

The Challenge of Substances of Emerging Concern in the Great Lakes Basin: A review of chemicals policies and programs in Canada and the United States



A report prepared for the
International Joint Commission
Multi-Board Work Group on Chemicals of Emerging Concern in the Great
Lakes Basin

Prepared by
Canadian Environmental Law Association
and
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Preface

This report was commissioned by the International Joint Commission (IJC) Work Group on Chemicals of Emerging Concern in order to assess the ability of existing policy structures to identify, assess, control, and prevent exposures to chemicals of emerging concern in the Great Lakes. In conjunction with the Canadian Environmental Law Association and the Lowell Center for Sustainable Production, the Work Group defined the scope of policies and programs that were to be included in this analysis. Given time and limited funding for the analysis, this scope included only policies and programs that broadly address the inherent hazards and exposures to a particular substance or group of substances (including identification, testing, and prevention – also called “chemicals policy” or “chemicals management policy”) and excluded media-specific policies and programs (i.e., water, air, sediment) as well as those that address only the end-of-pipe management of emissions. Although the report is substantially dedicated to the analysis of a limited number of policies and programs, the companion inventory highlights over 50 Canadian policies (including regulations and statutes) and programs, and over 200 U.S. municipal, state, regional, and federal policies and programs. This inventory provides a robust high-level summary of the breadth and depth of existing policy structures in the U.S. and Canada. Due to the sheer number of these policies, the inventory does not include an analysis of the strengths, weaknesses, or adequacy of each one, but rather summarizes areas where policies do exist. We recognize that, given the wide range of policies and programs in the Great Lakes region, there may be some policies and programs that were not identified in our research.

Despite the report’s focus on preventive, upstream approaches to chemicals of emerging concern in the Great Lakes, we recognize that a multi-pronged approach is necessary in order to establish a long-term, sustainable solution to the problem of chemicals of emerging concern in the Great Lakes. This approach must not only embrace ideas of pollution prevention, toxics use reduction, alternatives assessment, substitution, and green chemistry, but must also include the use of pollution control mechanisms and wastewater treatment technologies. Ultimately, given the societal need for some chemicals of emerging concern (such as pharmaceuticals) and the limited availability of preventive options in many cases (for example, pharmaceutical degradation or green chemistry alternatives for critical industrial or agricultural processes) upstream approaches must be utilized in conjunction with effective proactive management policies and controls. However, the report’s focus on preventive, upstream approaches was undertaken for a number of important reasons:

- The mandate from the Work Group was to examine policies and programs that could advance the dialogue on chemicals management policy options in the Great Lakes, building on the preventive and precautionary GLWQA vision of virtual elimination;
- Current end-of-pipe management regulatory structures have been reasonably effective at controlling many types of industrial point source emissions; however,

- most of the chemicals of emerging concern are dispersive, non-point, product-based emissions that cannot be effectively controlled through regulatory structures that focus primarily on end of pipe controls from industrial sources;
- Although wastewater treatment technologies are an essential component to the effective management of chemicals of emerging concern in the Great Lakes, such facilities were not designed to degrade these contaminants (which may hurt biological treatment processes). Hence, currently existing technologies cannot eliminate the threats posed by these chemicals, they can only reduce them and possibly transfer them from a water problem to a land disposal problem (for example biosolids); and
 - Given our increasing knowledge of chemicals use, effects of low dose exposures, evidence of presence of such chemicals in the environment and the human body, and prevention options, an upstream approach serves to broaden current burdensome and slow, chemical-by-chemical risk-based approaches to chemicals management by highlighting the need to consider the inherent hazards of a substance while at the same time using information about use and exposure to rapidly prioritize a large number of chemicals of emerging concern for preventive actions.

Acknowledgement

The Lowell Center for Sustainable Production and the Canadian Environmental Law Association want to thank and acknowledge the work of the members of the IJC Work Group on Chemicals of Emerging Concern for their focus and dedication to addressing a very complex scientific and policy problem confronting the Great Lakes Basin. The members of the IJC Work Group have provided substantial insight and recommendations on the draft reports. While the report may not have been able to address every issue and question raised in a comprehensive manner, the input and comments received by the authors of the report from IJC Work Group members were valuable to the production of the report. The quality of the final report was significantly improved with this level of contribution. The conclusions expressed in this report, while influenced by the Work Group, are ultimately the responsibility of the Canadian Environmental Law Association and the Lowell Center for Sustainable Production. This analysis builds on several decades of experience working with government, industry and non-profit sectors in Canada, the U.S., and internationally on chemicals assessment and management policies and practices.

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Executive Summary

For many decades, the Great Lakes Basin has been a significant repository of both direct and indirect sources of pollutants. The health and ecosystem impacts from these pollutants are well documented. Over the past two decades, targeted actions to control many industrial, municipal, and agricultural sources of contaminants have occurred, resulting in significant improvements in Great Lakes water quality. While industrial releases of pollutants continue to be a threat to the quality of the Great Lakes ecosystem, now there are new threats of pollutants that are emerging.

Scientists are beginning to recognize new, previously unaddressed chemicals in the Great Lakes – so called “chemicals of emerging concern.” These chemicals are coming from products, resulting in multiple, dispersive, and non-point sources. This change from reducing emissions from industrial *processes* to reducing emissions from the use and disposal of *products* poses new challenges for the protection of the Great Lakes. While the exact pathways of many of these chemicals of emerging concern, be it from long range transport, rain, waste water, or house dust, are not always well understood, often the original source is a particular product type – a pharmaceutical, a pesticide, a cosmetic, a consumer item (for example, a sunscreen, a couch, a plastic toy, etc.). An intentional and focused consideration of the sources of these chemicals and their control is necessary in efforts to ensure the quality of the Great Lakes ecosystem is protected.

The Canadian Environmental Law Association (CELA) and the Lowell Center for Sustainable Production have been asked by the International Joint Commission’s (IJC) Multi-Board Work Group on Chemicals of Emerging Concern in the Great Lakes to identify and analyze national, state/provincial, and regional policies and programs that address the identification, assessment, control, and prevention of the range of chemicals of emerging concern. As part of the project, the two organizations prepared inventories of the relevant programs and policies for Canada and the United States (U.S.) currently enacted in both countries. These inventories along with the results of this analysis and database of scientific studies on chemicals of emerging concern will serve to inform recommendations made by the Work Group to the IJC Commissioners. The analysis builds on several decades of combined experience in chemicals assessment and policy in Canada, the U.S., and internationally.

For the purposes of this report, we use the term “chemicals of emerging concern” to include:

- 1) Chemicals identified in the chemicals of emerging concern report developed for the International Joint Commission;
- 2) Chemicals which are persistent or bioaccumulative or toxic according to criteria outlined in the *Great Lakes Water Quality Agreement*;

3) Chemicals that may or may not have been detected in the Great Lakes Basin, but which are included in the categories of chemicals of emerging concern, such as veterinary drugs; and

4) Those chemicals that have been shown to occur widely in the environment and also identified as being a potential environmental or public health risk.

While these chemicals may not pose a high risk at this point in time, they do raise concerns about long term exposures and impacts.

CELA and the Lowell Center for Sustainable Production conducted their analysis based on the prevention-oriented foundations established through the *Great Lakes Water Quality Agreement*, which the governments of Canada and U.S. have committed to implement through bi-national efforts. This vision has been further elucidated and broadened through reports and statements of the International Joint Commission and national pollution prevention policies, which state that prevention through source reduction should be the first priority for managing waste and emissions. Building on the ultimate goal of prevention yet highlighting the pragmatic need for a multi-pronged approach to pollution prevention and control of chemicals of emerging concern in the Great Lakes Basin, our analysis focuses on the following questions:

1. To what degree do existing policies and programs facilitate rapid identification and assessment, prioritization, decision-making, and prevention for a broad range of chemical types before they become chemicals of concern?
2. What are the specific challenges of addressing chemicals of emerging concern in the region?
3. What policies and approaches are required to address chemicals of emerging concern in the Great Lakes Basin?

Different categories of substances are regulated in both the U.S. and Canada under different policy regimes and administrative agencies. Furthermore, there are differences in the federal and regional policy structures for regulating chemicals in Canada and the U.S. In Canada, the management and control of chemical substances is primarily regulated at the federal level, with provincial programs that focus primarily on end of pipe measures. In the U.S., both the federal and state governments have implemented significant programs to regulate chemicals and pesticides. As such, the report consists of the following four main sections:

1. An overview of the History of Efforts for Addressing Persistent Chemicals of Concern in the Great Lakes;
2. A review and analysis of Canadian policies and programs relating to the various categories of chemicals of emerging concern. This review and analysis focuses solely on federal level policies in Canada, with an emphasis of the Canadian Chemicals Management Plan (CMP);

3. A review and analysis of U.S. policies and programs relating to the various categories of chemicals of emerging concern. This review and analysis focuses on both federal and Great Lakes state policies relating to such chemicals; and
4. General observations on the challenges and gaps that constrain the ability to take national and regional action to prevent chemicals of emerging concern from entering the Great Lakes Basin and a roadmap for next steps.

Our analyses of Canadian and U.S. policies have identified policy gaps and a disjointed, chemical-by-chemical reactive approach that significantly restricts the ability of government to rapidly identify, characterize, and control or prevent the introduction of a broad range of chemicals of emerging concern into the Great Lakes Basin.

In Part 4 of the report, some of the key policy gaps have been identified. They include:

1. The lack of an integrated system for the proactive management of chemicals of emerging concern, in particular prevention, that spans chemical types, sources (whether industrial sources or product based), and jurisdictional boundaries. Despite the dispersive and product-based nature of such chemicals, current policies do not sufficiently address elimination through redesigning products or processes to eliminate hazards in the first place.
2. A slow and cumbersome chemical-by-chemical testing and risk assessment approach to chemicals of emerging concern. Current approaches to chemical testing, assessment, and management have tended to focus on assessing the risks posed by single chemicals within chemical types and classes. Such processes are costly and inevitably result in decisions not being made until uncertainties are reduced, which in some cases can take years. The availability of safer chemical, non-chemical alternatives, prevention, or other proactive management options that would significantly reduce or prevent emissions of such chemicals is rarely considered in decision-making processes. Finally, chemicals that span different classes and mechanisms of toxicity pose large challenges for regulatory authorities to manage and to accurately and comprehensively characterize their risks.
3. Diminishing attention to toxics prevention efforts in the Great Lakes Basin and limited coordination between government authorities in this area.
4. Significant reliance on voluntary measures and use of chemical by chemical risk assessment and risk management processes to control releases of chemicals to the environment. This means that efforts to control or prevent releases have not kept up with the number of chemicals that are being identified or detected as chemicals of emerging concern in the Great Lakes Basin.

The risks posed by chemicals of emerging concern in the Great Lakes Basin can likely be reduced to some degree through enhanced control measures, such as improved industrial process controls and waste water treatment. However, given that most of the chemicals identified as chemicals of emerging concern are product based, and result in non-point emissions such that traditional pollution controls measures on industrial processes may not be applicable. Thus, many of the significant new strides in pollution prevention for

product based emissions may be made through greater controls on products, the promotion of safer alternatives, and a broader vision of pollution prevention – in essence green chemistry and substitution. Nonetheless, a comprehensive approach to prevention of chemicals of emerging concern will include processes for rapid characterization of hazards and exposures, prevention, and controls (for example in the workplace or wastewater treatment). *Given the product-based sources of the emissions of most of the identified chemicals of emerging concern in the Great Lakes, our analysis has focused primarily on policies that address chemical products, rather than industrial chemical emissions.* Clearly, some media specific laws can regulate emissions of chemicals from products, such as air quality regulations for formaldehyde or restrictions on disposal of products containing toxic materials (e.g., mercury) and are important supplements to product regulations. However, controls on chemicals in products are may not be adequate to address hazards that occur throughout product lifecycles.

