care-giving adult. "To the extent that a caregiver is more likely to be involved when a child is recuperating, the total value of lost time is likely to be higher for a child's illness than for an adult's."⁹⁶⁰

Estimates of children's environmental health costs indicate that COI is substantial. In Minnesota, it is believed that \$1.5 billion was spent on childhood asthma, learning and behavioural disorders, cancer, lead poisoning, and birth defects per year.⁹⁶¹ It has been estimated that the cost of learning disabilities in Canada is over \$700 billion.⁹⁶² An estimate of money saved from the EU's REACH policy due to the avoidance of severe health effects is \pounds 210,000,000 – 2,500,000,000 by the year 2017.⁹⁶³

In addition to the COI for children's chronic health conditions due to environmental exposures, estimates of society's willingness to pay for risk aversion to aid children should be incorporated into the cost-benefit analysis. Parents, and society in general, are more likely going to be "risk averse with respect to their children's well-being than they are regarding their own".⁹⁶⁴ Also, in all the computations, a child's expected life span and lifetime wealth should be used in place of the current estimates based on a healthy white male who lives seventy years.⁹⁶⁵

As a part of the cost-benefit analysis, the costs associated with future site clean-up, water purification, disposal of chemical waste, and government costs should be assessed.⁹⁶⁶ This cost-benefit analysis, however, should also include the costs to society of imposing more stringent standards. Any financial gain involved in market-based incentives or registration fees should be included in this assessment of costs as it may off-set some of the burden.⁹⁶⁷ The costs associated with this would include lost employment, increased food costs, and the risks associated with the

⁹⁵⁸ J. Nathwani & J. Narveson, "Three Principles for Managing Risk in the Public Interest" (1995) 15:6 Risk Anal. 615 at 615.

⁹⁵⁹ U.S., Environmental Protection Agency, *Children's Health Valuation Handbook* (Washington, D.C.: Environmental Protection Agency, 2003) at 32.

⁹⁶⁰ *Ibid*.

⁹⁶¹ Wallinga, supra note 750 at 3; Health and the Environment Upstream Connections to Create Healthier Communities (Blue Cross and Blue Shield of Minnesota at 30, online: Blue Cross < http://www.bcbsmnfoundation.org/> (date accessed: 14 November 2009).

⁹⁶² *Phipps, supra* note 2 at 25.

⁹⁶³ Pedersen, supra note 815 at 7.

⁹⁶⁴ Children's Health Valuation Handbook, supra note 962 at 28.

⁹⁶⁵ *Ibid.* at 30.

⁹⁶⁶ Ibid.

⁹⁶⁷ Estimated that \$25-30 million per year generated by fees from Chemical Management Plan in Canada. *Phipps, supra* note 2.

substitute substance.⁹⁶⁸ An example of this kind of cost-benefit analysis can be provided by the EU's REACH policy which has shown that the European chemical industry's annual sales were $\mathfrak{S86}$ billion worldwide, the annual direct costs of REACH will be $\mathfrak{E10}$ million, the health benefits over thirty years will be $\mathfrak{S0}$ billion, the extra health and environmental benefits over twenty-five years will total $\mathfrak{S5}$ billion, and the benefits to worker's health will be $\mathfrak{S.5}$ billion over ten years.⁹⁶⁹

In order to incorporate this type of analysis into the risk-based approach, the government would have to amend the current policy. Guidelines and policy procedures would have to be developed clearly outlining what costs are to be included. By integrating this assessment of costs and benefit into the current risk-based approach the US and Canada may be able to actually set a level of acceptable risk that is not so removed from reality. The current *de minimis* standard fails to account for the costs for the loss of a child's life. Evidence indicates that this loss is often viewed by society as a greater loss than that of an adult's.⁹⁷⁰ This estimate of cost and benefit does not undermine the purpose of the risk-based approach, but rather aids in defining what an "acceptable risk" is.

5.3.3.4 Education Of The General Public

The premise of the risk-based approach is that by estimating harm and setting standards, through label instructions, MRLs, application recommendations, etc., the risks will not exceed what has been deemed acceptable. Currently, the government focuses on setting standards and providing label instructions and relies on the consumer for accurate application of the product. Evidence indicates that consumers often apply chemicals and pesticides without reading labels, therefore exceeding the proposed standard of exposure set by the government. In order to fulfill the aim of controlling the risk, it is essential that this include educating the general public as to the harms that are associated with misuse of the substances.