The *Great Lakes Water Quality Agreement*, subsequent reports by the IJC, and national and regional policies, such as the 1990 U.S. Pollution Prevention Act, have set prevention as the top priority for addressing chemical hazards. The region's preventive approach paralleled similar efforts being undertaken in the several Scandinavian countries. However, while progress has stalled in the Great Lakes Basin, it did not in other jurisdictions. Today, there is a renewed commitment to the prevention of chemicals of concern. Numerous drivers are changing the way governments and industry think about chemicals in everyday products. Regulations such as the European Union's *Registration, Evaluation, and Authorization of Chemicals* (REACH) legislation are affecting a cultural shift in industrial chemicals management by requiring data on chemical toxicity and uses, requiring preventive action for classes of chemicals, and shifting the burden of proof to industry to demonstrate safety for high concern chemicals. Stakeholders in several U.S. states and Canadian provinces, including Great Lakes states of Michigan, Minnesota, and New York and the province of Ontario, are engaged in discussions to develop comprehensive toxics reduction policies for industrial chemicals. We outline an integrated, prevention-oriented roadmap (Part 4) for improved management of chemicals of emerging concern in the Great Lakes that can serve to elevate Great Lakes leadership in chemicals policy, including:

- Processes for rapidly identifying, screening, and prioritizing chemicals of emerging concern, including uses, potential exposures, and toxicity.
- Publication of a Great Lakes list of chemicals of concern to inform regulatory-making processes, markets, research and innovation, and educational activities that support proactive management with a focus on prevention, and end of life responsibility measures.
- Development of action plans for high priority chemicals of emerging concern considering possible measures, including prevention and substitution options, which would lead towards safer chemicals and products throughout their lifecycles.
- Establishment of a bi-national safer alternatives initiative, which would aim to provide tools, technical support, and incentives for research, development, and application of alternatives, such as green chemistry, and establish a process to

assess safety of alternatives to ensure benefits to the Great Lakes environment, health, and economy.

This roadmap would build on existing legal and administrative structures in the U.S. and Canada and require new collaborations and infrastructure at the Basin level.

PART 1 - Introduction

For many decades, the Great Lakes Basin has been a significant repository of both direct and indirect sources of pollutants. The health and ecosystem impacts are well documented. In 2002, over 100 million kilograms of pollutants were released into the air and water from major U.S. and Canadian manufacturing facilities in the Great Lakes Basin, according to national pollution inventories.¹ Little is known about indirect emissions from everyday products that reach the Basin through run-off, wastewater treatment, or air deposition.

Tens of thousands of industrial substances are in use in the United States, while Canada has catalogued 23,000 of such substances. Historically, a large percentage of these have not been thoroughly evaluated for their effects on human health and the environment. Furthermore, when toxic substance laws came into effect, the vast majority (by volume) of these were “grandfathered,” and the burden of demonstrating their risks and demonstrating the need for action fell on government agencies. Both the governments of Canada and the United States are currently immersed in the process of screening and assessing these existing chemicals. Published studies show evidence of some of these chemicals accumulating in sediments, fish, birds, and other marine life, as well as humans. For this reason, they pose a potential threat to ecosystems and the human population around the Basin.

Over the past two decades targeted actions to control many industrial, municipal, and agricultural sources of contaminants have occurred, resulting in significant improvements in Great Lakes water quality. The Great Lakes can still benefit from further national and global reductions from industrial and agricultural sources. However, there are new threats of pollutants that are now emerging. Scientists are beginning to recognize new, previously unaddressed chemicals in the Great Lakes – so called “chemicals of emerging concern.” These chemicals are from products, which are multiple, dispersive, and non-point sources. The change in focus from reducing emissions from industrial *processes*, to reducing emissions from the use and disposal of *products*, poses new challenges for the protection of the Great Lakes.

The sources of these exposures are complex and difficult to characterize, including:

- product-based emissions, such as phthalates and perfluorinated compounds;

¹ Canadian Environmental Law Association and Environmental Defence, *Partners in Pollution: An Assessment of Continuing Canadian and United States Contributions to Great Lakes Pollution*, (February 2006). This is a project of PollutionWatch (www.PollutionWatch.org), and a joint project by CELA and Environmental Defence.

- contaminants entering the lakes through sewage treatment plants and overflows, such as ingredients in cosmetics, pharmaceuticals, and possibly nanomaterials;²
- contaminants, such as pesticides entering from run-off; and,
- end of life exposures, such as mercury from landfills.

Of particular concern are the persistence, continual availability or presence, bioaccumulation, and low-dose toxicity of many of these substances. In addition, these exposures are multiple in nature, making human or ecological health assessments extremely difficult due to the lack of methods for assessing cumulative and interactive effects of exposures.

While the exact pathways of many of these “emerging” contaminants, be it from long range transport, rain, waste water, or house dust, are not always well understood, often the original source is a particular product type – a pharmaceutical, a couch, a plastic toy, or a sunscreen. The emerging contaminants from these products are a potential source of contamination that may pose a threat to the health of the Great Lakes.

Addressing Chemicals of Emerging Concern

The term, “chemicals of emerging concern” has been defined by the Consortium for Research and Education on Emerging Contaminants as “those chemicals that have been shown to occur widely in the environment and also identified as being a potential environmental or public health risk, and yet adequate data do not exist to determine this risk.”

Chemicals of emerging concern include various types – (1) those that have just gained entry into the environment (new to commerce or a new formulation, nanomaterials or other chemicals); and (2) those that are newly characterized as a result of increases in concentrations in the environment, improvements in chemical analysis, ability to detect at a lower concentration, or in new environmental compartments.

The second category makes up the vast majority of chemicals of emerging concern. The types of chemicals defined as chemicals of emerging concern are those that are used every day in homes, on farms, or by business and industry, including industrial chemicals, household chemicals, fragrances, pharmaceuticals, personal care products, disinfectants, pesticides, and nanomaterials.

For the purposes of this report, we use the term “chemicals of emerging concern” to include:

- 1) Chemicals identified in a chemicals of emerging concern report developed for the International Joint Commission (see Table 1);³

² At present, according to Environment and Health Canada’s “Proposed Regulatory Framework for Nanomaterials under the *Canadian Environmental Protection Act, 1999*, Sept. 10, 2007,” there is “no definitive system of nomenclature for nanomaterials.”

- 2) Chemicals which are persistent or bioaccumulative or toxic according to criteria outlined in the *Great Lakes Water Quality Agreement*;⁴
- 3) Chemicals that may or may not have been detected in the Great Lakes Basin, but which are included in the categories of chemicals of emerging concern, such as veterinary drugs; and
- 4) Those chemicals that have been shown to occur widely in the environment and also identified as being a potential environmental or public health risk.

While these chemicals may not pose a high risk at this point in time, they do raise concerns about long term exposures and impacts.

Table 1: Chemical types identified by the International Joint Commission, and in research by Hornbuckle and Persoon, as emerging chemicals present in the Great Lakes Basin

Chemicals identified as Emerging Chemicals
Synthetic Musks
Fluorinated Surfactants
Brominated Flame Retardants (PBDEs)
Chlorinated Flame Retardants
Alkylphenol-Ethoxylates
Short Chain Chlorinated Paraffins
Phthalates
Hydroxylated PCBs
Pharmaceuticals and Personal Care Products
Pesticides

All of the chemical types in Table 1 are now being detected in the air, water, and sediment of many of the Great Lakes and at unexpected levels in tissues of various wildlife species.

As noted, due to the wide range of materials included in the definition of chemicals of emerging concern and their multiple sources, their detection, assessment, and preventive action represent significant challenges to the Great Lakes regulatory and policy makers. Because many chemicals were assumed to be released in small quantities (if at all) and to break down relatively easily, the importance of their impacts on the quality of the Great Lakes is the focus of the current discussion of the International Joint Committee (IJC) Multi-Board Work Group on Substances of Emerging Concern.

³ Keri Hornbuckle and Carolyn L. Persoon, *Bibliography of Emerging Chemical of Concern in the Great Lakes*, Prepared for the International Joint Commission, (2008).

⁴ For example, the *Great Lakes Water Quality Agreement* outlines levels for persistence and bioaccumulation levels that are different than the levels used in Canada under the *Persistence and Bioaccumulation Regulations* under the *Canadian Environmental Protection Act, 1999*. In this paper, chemicals of emerging concern may be persistent, or bioaccumulative or toxic or any two combined.

Purpose and Outline of this Report

The Canadian Environmental Law Association and the Lowell Center for Sustainable Production have been asked by the IJC's Multi-Board Work Group on Chemicals of Emerging Concern to identify and analyze national, state/provincial, and regional policies and programs that address identification, assessment, and control and prevention of the range of chemicals of emerging concern. The results of this analysis and the database of scientific studies on chemicals of emerging concern will serve to inform recommendations made by the Work Group to the IJC Commissioners. In addition, inventories of Canadian and U.S. statutes, policies, and programs on assessment and management of toxic chemicals were prepared as part of this project. The analysis builds on decades of experience of both organizations in chemicals assessment and policy analysis in Canada, the U.S., and internationally.

CELA and the Lowell Center for Sustainable Production conducted their analysis based on the prevention-oriented foundations established through the *Great Lakes Water Quality Agreement*, which the governments of Canada and U.S. have committed to implement through bi-national efforts. This vision has been further elucidated and broadened through reports and statements of the International Joint Commission and national and regional pollution prevention policies. Building on the *Great Lakes Water Quality Agreement's* goal of prevention, while highlighting the pragmatic need for a multi-pronged approach to pollution prevention and proactive management of chemicals of emerging concern in the Great Lakes, our analysis focuses on the following questions:

1. To what degree do existing policies and programs facilitate the rapid identification and assessment, prioritization, decision-making, and proactive management, in particular prevention, for a broad range of chemical types before they become contaminants of concern?
2. What are the specific challenges of addressing chemicals of emerging concern in the region?
3. What policies and approaches are required to address chemicals of emerging concern in the Great Lakes Basin?

The analysis is substantially focused on the current approach taken when identifying, assessing/prioritizing, and acting on each of the substance categories of interest: industrial chemicals, pharmaceuticals and personal care products, pesticides, and nanomaterials. Because of the vast range of regulations, policies, guidelines, and practices at the various governmental levels for end-of-pipe water, air, and waste regulations, these are not reviewed in this study, but their relevance to control and prevention of such contaminants should be considered in future research. Nonetheless, given that the majority of identified chemicals of emerging concern enter the Great Lakes through disperse, product-based emissions, it is unlikely that most media specific pollution control statutes that primarily address industrial emissions and waste products would be readily applicable for these contaminants. Even in the case of waste water treatment (see below) few contaminants are actually controlled under current laws. *Given the product-based sources of the emissions of most of the identified chemicals of*

emerging concern in the Great Lakes, our analysis has focused primarily on policies that address chemical products, rather than industrial chemical emissions. Clearly, some media specific laws can regulate emissions of chemicals from products, such as air quality regulations for formaldehyde or restrictions on disposal of products containing toxic materials (e.g., mercury) and are important supplements to product regulations.

The different categories of substances are regulated in both the U.S. and Canada under different policy regimes and administrative agencies. Furthermore, there are differences in the federal and regional policy structures for regulating chemicals in Canada and the U.S. In Canada, the management and control of chemical substances is primarily regulated at the federal level, with provincial programs that focus primarily on end of pipe measures.⁵ In the U.S., states have implemented significant programs to regulate chemicals and pesticides. Clearly, both federal, provincial, and state programs and policies reduce the entrance of chemicals of emerging concern into the Basin, but there is also a critical role for concerted regional action. As such, the report consists of four main sections:

1. An overview of the History of Efforts for Addressing Persistent Chemicals of Concern in the Great Lakes;
2. A review and analysis of Canadian policies and programs relating to the various categories of chemicals of emerging concern. This review and analysis focuses solely on federal level policies in Canada, with an emphasis of the Canadian Chemicals Management Plan (CMP);
3. A review and analysis of U.S. policies and programs relating to the various categories of chemicals of emerging concern. This review and analysis focuses on both federal and Great Lakes state policies relating to such chemicals; and
4. General observations on the challenges and gaps that constrain the ability to take national and regional action to prevent chemicals of emerging concern from ending up in the Basin and a roadmap for next steps.

The report was compiled primarily through internet searches, document review, and key informant interviews with federal and regional experts on the various categories of chemicals, Great Lakes policy structures, and Great Lakes water quality. The report builds on expert analyses and experience developed by the two organizations through more than a decade of research and participation in national, international, and regional chemicals policy discussions.

Our analysis of Canadian and U.S. policies has identified policy gaps and a disjointed, chemical-by-chemical reactive approach that inhibit the ability to rapidly identify, characterize, and prevent the introduction of a broad range of chemicals of emerging concern in the Basin. The Great Lakes is not alone in this approach to chemicals of emerging concern that focuses on artificial legal and jurisdictional approaches to

⁵ The Province of Ontario is committed to a Toxics Use Reduction Strategy and has released a White Paper to outline the main focus and elements of the Strategy. No proposed law has been released by the government at the time of this report.

addressing individual media and product types rather than moving upstream to focus on reducing the inherent toxicity of substances and advancing safer alternatives based on the principles of green chemistry. The Commissioners can demonstrate Great Lakes leadership in chemicals policy by advancing an integrated, prevention-oriented strategy for chemicals of emerging concern.

History of Efforts for Addressing Persistent Chemicals of Concern in the Great Lakes

This analysis is framed by a long-standing vision of toxics prevention in the Great Lakes region. The Great Lakes has a long history of leadership in characterizing and addressing chemical contamination. In fact, the experience of the Great Lakes community, particularly through the leadership of the IJC, on developing chemicals policy interventions grounded in the principles of prevention and precaution has influenced the development of international toxics agreements, such as the *Stockholm Convention on Persistent Organic Pollutants*. Under the 1978 *Great Lakes Water Quality Agreement (GLWQA)*, the governments of Canada and the U.S. made a commitment to:

restore and maintain the chemical, physical, and biological integrity of the waters of the Great Lakes Basin Ecosystem. In order to achieve this purpose, the Parties agree to make a maximum effort...to eliminate or reduce to the maximum extent practicable the discharge of pollutants into the Great Lakes System.⁶

Furthermore, Canada and the U.S. also agreed that:

the discharge of toxic substances in toxic amounts be prohibited and the discharge of any or all persistent toxic substances be virtually eliminated.⁷

In the past two decades, the IJC has made statements to interpret the purpose of the GLWQA through its biennial reports. In its Sixth Biennial Report, the IJC stated that “if a chemical or group of chemicals is persistent, toxic and bioaccumulative, we should immediately begin a process to eliminate it. Since it seems impossible to eliminate discharges of these chemicals through other means, a policy of banning or sunseting their manufacture, distribution, storage, use and disposal appears to be the only alternative.”⁸

⁶ *Revised Great Lakes Water Quality Agreement of 1978 Agreement*, with Annexes and Terms of Reference, between the United States and Canada signed at Ottawa November 22, 1978 and Phosphorus Load Reduction Supplement signed October 16, 1983, as amended by Protocol signed November 18, 1987, (September, 1989). Article 2.

⁷ *Ibid.* Article 2.

⁸ International Joint Commission, *Sixth Biennial Report Under the Great Lakes Water Quality Agreement of 1978 to the Governments of the United States and Canada and the State and Provincial Governments of the Great Lakes Basin*, (1992).

Again, in its Seventh Biennial Report, the IJC noted that given the wide range of persistent contaminants in the Basin, there was a need for an integrated new approach to policy that “goes beyond the scope of conventional regulatory tools and environmental policies to encompass broad tactics that eliminate the creation of persistent toxic substances.” In essence, the IJC advocated a solutions-and-prevention-based approach to addressing persistent contaminants in the Basin.

The purpose of the GLWQA is essential to the development of bi-national strategies on toxic substances. Particularly, under Annex 12, it states that “*the philosophy adopted for control of inputs of persistent toxic substances shall be zero discharge.*”⁹ As a result, both governments made significant progress to reduce these chemicals through bans on specific uses of chemicals and implementation of control measures. This vision represents a goal to achieve that should guide interventions, given that the longer such substances remain in the environment, the greater the likelihood for them to cause ecosystem or human health impacts. Yet, “to the maximum extent practicable” acknowledges that for certain chemicals, processes, and products, preventing inputs may not be technically or economically feasible at the current time, in which case interventions should include proactive management measures.

Today the challenges posed by the on-going emission releases, exposure, and possible impact of toxic substances in the Great Lakes Basin continue. The focus is not only on chemicals that have already been identified as problems, but also on a new generation of chemicals entering the Great Lakes Basin that are lesser known, but that could pose similar risks to human health and the ecosystem.

Limitations of Waste Water Treatment-Based Approach to Prevention

The Great Lakes Basin receives billions of litres of waste water annually from municipal sewage and stormwater runoff.¹⁰ As previously noted, concerns about chemical contaminants are moving from industrial point sources towards more dispersed sources. The challenge of managing these various sources of chemicals entering the Great Lakes is complex. Many of these contaminants pass through wastewater treatment plants before entering the Basin. Wastewater treatment plants function as a barrier, keeping contaminants in wastewater (sometimes including both storm run-off and sewage but often only sewage) from entering the environment through rivers, streams, and lakes receiving treated effluent.

These contaminants can include viruses and pathogens in addition to industrial chemicals, pesticides, and ingredients from pharmaceuticals and personal care products. However, because wastewater treatment plants do not typically run tests for most chemical

⁹ *Ibid.* Annex 12.

¹⁰ Ecojustice, *Green Cities, Great Lakes: Using Green Infrastructure to Reduce Combined Sewer Overflows*, (2008). Accessed at: www.ecojustice.ca/publications/reports/the-green-infrastructure-report/attachment.

contaminants, they can pass unidentified through treatment and into the environment.¹¹ Those not discharged into the environment through effluent can be precipitated out of the effluent and contained within biosolids. Recent studies have found that some flame retardants were almost completely (90%) bound to sludge particles, but that these compounds could still be found in effluent after treatment.¹² Likewise, the U.S. Geological Survey found measurable amounts of 85 organic water contaminants in 139 streams and rivers across 30 states as a result of contaminated effluent. These contaminants included antibacterial agents, hormones, pesticides, flame retardants, and pharmaceuticals both prescribed and available over the counter.¹³

The U.S. *Clean Water Act* established the National Pollution Discharge Elimination System (NPDES) to oversee the permits necessary to legally discharge wastewater to receiving waters. These point sources are usually overseen by individual states.¹⁴ Discharge limits have been established for what EPA refers to as conventional pollutants (fecal bacteria, etc.), non-conventional pollutants (phosphorus, for example), and toxic pollutants (some 60 substances) as defined by the *Clean Water Act*, which includes pesticides, volatile organic compounds, PCBs, and some metals,¹⁵ but does not list pharmaceutical or personal care product ingredients as toxic or apply related limits on their discharge to receiving water.

The focus of waste water treatment is to produce clean waste water by removing any solid materials. The effectiveness of sewage treatment plants' ability to remove toxic chemicals depends on the level of treatment (i.e., primary, secondary or tertiary) applied. For example, those sewage treatment plants using tertiary treatment technology may be able to remove a substantial level of pollutants from the effluent, but it will depend on the technology employed and the chemical targeted for removal.¹⁶ For the most part, wastewater treatment systems were not designed for removal of more than a small number of chemical contaminants and such contaminants can cause damage to the effectiveness of such systems. As such, even with the highest level of treatment, any hazardous solids that remain are consolidated into sewage sludge, also known as biosolids. However, waste water treatment plants are not and can not be designed to make these contaminants less harmful (PCBs for example are just as toxic after water

¹¹ The Groundwater Foundation, *Pharmaceuticals and Personal Care Products: An Emerging Issue*. Accessed at: www.groundwater.org/gi/docs_pack/fa13.pdf.

¹² Niklas Rickland, Amelie Kierkegaard, Michael S. McLacklan and Cajsa Wahlberg, "Mass Balance of Decabromodiphenyl Ethane and Decabromodipheyl Ether in WWTP," *Chemosphere*, (2008).

¹³ Dana W. Kolpin, Edward T. Furlong, Michael T. Meyer, E. Michael Thurman, Steven D. Zaugg, Larry B. Barber, and Herbert T. Buxton, "Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999–2000: A National Reconnaissance," *Environmental Science & Technology*, 36 no. 6 (2002), 1202-1211. Accessed at: pubs.acs.org/cgi-bin/article.cgi/esthag/2002/36/i06/html/es011055j.html.

¹⁴ U.S. Environmental Protection Agency, *National Pollution Discharge Elimination System (NPDES)*. Accessed at: cfpub.epa.gov/npdes/.

¹⁵ Wastewater Engineering Virtual Library, *Overview of Federal Wastewater Discharge Limits*. Accessed at: www.cleantw2o.com/ww/limits.html.

¹⁶ Great Lakes Sustainability Fund. Accessed at: sustainabilityfund.gc.ca/default.asp?lang=En&n=68D63344-1#stp.

treatment as they were prior) so it is possible for these biosolids to accrue high levels of dangerous materials.¹⁷

Because biosolids are also rich in organic matter and nutrients, they are widely used as fertilizer. There have been considerable and on-going debates on the use of biosolids on agricultural fields. The use of biosolids falls under Part 503 of the *Clean Water Act*, making EPA responsible for preventing any foreseeable harm to public health as a result. If the biosolids are too contaminated for use as a fertilizer, they can also be incinerated or sent to landfills. This provision of the *Clean Water Act* does not prescribe the types of treatment processes used in wastewater treatment or regulate sludge deemed to be hazardous, and the only pollutant specifically identified as being exempt from Part 503 due to being regulated elsewhere are PCBs. Chemicals of emerging concern, such as pharmaceuticals, flame retardants, or nanoparticles are therefore not within the scope of this biosolids rule.¹⁸

While EPA regulates spreading of biosolids on agricultural and forest lands (most biosolids are not allowed for use on human crops), in some instances application of such biosolids may result in health or ecosystem risks due to their reintroduction into surface or ground water systems. In 2003, Georgia courts ruled that biosolids were the cause of death for 300 dairy cows after they had been fed hay grown with biosolid fertilizers. The Center for Food Safety, a non-government organization, cited the deaths of a man and two children who died suddenly after contact with biosolids, which were also compliant with relevant EPA regulations, as well as the potential for biosolids contaminated with the carcinogen dioxin to enter the human food chain, in their 2003 petition to EPA to end the use of land applications of biosolids.¹⁹

In Canada, the quality of effluent discharged by wastewater treatment plants has been a focus of the Canadian Council of Ministers of Environment's (CCME) standard setting process. The CCME proposed a Canada Wide Strategy for Municipal Wastewater Effluent aimed at outlining a national strategy for managing wastewater through a model sewer use by-law.²⁰ However, concerns about this proposal include the lack of enforceability of standards established through the CCME and whether the standards proposed are fully protective of health and the environment. Standards would be enforceable only if they were adopted into law by the province, territory, or federal government.²¹ For example, several municipalities including the City of Toronto, have Sewer Use By-laws. The City of Toronto passed its By-law in 2000 with requirements for pollution prevention planning. It targets over 35 toxic chemicals, including 11 heavy

¹⁷ Mary Lee Dunn, "Sewage Sludge Draws New Attention," *New Solutions*, 13 no. 4 (2003), 341-348.

¹⁸ See *The Plain English Guide to the EPA*, Part 503 Biosolids Rule, chapter 1. Accessed at: www.epa.gov/OW-OWM.html/mtb/biosolids/503pe/503pe_1.pdf.

¹⁹ Mary Lee Dunn, "Sewage Sludge Draws New Attention," *New Solutions*, 13 no. 4 (2003), 341-348.

²⁰ Canadian Council of Ministers for the Environment, *Municipal Wastewater Effluent*. Accessed at: www.ccme.ca/ourwork/water.html?category_id=81.

²¹ Ecojustice, *Green Cities, Great Lakes: Using Green Infrastructure to Reduce Combined Sewer Overflows*, (2008). Accessed at: www.ecojustice.ca/publications/reports/the-green-infrastructure-report/attachment.

metals.²² The City of Toronto tested the levels of contaminants in its biosolids and attributed the improved quality of the biosolids, particularly specific heavy metals (i.e., mercury, arsenic, lead, nickel, etc.)²³ to the Sewer Use By-law and the requirements for pollution prevention plans.