In addition to the above-mentioned procedural changes to the risk-based approach, the Canadian and American governments should increase the awareness of the potential harms toxic substances have on children and how best to prevent unnecessary exposures. This educational campaign should aim at providing caregivers and parents with information on how best to handle pesticides and chemicals, areas where the highest level of exposures occur, and what the government's role in providing safety is.

There is often an assumption by the general public that because the chemical or pesticide is for sale within the US or Canada it is safe.⁹⁷¹ As this thesis has outlined, legal and safe are not the same. Rather, legal means that standards which result in risks that are deemed "acceptable" have been set. It is important that parents, teachers, and caregivers

⁹⁶⁸ G. Gray & J.K. Hammitt, "An Exploratory Analysis of the Public Health Effects of a Ban on Organophosphate and Carbamate Pesticides" (2000) 20:5 Risk Anal. 665 at 665.

⁹⁶⁹ M. Contiero, *Toxic Lobby How the Chemicals Industry is Trying to Kill REACH* (Greenpeace International, 2006), online: Greenpeace http://www.greenpeace.org/international/press/reports/toxic-lobby-how-the-chemical (last modified: 4 May 2006).

⁹⁷⁰ M. Dickie "Parental Altruism and the Value of Avoiding Acute Illness: Are Kids Worth More than Parents?", online: University of Central Florida < http://www.econ.ucsb.edu/~tedb/Courses/UCSBpf/readings/dickieulery.pdf> (last modified: December 2002).

⁹⁷¹ J.A. Tickner, "Challenges and Opportunities for Effective Implementation of TSCA" (US EPA National Pollution Prevention, Lowell, Massachusetts, July 2004) at 2.

become aware of this differentiation. These standards are set based on calculation of the average exposure of a person on a daily basis, to establish an acceptable level of intake that is thought to produce with "reasonable certainty" no harm to health. The government must make clear that there are a number of unknowns associated with chemical and pesticide risk assessments as well as make known that chemicals do not undergo a full risk assessment prior to market availability.

Information needs to be disseminated on the appropriate use of chemicals and pesticides in residential settings. For instance, the importance of reading labels and applying the suggested amount of the substance to ensure that children do not exceed the daily recommended amount should be stressed to caregivers. Another example is that in calculating the MRLs for some produce, the government assumes that the produce is washed. It is estimated that six percent of consumers never wash any of their produce before consumption. This number increases depending on the fruit or vegetable, with the highest percent of a specific fruit not washed being thirty-five percent of those surveyed never washing melon.⁹⁷² Though washing or peeling the produce does not eliminate all pesticides, because many are systemic, it does reduce a child's ingestion of pesticides, so caregivers should be reminded of this.⁹⁷³

Caregivers should also be given information about the probability of a child's exposure in a school, daycare, or recreational setting. While a number of states and provinces have adopted legislation that restricts pesticide use on school grounds, there remain a number of regions where parents are not notified of pesticide use or where indoor pesticide use has not been addressed through policy.⁹⁷⁴ The US "GAO documented over 2,300 reported pesticide poisonings in schools between 1993 and 1996".⁹⁷⁵ This number can be reduced if the schools notify parents and spray when children are not around.⁹⁷⁶ If parents are given notice, and are educated as to how pesticide transfer may be reduced (i.e. cleaning clothes immediately, removal of shoes before entering house, washing of hands), childhood pesticide exposure can be reduced without any real policy changes at the federal level. Parents, school teachers, and caregivers should be informed of the possible alternatives to pesticides and chemicals, such as IPM, which aims at prevention and promotes the least caustic control of pests.⁹⁷⁷

Both the EPA and the Ministry of Health have launched efforts to educate parents and caregivers. Their websites contain a great deal of information on the safe handling of chemicals and pesticides, as well as offering tool kits that

⁹⁷⁵ *Ibid.* at 19.

⁹⁷⁶ *Ibid*.

⁹⁷² J. James et al., *Microbial Hazard Identification in Fresh Fruit and Vegetables* (Hoboken, New Jersey: John Wiley & Sons, Inc., 2006).

⁹⁷³ U.K., Food Standards Agency, *Your Questions on Pesticides* (London: Food Standards Agency, 2004), online: Food Standards Agency < http://www.food.gov.uk/safereating/chemsafe/pesticides/pesticidesmainqa/#h_407587> (last modified: 13 March 2004).