Creative wastewater treatment techniques may be more successful in removing chemicals of emerging concern than traditional systems and could act as a short-medium term solution for preventing these substances from entering the environment. For example, it is unlikely that redesign of pharmaceuticals for biodegradation will occur in the near future, yet these products provide important life saving functions. In this case, improved wastewater treatment capacity (such as increasing retention time to improve removal efficiency) combined with end of life “take-back” type programs will likely be the most effective control measure at this point.²⁴ Researchers at one Louisiana wastewater treatment plant, where lagoons and artificial wetlands were used as part of the treatment process, were able to reduce pharmaceutical residues by 90% in treated waters.²⁵ Samples taken from a wastewater treatment plant in the UK found that activated sludge treatment removed 15% more contaminants from pharmaceuticals and personal care products than trickling filter beds.²⁶ There is also some evidence that sand filtration as the final step in advanced waste water treatment was the most successful technique in removing two brominated flame retardants. Based on these findings, it may be possible to expect other contaminants prone to settling in sludge to be removed in the same manner.²⁷ While these techniques produce cleaner effluent, they do not solve the problem of contaminated biosolids.

In addition to the inability of wastewater treatment plants to fully prevent direct or indirect (e.g., biosolids) introduction of chemicals of emerging concern to receiving waters, most sewage treatment systems do not have the capacity for handling water flow during high rain or flood conditions. Most sewage systems combine both household and industrial effluent and run-off from roads and other areas. When there are high water-flow conditions, wastewater treatment plants become overwhelmed and must implement sewage overflow systems, wherein sewage is released untreated directly into receiving waters. This poses the threat of direct discharge of chemicals of emerging concern into the Basin. While this threat is being addressed through redesign of sewage systems to

²² City of Toronto, Sewer Use By-law, *Municipal Code*, Chapter 681. Accessed at: www.toronto.ca/legdocs/municode/1184_681.pdf.

²³ David McKeown, “Human Health and Ecological Assessment of Toronto Biosolids Pellet: Technical Summary,” (Toronto: Medical Office of Health, Toronto Public Health, November 2004).

²⁴ Sushil K. Khetan and Terrance J. Collins, “Human Pharmaceuticals in the Aquatic Environment: A Challenge to Green Chemistry,” *Chemical Reviews*, 107 (2007) 2319-2364.

²⁵ Jeremy L. Conkle, John R. White, and Chris D. Metcalfe, “Reduction of Pharmaceutically Active Compounds by Lagoon Wetland Wastewater Treatment System in Southeast Louisiana,” *Chemosphere*, 73 (2008), 1741-1748.

²⁶ Barbara Kasprzyk-Hordern, Richard M. Dinsdale, and Alan J. Guwy, “The Removal of Pharmaceuticals, Personal Care Products, Endocrine Disruptors, and Illicit Drugs During Wastewater Treatment And Its Impacts on the Quality of Receiving Waters,” *Water Research* (Article in press).

²⁷ Niklas Rickland, Amelie Kierkegaard, Michael S. McLacklan and Cajsa Wahlberg, “Mass Balance of Decabromodiphenyl Ethane and Decabromodipheyl Ether in WWTP,” *Chemosphere* (Article in press, 2008).

eliminate combined sewage overflow, this conversion will likely take years. Further, this will not eliminate run off exposures of pesticides and veterinary medicines from pesticide and manure (as fertilizer) application on fields.

PART 2 – Canadian Analysis and Findings

This section reviews the most relevant Canadian legislation with respect to the entry of chemicals of emerging concern into the Great Lakes. As noted in the Preface of this report, the *Canadian Inventory of Statutes, Policies and Programs on Chemicals Management* prepared for the IJC Work Group on Chemicals of Emerging Concern provides a listing and description of relevant policies and programs focused on management of toxic chemicals in Canada that may not be substantially covered in this section of the report. In separate sections, we examine the *Canadian Environmental Protection Act* and the Chemicals Management Plan; procedures for assessing and managing new chemicals under the *New Substances Notification Regulations*, the *Food and Drugs Act* and the *Pest Control Products Act*. The following section does not include a review and commentary on the role of the *Fisheries Act* in assessing and managing toxic chemicals in Canada. While the *Fisheries Act* includes important provisions prohibiting the deposit of deleterious substances into waters frequented by fish and the destruction of fish habitat, it does not establish a set of criteria or regime for identifying and managing chemicals so as to protect fish habitat such as the Great Lakes Basin.

In Canada, the primary responsibility for chemicals policy resides with the federal government, where the primary decisions are made as to which chemicals are acceptable for manufacturing, importation and use. The emphasis in the case of each review is on the ways in which these federal laws would need to be strengthened if the primary goal were to reduce or eliminate the continuing release or new releases of known or emerging chemicals into the Great Lakes. A final analysis and summary of the findings is offered at the end of this section. In addition, a separate and complementary inventory has been prepared that identifies a broader number of statutes that control or have the potential to control chemical inputs into the Great Lakes. This inventory includes not only the important federal statutes but also international and provincial legislation or agreements.

2.1 Current Canadian Regulatory System

The main federal environmental legislation is the *Canadian Environmental Protection Act* (CEPA). This Act governs many aspects of chemical assessment and regulation in Canada. In 1999, aspects of this Act were strengthened, including the requirement for the government to screen/categorize chemicals, mandatory time limits on actions, and the addition of pollution prevention planning as a tool for pollution reduction. The revisions also included important new guiding principles on pollution prevention, virtual elimination and precautionary principle.

Before any federal regulatory action can be taken to reduce exposure from a chemical in Canada, it must be found to be 'toxic' under CEPA. CEPA 1999 defines "toxic" substances as those that enter or may enter the environment at levels or conditions that:

- have or may have a harmful effect on the environment;
- are or could be dangerous to the environment that life depends on; or
- are, or could be, dangerous to human life or health.²⁸

These substances are called "CEPA-toxic." Before the government can regulate these substances, they have to be first proposed, and then following public comment, added to the Schedule 1 List of Toxic Substances. For "CEPA-toxic" substances, CEPA 1999 sets a two year time limit for proposing risk management tools and an 18 month time limit for finalizing the regulatory tools. The dates to phase in reduction or action usually extend well beyond these time periods.

The basic steps for action on chemicals in Canada are: development of a draft risk assessment, public comment, and the finalization of risk assessment including a determination if the chemical is CEPA toxic. If it is determined that a chemical is not CEPA toxic, no further action is taken. If it is determined that a chemical is CEPA toxic, there is a process: a proposal to add the chemical to Schedule 1, public comment, decision to add the chemical to Schedule 1, development of draft risk management tools, public comment, and finalization of risk management tools. In the past, this has been a lengthy process that can take up to 10 years.

CEPA 1999 also required the government to categorize all existing chemicals in Canada, catalogued in an inventory of chemicals called the Domestic Substances List, and to identify chemicals with the potential to be CEPA toxic. A Chemicals Management Plan was announced in December 2006 to address the results of categorization. Under the Chemicals Management Plan a slightly different approach has been instituted; the proposed screening level risk assessment and management process is outlined below. The timeframes for public engagement, development of risk management tools and implementation of those tools have not changed.

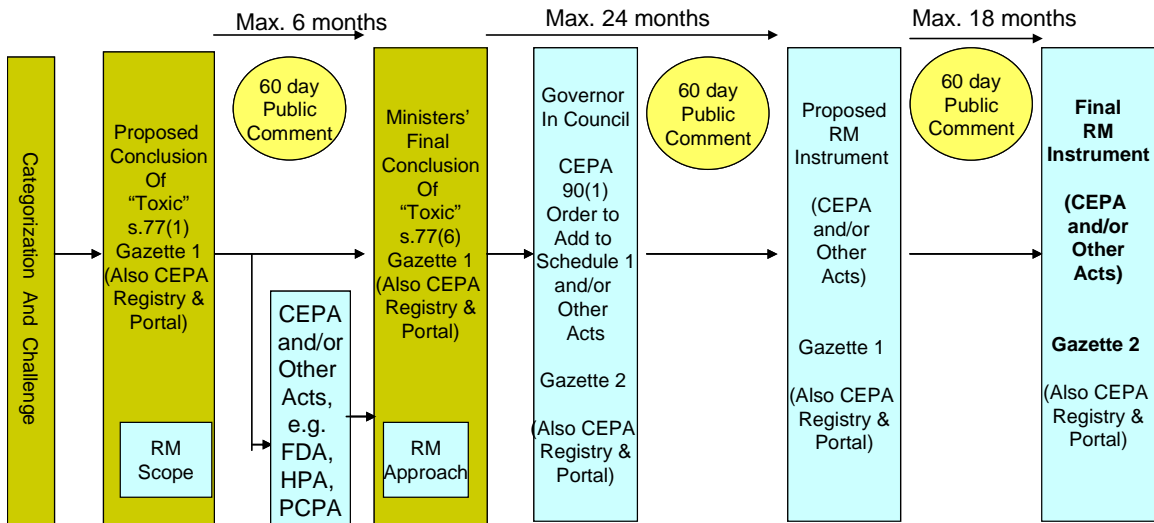
²⁸ Under the CEPA, section 64 states "For the purposes of this Part and Part 6, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

(b) constitute or may constitute a danger to the environment on which life depends; or

(c) constitute or may constitute a danger in Canada to human life or health."

Risk Assessment and Risk Management Process



RA - Risk Assessment phase ; **RM** - Risk Management phase

Source: Government of Canada, Risk Management of Existing Substances under CMP and the Challenge. Presentation to Stakeholder Advisory Council, May 30, 2008, Ottawa.²⁹

It is important to note that CEPA has a risk-based method for making decisions. Risk is considered to be the product of the harmful properties of the chemical (hazard), the extent of exposure to humans and the environment and the probability of a harmful effect.

²⁹ A substance is considered “toxic” under CEPA if it meets the criteria outlined in section 64.

2.2 Existing Chemicals

Existing substances are those chemicals listed on the federal Domestic Substances List (DSL)—chemicals used, manufactured or imported into Canada for commercial purposes, in volumes greater than 100 kilograms (kg), between January 1, 1984 and December 31, 1986. The original DSL included about 23,000 chemicals. If a chemical is on the DSL, it is considered an existing chemical, and subject to the regulatory framework for existing chemicals.

In Canada, over the past fifteen years, considerable effort has been directed towards improving the assessment and management of existing chemicals. While some significant improvements have been made, many gaps and limitations remain.

In the 1990's, detailed health and environmental assessments were made on 69 chemicals or groups of chemicals and their potential releases, mainly through the Priority Substances List. Some of these chemicals were found to be toxic under CEPA and placed on the Schedule 1 List of Toxic Substances. Emerging chemicals such as nonyl phenol ethoxylates and short chain paraffins were assessed under this program. The following case study illustrates how these priority substances were evaluated. This government approach was widely acknowledged to be slow and not appropriate for the 23,000 chemicals identified by the DSL.³⁰

³⁰ Office of the Auditor General, "2008 March Status Report of the Commissioner of the Environment and Sustainable Development," (2008); Office of the Auditor General, "2002 October Report of the Commissioner of the Environment and Sustainable Development," (2002). Accessed at: www.oag-bvg.gc.ca/internet/English/parl_cesd_200803_01_e_30127.html#ch1hd5a.

Case Study: Chlorinated Paraffins

Chlorinated Paraffins (CPs) have been detected in the Great Lakes, as demonstrated by the literature review of Hornbuckle and Persoon. Their continuing presence illustrates the several flaws in the current approach developed under CEPA to identify toxic chemicals, and to reduce their presence in the environment.

They were first identified in the group of 44 substances to be assessed under the Priority Substances List in 1988, and were declared toxic under CEPA ten years later in 2008. The assessment and proposed management regime took a total of 20 years to be completed.³¹

Short, long and medium chain chlorinated paraffins are predominantly used in the formulation of fluids such as cutting oils and high pressure lubricating oils used in the metalworking industry, and as plasticizers and flame retardants in polyvinyl chloride (PVC) applications.

The initial assessment for CPs was completed in 1993 with an initial finding that short chain CPs were toxic under CEPA. However, the government did not propose to define short chain CPs as toxic under CEPA at the time. Nor did the government make a conclusion on the toxicity of medium and long chain CPs.³² Instead, the government decided to collect additional data needed to determine whether medium or long chain chlorinated paraffins were harmful to the environment, or a danger to human health. This investigation also included exploring how CPs could be managed as Track 1 (virtual elimination) or Track 2 (life cycle approach) under the Toxic Substances Management Plan.

After the data were collected, the final assessments were released for public comment in 2005. Although the government determined that short chain CPs met the criteria for substances considered toxic under CEPA in 1993, at the time of the final assessment in 2005 no interim action had been taken to reduce the presence of short chain CPs in the environment between 1993 and 2005.³³

In 2008, the finalized assessment report concluded that short, medium and long chain CPs met the definition of toxic under CEPA. Information gathered since the 1993 assessment indicated that there had been no substantial changes in the uses of CPs. They were still being used in the metal working industry and in the PVC industry, as well as in the production of paints, sealants, and adhesives. Meanwhile, releases of CPs to the environment, in particular to the aquatic

³¹ Also see: Auditor General of Canada, "2008 March Status Report of the Commissioner of the Environment and Sustainable Development," Chapter 1. Accessed at: www.oag-bvg.gc.ca/internet/English/parl_cesd_200803_01_e_30127.html#ch1hd5d.

³² Environment Canada and Health Canada, *Canadian Environmental Protection Act, Priority Substances List Assessment Report. Chlorinated Paraffins*, (1993). Accessed at: www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/psl1-lsp1/paraffins-paraffines/paraffins-paraffines-eng.pdf.

³³ Environment Canada and Health Canada, *Canadian Environmental Protection Act, 1999: Follow-up Report on a PSLI Assessment for Which Data Were Insufficient to Conclude Whether the Substances Were "Toxic" to the Environment and to the Human Health: Chlorinated Paraffins*, (August 2008). Accessed at: www.ec.gc.ca/CEPARRegistry/documents/subs_list/ChlorinatedParaffins/CPs_TOC.cfm.

environment and to the Arctic environment continued to be documented.

The assessment also documented the availability of alternatives to the uses of CPs, although their cost and technical feasibility could have been a challenge to implementing controls.

Based on the final assessment results, the government is considering managing CPs by prohibition regulations aimed at manufacture, use, import sale and offer for sale of CPs with the possibility of exemptions for specific uses. However, government management proposals will not address all long chain CPs, as it excludes a subset of long chain CPs (those that are greater than 20 carbon atoms).

The lack of early action to reduce short chain CPs based on the initial assessment has contributed to CPs being detected in the Great Lakes today. Similarly, the prohibitions which will include exemptions and not address imported products that may contain CPs will contribute to the continued release of CPs to the aquatic environment. Finally, although safer alternatives have been identified, industry has seen the issues of technical and economic feasibility related to these alternatives to CPs as barriers to change.

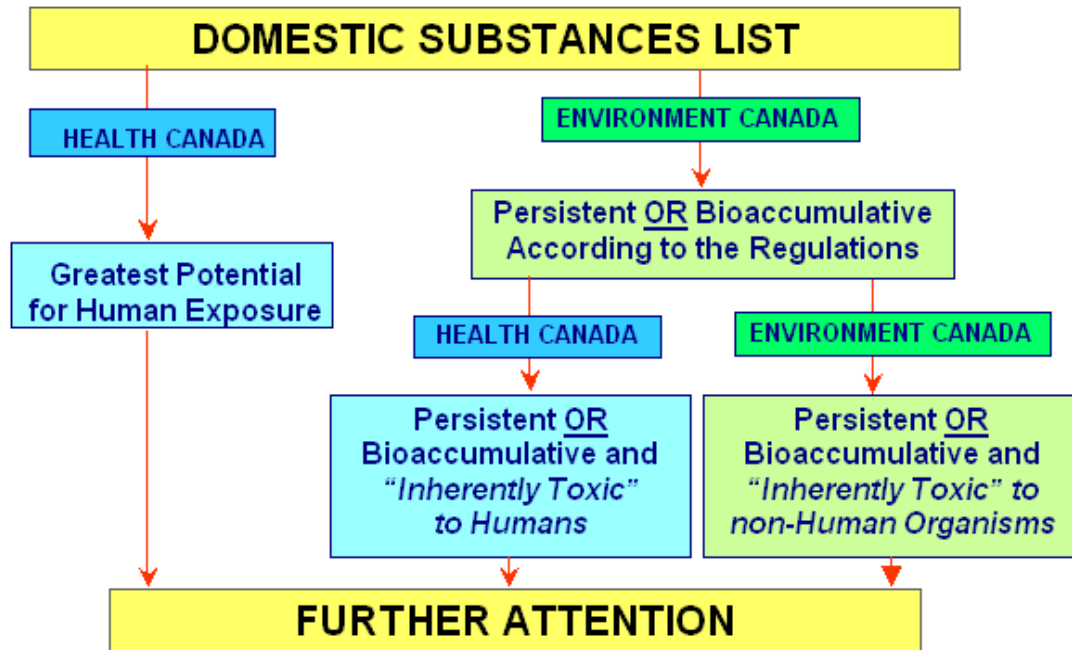
To meet the GLWQA's goals, only a complete prohibition on CPs and the substitution of safer alternatives or process changes would eliminate discharges and non-point source releases into the Great Lakes.

What is the current program for existing chemicals?

As part of the revised CEPA 1999, "categorization" was created to identify chemicals that should be subjected to screening level risk assessments. Under the categorization process, chemicals were assessed on:

- Environmental criteria (3 criteria: persistence (P), bioaccumulation (B) and inherent toxicity (iTe) to aquatic organisms);
- Health criteria (2 criteria: greatest potential for exposure (GPE) and inherently toxic to humans (iTh)).

By September 2006, the government completed its legal obligation to categorize substances, relying on available data to make categorization decisions.



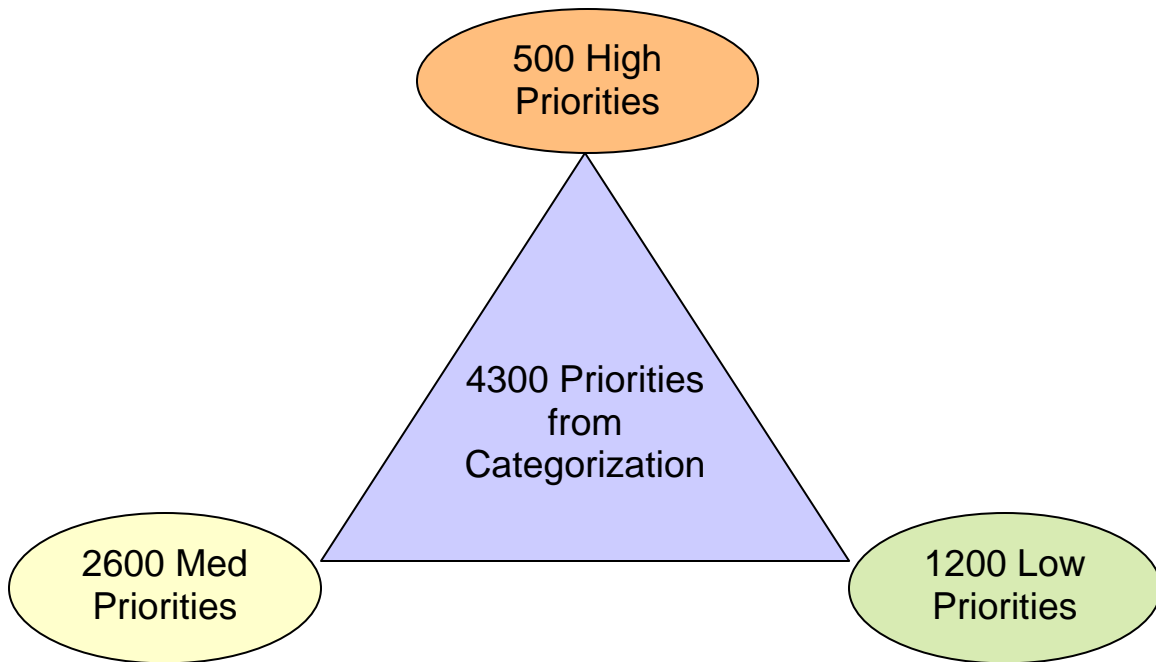
What were the implications of categorization for emerging chemicals?

The exercise of categorization was unique to Canada because it had been a legal requirement under CEPA 1999. In the course of categorizing Canada's 23,000 chemicals for health and environmental criteria, the government determined that a total of about 4,300 chemicals needed further evaluation.

About 3,200 chemicals met two of the three environmental criteria under categorization – persistent and inherently toxic, and bioaccumulative and inherently toxic (P and iTe, B and iTe). This number gives a sense of the potentially large number of emerging chemicals that could be found in the Great Lakes, although an unknown number may no longer be in commerce in Canada.

About 400 chemicals met all three environmental criteria, P and B and iTe. An additional 100 chemicals were identified as high priority to human health. This total of 500 substances was identified as high priority substances based on the categorization process (as shown in the chart). However, about 145 of these are no longer used in Canada. Although they remain on the DSL, they are flagged so that anyone wishing to use them in the future is required to notify the government.

In December 2006, based on the results of categorization, the Prime Minister announced a new approach to chemicals known as the Chemicals Management Plan. Under the Chemicals Management Plan, a goal of 2020 was set to address the results of categorization.



Source: Government of Canada, An Overview of the Chemicals Management Plan and Challenge, Presentation to the CMP Stakeholder Advisory Council, January 25, 2008

A major focus of the Chemicals Management Plan is to collect additional information from industry and potentially develop risk management tools on a group of about 200 chemicals considered high priority, known as the “Industry Challenge Chemicals.”

About 129 of the approximately 200 Industry Challenge chemicals were selected for environmental reasons. These 200 high priority Industry Challenge chemicals are broken into smaller groups of 15-30 chemicals, known as “batches” and are released sequentially about every three months. Industry is required to provide information on the use, manufacturing, and importation of these chemicals. Stakeholders are also invited to provide additional information on a voluntary basis.

As of September 17, 2008, Batches 1-7 have been released for the call for information and are at various stages of the process. This process of completing screening assessments for all 200 challenge chemicals is expected to take three years (2007-2010). After which the process of risk management for the challenge chemicals is expected to be completed within three years following the screening assessment (2010-2013).

Case Study: Synthetic Musks

Synthetic musks illustrate the inconsistencies in the categorization process, as well as the limits of the assessment and control programs under the Chemicals Management Plan. Some musks have been identified as high priority chemicals, while others in popular use will not be assessed under the current framework even though they have been found to be chemicals of emerging concern in the Great Lakes.³⁴

Musks are a group of chemicals used as fragrances in a number of consumer products such as soaps, detergents, cosmetics, perfumes, cleaning agents and air fresheners. They can also be used in food additives, cigarettes and fish bait. In the Great Lakes, waste water treatment plants are major sources of musks. Volatilization contributes to a majority of the loss of musks from Lake Michigan.³⁵

The highest concentrations accumulated in fish from the lower Great Lakes were from three major synthetic musks: Galaxolide® (HHCB), Tonalide® (AHTN), Traseolide®(ATII), respectively.³⁶ In addition, sediment concentrations in Lake Erie and Ontario showed that the input of synthetic musk fragrances into the lakes is increasing over time. The rate of increase in deposition of these compounds in Great Lakes sediments corresponds to rates of increase in production of synthetic musk fragrances.³⁷

There are two general families of musks that include a number of different chemicals, each of which has its own hazardous properties:

1) the nitromusks (musk ambrette, musk xylene, musk ketone, musk tibetene and musk moskene), and,

2) the polycyclic musks (Tonalide® (AHTN), Galaxolide® (HHCB), Traseolide® (ATII), Celestolide®, Cashmeran® and Phantolide®).