⁹⁷⁴ K. Owens & J. Feldman, "The Schooling of State Pesticide Laws-2000" (2000) 20:2 Pestic. You 16 at 18.

⁹⁷⁷ U.S., Environmental Protection Agency, *Integrated Pest Management (IPM) Principles* (Washington, D.C.: Environmental Protection Agency, 2009), online: Environmental Protection Agency < http://www.epa.gov/opp00001/factsheets/ipm.htm> (last modified: 10 September 2009).

attempt to ensure homes are as safe as possible.⁹⁷⁸ While this data is valuable, it is important that funding to distribute this information in other ways is made available. Low socio-economic groups, for example, may not have access to these sites.

Paediatricians and nurse practitioners are one way that this information can be made available. For instance, the American Academy of Pediatrics has developed literature on environmental health issues.⁹⁷⁹ These health care workers are also able to aid in gathering information on environmental health issues if they have been trained to take routine environmental history on children.⁹⁸⁰ By gathering this information and pursuing research, this group can aid in policy-making. For example, in Canada "[t]he Canadian Cancer Society, Canadian Association of Physicians for the Environment and the Registered Nurses Association of Ontario have each spoken out against cosmetic pesticide use" and this has influenced provincial policy.⁹⁸¹

In an effort to educate the general public about the risks involved, the US and Canadian government should increase transparency regarding what the assessment process entails. This should include an explanation concerning why specific chemicals and pesticides are permitted for use within their jurisdiction but have been banned in other OECD nations.⁹⁸²

5.4 Concluding Remarks

Recent epidemiological data indicates that children are more likely to be negatively affected by toxic exposures; however, there remain a great number of unknowns associated with environmental exposures and health outcomes. International efforts have brought attention to the issue of children's environmental health, but have failed to result in any definitive outcomes. Because of this, the responsibility lies with the federal and supranational governments to protect children from undue harm.

What has been central to this thesis is that the methods by which governments have chosen to assess environmental risks do not necessarily result in the same level of protection for children's health. Canada and the US have relied on a risk-based approach, with the purpose of controlling the risk. The premise behind this approach is that by relying on a scientific process one can determine what levels of exposure result in no significant harm. As the case-studies of pesticide and chemical policies have shown, this dependence on science does not always result in the most stringent of standards, the reason being that there are too many scientific unknowns.

⁹⁸¹ N. Arya, "Pesticides and Human Health" (2005) Can. J. Public Health 89 at 92.

⁹⁷⁸ Phipps, supra note 2 at 70; Canada, Health Canada, *Indoor Air Quality – Tools for Schools Action Kit for Canadian Schools* (Ottawa: Health Canada), online: Health Canada http://www.hc-sc.gc.ca/ewh-semt/pubs/air/tools_school-outils_ecoles/health-sante_e.html (date accessed: 14 May 2008); U.S, Environmental Protection Agency, *Indoor Air Quality Tools for Schools Kit* (Washington, D.C.: U.S, Environmental Protection Agency), online: U.S, Environmental Protection Agency http://www.epa.gov/iaq/schools/toolkit.html (date accessed: 14 May 2008).

⁹⁷⁹ Wallinga, supra note 750 at 4.

⁹⁸⁰ *Ibid*.

⁹⁸² Though not the focus of this thesis, this should also include disclosure as to ingredients in chemical products and non-active ingredients; *Boyd, supra* note 581.

Though both Canada and the US have attempted to address some of the uncertainties with use of mathematical adjustments, such as additional safety factors, this does not resolve the problem of inaccuracies. Not only are the unknowns associated with cause and effect problematic, but the data used on childhood daily exposure is lacking. The use of an additional safety factor alone does not excuse these many ambiguities in the scientific evaluation of substances.

The problems with the risk-based approach extend beyond its reliance on a mathematical equation with too many unknown variables. The risk-based approach is narrowly defined, considering the harms and risks associated with each individual substance. It fails to minimize exposure to the greatest extent possible. In fact, the objective of the risk-based approach is to provide the least restrictive standard. The result is that industry rights are protected over children's health. For instance, the TSCA chemical test rule ensures that companies are not required to provide more data than necessary. Similarly, the risk assessment process for pesticides presumes no harm until evidence demonstrates otherwise. These aspects of both the chemical and the pesticide assessment procedures indicate that corporate rights have priority over health.