According to the criteria used under categorization of these musks, 5 are considered persistent (P), 5 are bioaccumulative (B) and 8 are toxic to aquatic organisms (iTe).

Two of the musks, musk tibetene and musk moskene, met all three environmental criteria – persistent, bioaccumulative and toxicity (P,B, iTe). These two musks are therefore considered high priority under categorization, and one of them, musk moskene is included in the Industry Challenge Chemicals (Batch 12).

The other musk, musk tibetene, is considered high priority, but is not an Industry Challenge

³⁴ Keri Hornbuckle and Carolyn L. Persoon, *Bibliography of Emerging Chemical of Concern in the Great Lakes*, Prepared for the International Joint Commission, (2008).

³⁵ A. Peck and K.C. Hornbuckle, "Synthetic Musk Fragrances in Lake Michigan," *Environmental Science & Technology*, 38 no. 2 (2004), 367-72.

³⁶ S.O. Metcalfe and C. Metcalfe, "Synthetic Musks in Fish from Urbanized Areas of the Lower Great Lakes, Canada," *Journal of Great Lakes Research*, 32 no. 2 (2006), 361-369.

³⁷ A. Peck, E.K. Linebaugh and K.C. Hornbuckle, "Synthetic Musk Fragrances in Lake Erie and Lake Ontario Sediment Cores," *Environmental Science & Technology*, 40 no. 18 (2006), 5629-5635.

Chemical. This musk will require notification to the government as a Significant New Activity under CEPA since it was determined that it is not in commerce in Canada.

Of all the musks, three are considered PiTe, and so met the environmental criteria for categorization. These three PiTe musks are musk ambrette, musk ketone and Traseolide®. These three PiTe musks will be further screened in the medium priority group (2010-2020) or the low priority group. Risk management actions will be developed only after screening level risk assessments are completed and a conclusion of toxic is made under CEPA. As a result, it may be a decade or longer before risk management actions are proposed for these three musks since these musks did not meet the criteria to be considered high priorities under CMP.

Two of the most commonly used musks are Galaxolide® and Tonalide®. Both of these musks are considered high production volume chemicals by the OECD.³⁸ They are both toxic to aquatic organisms (iTe), and Galaxolide® is found at high concentrations in Great Lakes' fish. Although these musks are used in large amounts and are detected in the Great Lakes, they will not be considered for any further assessment or management action under the CMP because they are only toxic to aquatic organisms and do not meet the definition of persistence or bioaccumulation under the CMP. Currently, no other Canadian programs aim to assess or manage these musks.

In the European Union (EU), musk xylene, another very commonly used musk, has been nominated as a substance of very high concern under REACH. Under EU REACH criteria, it is identified as a very persistent and very bioaccumulative compound (vPvB), with borderline toxicity. However, under CMP criteria, musk xylene is considered only persistent (P) and does not meet the criteria for bioaccumulation or inherent toxicity as outlined under CMP. The reason for these different conclusions about the same chemical lies in the different definition of the terms persistent, bioaccumulative and inherent toxicity. Musk xylene is an example of a chemical that Canada is not expected to assess or manage. However, this musk is considered persistent and bioaccumulative by other jurisdictions wherein action on this substance is required.

Several musks (e.g., isomers of Galaxolide®) are not currently listed on the Domestic Substances List. Therefore, the government was not required to categorize these musks. This means no further screening level risk assessment or risk management action are required for these chemicals.³⁹

The use of the nitromusks has decreased over the years, following the International Fragrance Association and other organizations restrictions on some nitromusks. Musk ambrette and musk tibetene are on Canada's Cosmetic Hotlist and so are restricted from use in cosmetics. Both are also banned from use in cosmetic products in the European Union. In the United States however, there are no restrictions on any of the musks. As the nitromusks have declined in production, they have been replaced with the polycyclic musks.

In short, there is no opportunity under the CMP to consider the toxicity of musks as a class and to make decisions about which ones should be allowed for use in Canada and which ones should be

³⁸ Organization for Economic Cooperation and Development Environment Directorate, *The 2004 OECD List of High Production Volume Chemicals*, (2004).

³⁹ Since assessment results through the New Substances process are not public, it is not possible to know if these musks have been assessed under the new substances program. This shows that chemicals that may be in use in Canada are not necessarily on the DSL; they may not have been categorized and have not started to be assessed for environmental impacts.

restricted or prohibited. Under Canada's CMP, the most commonly used musks, Galaxolide® and Tonalide®, which are toxic to aquatic organisms (iTe), will not be further assessed or managed. Only one of the musks, the little used musk moskene, is an Industry Challenge Chemical and so is expected to be assessed in 2009. Although the use of this musk in cosmetics is already banned in Europe, it is not on Canada's Cosmetic Hotlist. Another little used musk, musk tibetene, will be subjected to a Significant New Activity flag on the DSL, indicating that companies wishing to use it must notify the government under the *New Substances Notification Regulations*. There are only three other musks that met the environmental criteria for categorization, and so these will be further assessed and risk management actions proposed over long time frames, probably over the next decade. These are the least commonly used musks: musk ambrette, musk ketone and Traseolide®. No actions are expected on any of the other musks under CMP.

What management tools are applied to substances found to be CEPA toxic?

A major outcome of the categorization process is to conduct a screening level risk assessment to determine if the chemical meets the definition of toxic under CEPA. If a chemical does meet the definition of toxic, it is placed on Schedule 1, List of Toxic Substances. Then, Health Canada and Environment Canada can manage the risks by imposing controls on the manufacture, import, use, release into the environment, and/or disposal of the substance.

The controls can include prohibitions, restrictions, guidelines, or codes of practice, and can govern the entire life cycle of a substance, including where and how it is produced and used, and the amount that can be produced and used in a given time period. If a chemical is not found to be toxic under CEPA, this usually means no further action.

Some examples of risk management tools available under CEPA

- **regulations** that are enforceable laws that can restrict the use or release of a chemical substance, set limits on the concentrations allowed under various conditions, or prevent the use of chemical substances in certain products;
- **pollution prevention notices** that require companies to develop and implement actions to minimize or avoid the creation of pollution or waste;
- **guidelines** or codes of practice on the best ways to manage the use, release or dispose of a chemical;
- **voluntary Environmental Performance Agreements**; and,
- **Significant New Activity notices** which aim to identify substances for which some concerns may have been identified. In some cases, further notification beyond current uses will be required for those substances.

In addition, the *Hazardous Products Act* also offers opportunities to the federal government to develop regulations that could control the use of toxic substances in products. In the past, several toxic substances such as lead and asbestos have been restricted for use in children's toys, using the *Hazardous Products Act*. While the focus

of the Act is primarily consumer protection and the prevention of injuries or disease, the Act offers considerable scope to prohibit or restrict any products or substances in products.

Gaps identified with Categorization and Chemicals Management Plan

Gap # 1: A chemical considered persistent and bioaccumulative does not meet the environmental criteria of categorization, and is not considered for further screening or reduction action.

- To meet the environmental criteria for categorization, a chemical must be inherently toxic to the environment and either persistent or bioaccumulative. CEPA outlines the specific criteria that must be met. A chemical must be considered inherently toxic to aquatic organisms (iTe) to pass, and then can be either persistent (P) or bioaccumulative (B). The result is known in shorthand slang as PiTe or BiTe. If a chemical is just persistent and bioaccumulative (P and B), it is not considered an environmental priority in the categorization process, and no further action is likely. Many emerging chemicals are persistent and bioaccumulative but not toxic. Over 250 substances from the DSL have been identified to meet the P and B criteria but not iTe. This means that approximately 250 chemicals that are persistent and bioaccumulative but not inherently toxic will not be assessed or managed under the CMP. These chemicals may be chemicals of emerging concern in the Great Lakes.⁴⁰

Gap #2: Many existing and emerging chemicals do not meet the high PBT criteria of the CMP, which results in no further action for many chemicals. If the criteria used in other jurisdictions were applied to the CMP, many more chemicals would have been identified as bioaccumulative or persistent. Again, these chemicals are potential chemicals of emerging concern in the Great Lakes.

- There are differences in these criteria used to classify a chemical as persistent, bioaccumulative or toxic under Canada's Chemical Management Plan, compared to other jurisdictions. These PBT criteria under CMP are set higher than the *Great Lakes Water Quality Agreement* (GWLQA), Europe's REACH, and U.S. Environmental Protection Agency (EPA) PBT and Chemicals Assessment and Management Program (ChAMP)⁴¹ and the *Stockholm Convention on Persistent Organic Pollutants* (POPs) (see box at the end of this section).

⁴⁰ Substances identified as persistent and bioaccumulative were identified using the results of categorization provided on the Government of Canada web site for Chemical Substances. Accessed at: www.ec.gc.ca/CEPARRegistry/subs_list/dsl/DSLsearch.cfm?critSearch=PB. Substances that met the criteria for categorization had to be persistent, bioaccumulative and inherently toxic to the environment or to meet other human health categorization criteria that were deleted from the list. A total of 280 substances were found to be persistent and bioaccumulative but did not meet the categorization criteria outlined in CEPA.

⁴¹ Accessed at: www.epa.gov/champ/pubs/basic.htm.

- For example, the *Great Lakes Water Quality Agreement* considers a chemical persistent if its half life in water is 8 weeks, compared to the 26 weeks under CMP.
- In comparison with other jurisdictions, the Chemicals Management Plan criteria require a chemical to be highly persistent or highly bioaccumulative before meeting the CMP criteria. These criteria will determine the way a chemical is classified, and hence whether it progresses for further assessment and management activities under the CMP.
- CMP criteria for PBT are absolute yes/no answers. In other jurisdictions, determinations of PBT are scaled answers. REACH has persistent and very persistent categories for example. Other jurisdictions also consider chemicals that are close to meeting PBT criteria as “borderline,” and this forms part of the judgement. CMP does not consider chemicals close to PBT as “borderline;” indeed they are classified as not meeting PBT criteria.
- The criteria used in CMP were developed by the federal government based on the *Persistent and Bioaccumulation Regulations* under CEPA, and used in the Toxic Substances Management Plan.

Gap #3: Assessment of health effects does not consider important mechanisms of toxicity such as endocrine toxicity, which characterizes some emerging chemicals.

- Categorization also required Health Canada to determine what chemicals posed the greatest potential for exposure to humans (GPE) and identify chemicals that were hazardous to human health (iTh). The health criteria used to judge inherently toxic to humans are: carcinogenicity, genotoxicity, reproductive toxicity, developmental toxicity and mutagenicity. Endocrine toxicity is not included in the health criteria and so was not considered in categorization decision making process. Based on the results of health hazard models, chemicals were sorted into two baskets: high hazard and low hazard.
- Health Canada also reviewed the potential for exposure of a chemical. This review was based on quantity, number of submitters and expert ranked use, with much information originating from the DSL. Concerns have been raised about the accuracy of the DSL information as it is now twenty years old. Based on the exposure information, Health Canada then sorted chemicals into three baskets: those with greatest potential for exposure (GPE), those with intermediate potential for exposure (IPE) and those substances with low potential for exposure (LPE). Health Canada notes that there are large uncertainties and many data gaps in the exposure data for many chemicals.
- Health Canada was also to consider persistence and bioaccumulation in their health evaluation. However, Health Canada, on a number of occasions indicated that persistence was not a significant factor when making determination on hazards to humans and setting priorities.⁴² Exposure was the more important

⁴² Health Canada, “Healthy Environments and Consumer Safety: Overview – Health Assessment of Existing Chemicals under CEPA,” (Presented by Bette Meek at the Toronto Information Session, March 8, 2004).

parameter for consideration. The end result of the health assessment is a chemical with a combination of the hazard ratings (high or low hazard) and also an exposure rating (GPE, IPE or LPE). For example, a chemical can be high hazard and GPE and another chemical can be low hazard and GPE.

- In addition to this process (and somewhat confusing the process), Health Canada then also grouped chemicals into a category called “other human health priorities.” Chemicals were sorted into four baskets in this category: those chemicals with high, medium, low or post 2006 priorities. The focus of the government Industry Challenge is on high priority chemicals until 2010. Medium priority chemicals are expected to be completed by 2020 but there is no set timeframe for assessments of low or post-2006 priorities to human health.

Gap #4: Critical categorization decisions are based on a list of chemicals (DSL) which is over 20 years old and subject to inaccuracies.

The outdated DSL affects existing and emerging chemicals in several ways:

- Outdated use information may lead to incorrect conclusions about exposure and incorrect choice of management action. Because the DSL is over twenty years old, many inaccuracies have been identified. For example, chemicals on the DSL may no longer be in commercial use in Canada, or their volume or use may have changed, and in some cases, it significantly increased. In a study done for Health Canada in 2001 to determine the accuracy of the DSL, 7 of 110 chemicals surveyed were found to be more than an order of magnitude greater than the base year of 1986.⁴³
- Chemical use formulations are constantly changing, so it is reasonable to expect large changes in use for many chemicals on the DSL. For example, the type and volumes of musks used in products has changed dramatically since the compilation of the DSL. Indeed further work under the CMP has demonstrated that some use information is inaccurate. A chemical could be considered low potential for exposure based on this outdated information, when really it could be a high potential for exposure and vice versa. A chemical considered low potential for exposure will likely not be further assessed for more than a decade, and is not usually chosen for any reductions. The government has recognized this gap, and has started work on an update of the DSL.

Gap #5: There is uncertainty in the results of categorization because of the number of data gaps and changes in the categorization decisions.

- The categorization decisions made by Health Canada and Environment Canada relied on available data. Little new data on P, B and iT were generated by industry or government agencies. The government decisions reflected an

⁴³ Health Canada, *A Study to Determine Currency of DSL Quantity Data for Use in Categorization of DSL Substances*, (August 2001).

approach focused on data rich substances and used models to fill in data on substances that had limited or no data.

- Throughout the process of categorization, there were missing information and data gaps. These were filled in by a number of methods - through the use of analogues (using information from a chemical that is similar but not identical to the chemical under study), and through the use of modeling results (i.e., QSAR models, etc.). Many groups have taken issue with the approach undertaken by Health Canada to address data gaps, arguing that the reliance on the use of analogues may lead to faulty decisions, such as including chemicals not actually meeting the criteria and excluding chemicals that should be included.
- Other limitations identified in categorization included: absence of consideration of breakdown products of parent chemicals, absence of class approach, lack of consideration of toxicity for parent chemicals' full life cycle, and limited use of surveys to gather data from industry to fill in data gaps.
- A number of the chemicals in batch 1-3 were considered PBiT under categorization. Decisions for some batch 1 substances that were PBiT changed during the final screening assessment. During the comment period, the government received information which resulted in the PiT and BiT designation being dropped. Therefore a chemical that came into the process meeting the environment criteria was found to no longer meet the environmental criteria. No further action will be taken for these chemicals.

Gap #6: There is further immediate assessment work being done on only 4% of chemicals meeting environmental criteria under categorization under CMP. No further action is slated for about 25% of the chemicals categorized as low priority.

- The Government of Canada established a goal of 2020, to address the legacy of unassessed chemical substances in Canada so as to significantly reduce risks to health and the environment.⁴⁴ Categorization found about 3,200 chemicals met the environmental criteria of PiTe and BiTe. Of these 3,200 chemicals about one third (1,066) were identified as having low use (imported, manufactured or otherwise in commerce at amounts equal to or less than 1,000 kilogram) and so were subject to another screening process know as “rapid screening.” A total of 754 chemicals were removed through the rapid screening process. This process is important because it is one of the main ways that chemicals, including emerging chemicals that meet environmental criteria (P or B and iTe), are further evaluated.
- A variety of screens were used to evaluate these chemicals including chemical category, exposure estimation, mechanical filters such as presence on a existing restricted list, and manual process. This rapid screening process found 312 of the total 1,066 chemicals were identified at one or more steps and therefore required further attention. The group of 312 chemicals which are PiTe or BiTe have been added to the medium priority category for future assessment. A timeframe of 2020 has been set for the assessment of this medium priority group of chemicals.

⁴⁴ Government of Canada, “Risk Management of Existing Substances under CMP and the Challenge for Stakeholder Advisory Council,” (Power point presentation, presented by France Jacovella) (Ottawa: Environment Canada, May 30, 2008).

- Of concern is the fate of the 754 chemicals identified as low use which did pass through all the screens. These chemicals were deemed to be “non toxic” under CEPA using the rapid screening tool. No further action will be taken on these 754 PiTe and BiTe chemicals. The uses and quantities will be monitored using the inventory update information.
- The low priority chemicals were identified as those chemicals that were in quantities below 1,000 kilograms. From previous knowledge about low level effects of chemicals in the Great Lakes such as dioxins, chemicals inadvertently produced in very small amounts may still have large impacts on the environment and human health. To date, none of these 1,066 low priority chemicals are on the Great Lakes Bi-national Toxics Strategy list, and only 2 were on the Great Lakes Air Inventory list.
- The rapid screening process eliminated many of the chemicals meeting environmental criteria from further action or management. Yet, these chemicals may be chemicals of emerging concern in the Great Lakes.

Gap #7: The goal of 2020 to complete assessments for medium priority substances leaves substances of potential concern unassessed for many years.

- Categorization was established to determine the potential toxicity of thousands of chemicals in use in Canada. While the Industry Challenge will help provide additional information on the 200 chemicals, there is still a need to deal with the remaining approximately 3,800 chemicals identified through the categorization process as requiring further attention. The government stated that “The remaining medium priority substances are expected to be addressed in total by 2020.”⁴⁵ This is still 12 years away from taking reduction action.

Gap #8: There will be no management tools proposed for chemicals already found to be CEPA toxic under earlier processes that would further reduce these chemicals.

- Currently, the Chemicals Management Plan does not propose any further action on chemicals already found to be CEPA “toxic” and on Schedule 1 under earlier processes. These chemicals are considered already managed even though some of these chemicals continue to pose problems. This group includes many chemicals important to the Great Lakes such as lead, cadmium, arsenic, particulate matter, nonylphenol ethoxylates (NPEs), and benzene.
- NPEs, for example, which have been identified as emerging chemicals by Hornbuckle and Persoon, were already previously assessed and found to be CEPA “toxic” before categorization. The management regime for NPEs included pollution prevention planning for the textile industry as well as for municipalities. Furthermore, efforts by industry were undertaken to replace NPEs in detergents. Since there are no requirements by industry to release pollution prevention plans

⁴⁵ Government of Canada, (Presentation to CMP Stakeholder Advisory Council) (Ottawa: January 25, 2008).

to the public, it is very difficult to assess the effectiveness of such plans in reductions or prevention.

Gap# 9: Management options need to be refocused on actions that lead to the phase out and elimination of CEPA toxic substances and their replacement with safer alternatives.

- CMP was announced as promoting a precautionary approach and increasing accountability to industry through the Industry Challenge. Government stated that it would take “regulatory action” on toxic substances. Early results from the Challenge program indicate that government action does not strongly focus on regulatory measures.
- To date, it seems that most of the government efforts have been directed to the completion of assessment of chemicals under the Industry Challenge. The proposed regulatory management packages for CEPA toxic substances do not appear to reflect the action necessary to reduce these CEPA toxic substances. The value of the categorization process to Canada is significant given the amount of time required to complete assessment of substances found under the PSL process. Furthermore, the results of categorization can be used to inform the efforts of other countries on these substances. Additional review and consideration is indeed needed to assess the adequacy of the CMP process in responding to the challenges created by the categorization process. Based on this initial assessment, there may be a greater need to promote a preventative management approach for many of the chemicals identified through categorization.
- For substances identified in Batch 1 as CEPA toxic, there have been few new control measures proposed in the risk management documents released for public comment. No measures that promote safe alternatives or pollution prevention have been proposed. This is despite the finding that 7 of the 8 substances are found to be non-threshold carcinogenic substances.
- For all eight substances found to be CEPA “toxic” under Batch 1 there is a greater reliance on monitoring for releases, and requirement of notification for future new uses.
- Of the 31 chemicals found to be persistent, bioaccumulative and inherently toxic under categorization in Batch 1-3 of the Industry Challenge, 24 were subsequently found to be not CEPA toxic (for a number of reasons). So 77% of the P/BiTe chemicals identified by categorization will not have a risk management scoping document. Six of the 24 P/BiTe chemicals rejected as CEPA toxic were subject to SNAc provisions.
- Based on these initial efforts, the list of chemicals considered CEPA toxic may slowly grow over the years. However, it is uncertain whether substantial reductions in use, releases or presence of chemicals will result from government proposals.
- For one chemical, CHPD, confirmed to be a P/BiT ([4-[[2-(4-cyclohexylphenoxy)ethyl]ethylamino]-2-methylphenyl]methylene)-, propanedinitrile (CHPD) (CAS no. 54079-53-7), the government has proposed to add this chemical to Schedule 1 (Toxic Substances List), but it has not proposed a

complete prohibition. Rather, the government has proposed regulations, which will specify “the concentration of CHPD that may be released from industrial facilities to the environment or to wastewater sewer.”⁴⁶ This would impose some controls on CHPD but does not meet the GLWQA’s goal of zero discharge for persistent toxic substances.

Gap # 10: The government reliance on the use of Significant New Activity (SNAc) flags for high priority substances identified under categorization as a major method of chemical control is a weak approach.

- One of the major tools to be used in the CMP is the Significant New Activity flag. SNAc flags have been proposed for a few Challenge chemicals in the early batches, for chemicals banned in other jurisdictions and for some new substances.
- As a result of categorization, 397 chemicals were found to meet all three environmental criteria, persistence, bioaccumulation and inherent toxicity. This is less than 3% of the 23,000 chemicals screened. After a series of surveys, 145 of these 397 high priority chemicals were found not to be used in Canada. In June 2008, Significant New Activity (SNAc) flags were placed on these 145 chemicals in the DSL with the stated goal to prevent these chemicals from being reintroduced in Canada. On the DSL there is a listing of the chemical name, CAS number and the indication S` to indicate the chemical is subject to a significant new activity restrictions. These flags mean that a company wanting to manufacture, import or use these chemicals in quantities greater than 100 kg per year, must notify Environment or Health Canada and must undergo environmental and human health assessment before being introduced to Canada. The exact nature of the restrictions can vary by chemical.
- SNAc provisions do not guarantee the prohibition of these high priority substances in Canada over the long term. The alternative option is the addition of these substances to the Prohibition of Certain Toxic Substances Regulation. Through a notification process, such chemicals may continue to be used in Canada. Because SNACs are being utilized for substances identified under categorization, the monitoring and enforcement of SNAc flags remains unproven. Furthermore, it was noted by some groups that notifications on substances with SNAc flags should be evaluated using more rigorous set of toxicity data because these substances have been identified as high priority substances.

Gap #11: There are few evaluations of the effectiveness of existing regulatory tools. This limits the ability to apply previous experience to substances newly considered CEPA toxic.

- Before CMP, industry was required to develop pollution prevention plans for a number of chemicals. Some of these plans (such as trichloroethylene and

⁴⁶ Environment Canada and Health Canada, *Proposed Risk Management Approach for [[4-[[2-(4-cyclohexylphenoxy)ethyl]ethylamino]-2-methylphenyl]methylene]-, propanedinitrile (CHPD) Chemical Abstract Service (CAS) Registry Number: 54079-53-7, (July 2008). Accessed at: www.ec.gc.ca/substances/ese/eng/challenge/batch1/batch1_54079-53-7_rm.cfm#9.*

tetrachloroethylene) took over 10 years from the chemical being a proposed CEPA toxic substance to the development and finalization of a pollution prevention plan. In total, it will take over 15 years from CEPA toxic designation to the first date for reductions. However, it is not currently possible to evaluate the effectiveness of these pollution prevention plans in actually reducing uses and releases, because the plans are not public, and there is no public summary.