Advocates of the risk-based approach hold that by using this scientific process, they have eliminated subjectivity. This is far from true. A NAS report on the US risk assessment process highlighted over fifty different forms of "inference choices", including how it is up to the risk assessor to determine what weight is given to animal effects compared to human effects.⁹⁸³ Furthermore, this use of "science" is a political choice. It has been said by risk assessors that "[t]he government asks certain questions as if they were scientific questions, when actually they are political questions, and sometimes we mix things up and try to respond to political questions using strictly scientific criteria".⁹⁸⁴ There are many examples of how "political" this scientific process is. For instance, there are a multitude of substances which have been banned in European countries but have not been phased out in Canada or the US. Similarly, Canada has indicated that it is willing to reduce MRLs that are higher than that of the US in an effort to aid in NAFTA trade.⁹⁸⁵ The already mentioned asbestos case illustrates how the interpretation of science varies.⁹⁸⁶

Because of children's physical and biological vulnerabilities, it is essential that the approach taken to environmental risk assessment offer the most protective, preventative, and cautionary outcomes. For these reasons, the hazard-based approach is preferable. Though it is political, it is based on the same science as the risk-based approach is, but it has a cautionary overlay which better protects children's health. This approach eliminates risks, rather than controlling them. This removes many of the concerns associated with the uncertainties found in the scientific process. If the product is not available, then any knowledge gaps about the health impact it might have made at

⁹⁸³ *Phipps, supra* note 2 at 70; Canada, Health Canada, *Indoor Air Quality – Tools for Schools Action Kit for Canadian Schools* (Ottawa: Health Canada), online: Health Canada <<u>http://www.hc-sc.gc.ca/ewh-semt/pubs/air/tools_school-outils_ecoles/health-sante_e.html></u> (date accessed: 14 May 2008); U.S, Environmental Protection Agency, *Indoor Air Quality Tools for Schools Kit* (Washington, D.C.: U.S, Environmental Protection Agency), online: U.S, Environmental Protection Agency <<u>http://www.epa.gov/iaq/schools/toolkit.html></u> (date accessed: 14 May 2008).

⁹⁸⁴ Wallinga, supra note 750 at 4.

⁹⁸⁵ Ibid.

⁹⁸⁶ N. Arya, "Pesticides and Human Health" (2005) Can. J. Public Health 89 at 92.

specific doses is not of concern. Because the process is openly subjective, the decisions do not lie with the risk assessor alone. Politicians have made decisions that determine what thresholds of caution need to be heeded. Most importantly, because the hazard-based approach is preventative, it offers an overarching reduction in pollution rather than a substance-by-substance review. This will result in lower exposure rates to children, and therefore, reduce chronic health conditions and even deaths.

The EU has recognized that there are too many unknowns in the risk assessment process. The government has identified that the impact these uncertainties have on children are measurable, as they have stated that "an individual's loss of just one IQ point [from neurotoxic chemicals] is associated with an overall reduction in lifetime earnings of more than 2%".⁹⁸⁷ The government estimates that the medical cost of aiding children with brain damage from toxic exposures is 52.6 billion dollars a year.⁹⁸⁸ In an effort to reduce the costs, both financially and socially, that these exposures may have on the EU, the EU government has decided that when faced with a possible threat to human health it is better to act cautiously. To provide similar standards in Canada and the US, both nations need to adopt a hazard-based approach. Possibly as the US moves towards a public health insurance system⁹⁸⁹ and as costs and benefits are analyzed, these governments will see that this choice is not only better for children's health but for society as a whole.

⁹⁸⁷ Though not the focus of this thesis, this should also include disclosure as to ingredients in chemical products and non-active ingredients; *Boyd, supra* note 581.

⁹⁸⁸ "Children are not Adequately Protected by Current Chemicals Regulation" *Health & Environment Alliance* (12 June 2007), online: Health & Environment Alliance <

http://www.chemicalshealthmonitor.org/IMG/pdf/01_Children_are_not_adequately_protected_by_current_chemicals _regulation.pdf> (last modified: 12 June 20070.

⁹⁸⁹ U.S., Health Reform, *Health Insurance Reform* (Washington, D.C.: Health Reform, 2009), online: HealthReform.Gov < http://www.healthreform.gov/> (date accessed: 12 November 2009).

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