- Regulations were also developed for some emerging chemicals such as NPE. Again there is no summary of progress under these regulations, and no way to currently assess progress.
- It is difficult therefore, to tell what CEPA management tools are working, to learn from these experiences, and to apply the lessons learned to substances newly declared CEPA toxic.
- Some of the other CEPA tools have yet to be tested (e.g., section 75 (Review of decisions by other jurisdictions); section 76(3) (request for addition to Priority Substances List); and section 80 (new substances)) to determine if additional action on chemicals may be required in addition to those chemicals identified under CMP.

Gap #12: There is little correspondence between categorization results and mandated reporting requirements under NPRI.

- All chemicals identified through categorization are not listed for reporting by major facilities under the National Pollutant Release Inventory, Canada's main inventory for releases and transfers of pollutants. The government has undertaken initial discussions on this issue. However, no proposal by government on how the NPRI should address results of categorization has been released.

Detailed Comparison of PBT Criteria (see Appendix A)

Comparing Persistence Criteria

Take the criteria for persistence for example. CMP consider a chemical persistent if its half life in water is greater than or equal to 26 weeks (182 days).⁴⁷ The GLWQA, the U.S. EPA PBT program and the *Stockholm Convention on Persistent Organic Pollutants* consider a chemical persistent if its half life in water is greater than 8 weeks. Therefore, the CMP persistence criteria require a chemical to be three times more persistent than the GLQWA or the U.S. EPA program. This means a chemical that takes 10 weeks to degrade, would be considered persistent under the GLWQA, EPA PBT program and European REACH program but not under CMP. This means that this chemical will not require further action under CMP.

Comparing Bioaccumulation Criteria

The same situation is also found with criteria used to judge bioaccumulation. Canada's CMP

⁴⁷ Based on persistence and bioaccumulation criteria outlined under the *Persistence and Bioaccumulation Regulations* under CEPA 1999.

considers a chemical bioaccumulative with a bioconcentration factor of greater than or equal to 5,000, whereas this value is more than double the REACH criteria ($BCF > 2,000$). The criteria for bioaccumulation under EPA PBT is a BCF greater than 1,000 with highly bioaccumulative at a BCF of greater than 5,000. A chemical that is bioaccumulative under REACH and U.S. EPA PBT and ChAMP programs would not be considered bioaccumulative under CMP. As further evidence that the bioaccumulation criteria are set too high in CMP: A chemical that is considered bioaccumulative in Canada would be considered VERY bioaccumulative in Europe and HIGH hazard in the U.S. under the ChAMP program. GLWQA does not establish a BCF and the Stockholm Convention is comparable to Canada's CMP.

Canada's CMP also set a criteria of $\log K_{ow} > 5$ whereas U.S. EPA and REACH use a criteria of $\log K_{ow} > 4.5$. There are a large number of chemicals between $\log K_{ow}$ 4.5 and 5. For example, some of the emerging chemicals such as the NPEs have $\log K_{ow}$ between 4.5 and 5. It is unclear how many substances under the DSL would be identified whose $\log K_{ow}$ is between 4.5 and 5.

Comparing Toxicity Criteria

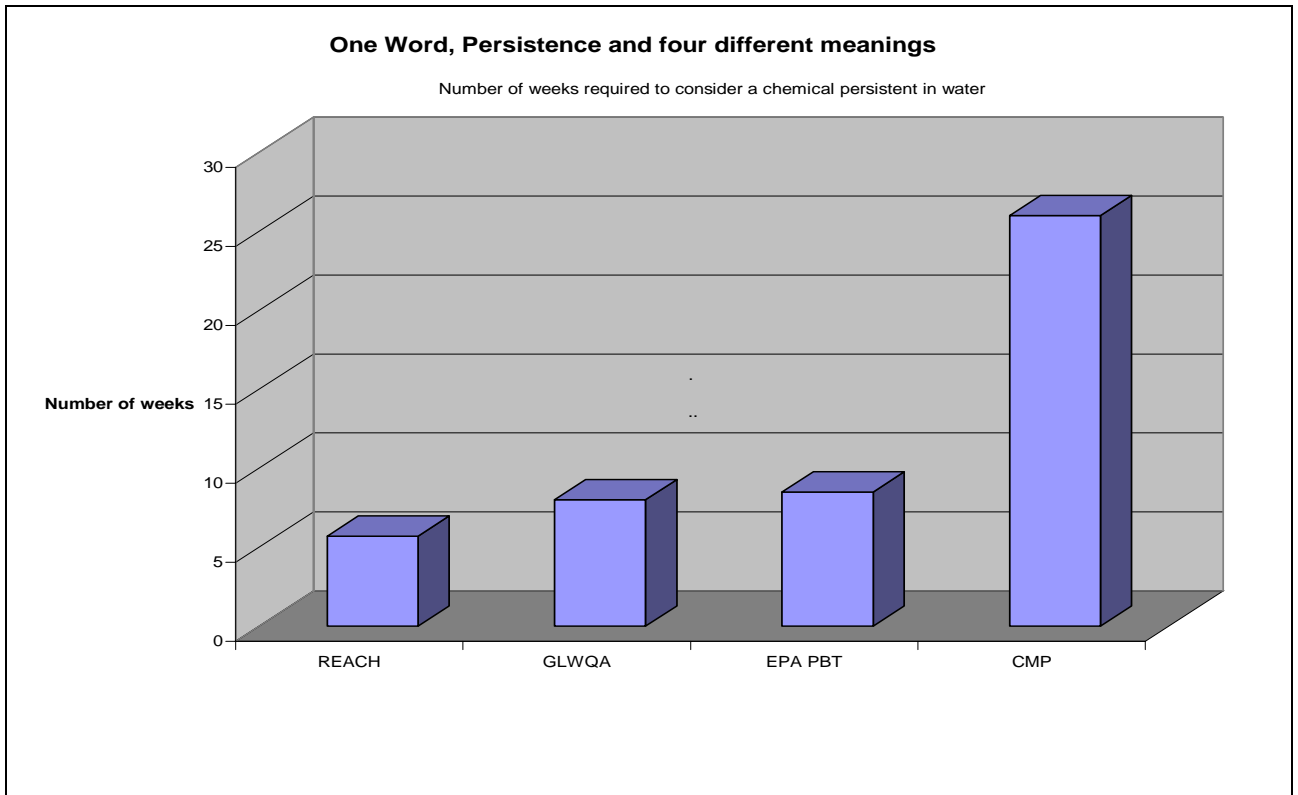
The same situation of high CMP yardsticks is found for toxicity criteria. Chemicals with an acute or chronic toxicity of 5 mg/l would be considered a moderate hazard under U.S. EPA PBT program and toxic under REACH, but would not be considered inherently toxic under CMP.

Conclusion

The P, B, iTe criteria used in CMP are much higher than those used in the *Great Lakes Water Quality Agreement*, the European REACH, and the U.S. PBT and CHAMP and Organisation for Economic Cooperation and Development (OECD) programs. This difference in criteria results in an uneven playing field, such that chemicals considered persistent and bioaccumulative under the GLWQA, U.S. EPA PBT program, or REACH, are not considered persistent and bioaccumulative under CMP. So while organizations agree on reducing PBT chemicals, the same criteria are not being used consistently. The consequences of these different yardsticks are significant. In CMP, chemicals are "screened out" from further consideration for any management tools for reduction, if they do not meet the criteria for P or B and iTe. This means no further action for many chemicals. These inconsistent yardsticks are a major gap in Canada's Chemicals Management Plan.

This situation is analogous to countries agreeing to allow only "tall" people to compete in a race, and then each country has a different height cut-off for deciding who is "tall."

These stringent P, B, iTe yardsticks affect emerging chemicals in several ways. They can result in inconsistent decisions on persistence, bioaccumulation and toxicity. Many emerging chemicals are not considered persistent, bioaccumulative and toxic under CMP, but are considered so using definitions from GLWQA, U.S. EPA and REACH. These chemicals failing P, B, iTe are then not considered for further assessment or management under CMP.



2.3 New Substances

The critical question to ask with respect to new substances is whether the legislative screening mechanisms currently in place ensure that new substances do not become future chemicals of concern.

The stated policy goal that new substances would be screened for potential toxicity before their entry to the market has been achieved to a limited extent in Canada. However, these screening processes, which are conducted in a risk-based approach, do not fully document the potential toxicity of a chemical in a way that would serve the interests of long-term protection of the Great Lakes.⁴⁸ This is demonstrated by the fact that there are now chemicals, such as organotins, that have undergone screening under the *New Substances Notification Regulations* (NSNR) that are currently being investigated as chemicals of emerging concern.⁴⁹ It is also shown by the fact that many potentially toxic substances, such as ingredients in cosmetics discussed in the next section of this report, may not reach thresholds of use in Canada that require the submission of toxicity data.

This section discusses the new substances program in place in Canada as prescribed under the *Canadian Environmental Protection Act*, 1999, and the limits to its effectiveness in restricting or prohibiting chemicals that may be relevant to the Great Lakes.

What is a New Substance?

In Canada, substances are considered “new” if they are not listed on the Domestic Substances List (DSL), a government inventory of substances in use in Canada conducted between January 1, 1984 and December 31, 1986, and described in the previous section on Existing Substances.

Approved substances that have gone through the new substances review may be added to the DSL through a notice in the *Canada Gazette*. The DSL is currently about 26,500 chemicals, with the addition of new substances to the original inventory.⁵⁰

⁴⁸ The assessment process for new substances is governed by CEPA Part 5, Sections 80 to 90.

⁴⁹ Several organotins were assessed through the *Priority Substances List* in 1993 and 2003. However, several organotins that were assessed through the New Substances process were found to meet the criteria set out for toxic under CEPA. Based on the finding of toxic under CEPA for organotins considered “new” in Canada, follow-up assessments of organotins on the DSL have been undertaken. The assessments reports have not been finalized. Accessed at: www.chemicalsubstanceschimiques.gc.ca/organotins-organostanniques_e.html.

⁵⁰ Personal Communication with Bernard Madé, Director, New Substances Division, Environment Canada, December 23, 2008.

How do the New Substances Notification Regulations Work?

For new chemicals coming on to the market in Canada, there are two major entry points.

The first point of entry is the *New Substances Notification Regulations* (NSNR). The intention of the regulations was “to ensure that no new substances are introduced into the market before an assessment of their potential toxicity has been done.” If the substance is shown to be toxic to the environment or human health, appropriate risk management measures are taken.

The government receives approximately 550 notifications per year from manufacturers or importers proposing to introduce new substances on to the Canadian market.⁵¹ Not all these substances are listed on the DSL.

The NSNR establish the basic rules for those chemicals. The substances being evaluated under the NSNR are generally those that have an industrial application. However, substances used in products approved under the *Food and Drugs Act* are also subject to the NSNR, as explained in the next section. Some types of nanomaterials are also assessed under the NSNR. However, the regulations do not cover the active ingredients in pesticides which are evaluated under the *Pest Control Products Act* (Section 2.5).

The regulations require companies that want to introduce a new chemical to:

- notify the Minister of the Environment;
- submit basic information for an assessment by the government;
- pay a fee; and,
- wait for the defined assessment period to end.

If the companies have met all these requirements and the government does not take action to prohibit its entry or apply a condition, the substance receives approval for use, import or sale on the Canadian market. If conditions are placed on the substance, the use and import must comply with conditions.

What triggers the New Substances Notification Regulations?

The NSNR establish a tiered system of requirements. This means that companies must submit different types of data depending on the volume of a proposed new substance that will be manufactured or imported. Requirements also differ based on the type of substance – whether it is a chemical, a polymer or a biotechnology product. Additionally, there are longer assessment periods based on higher volumes and according to different types of substances. The following sections describe the information requirements for new industrial chemicals.

⁵¹ Personal communications with Bernard Madé, Director, New Substances Division, Environment Canada, July 14, 2008.

Quantities between 100 to 1,000 kilograms

The threshold for notifying the Minister of a proposed new importation or manufacturing of a chemical is 100 kilograms (kg) per year. If several companies use chemicals not listed on the Domestic Substances List at less than 100 kg per year, the notification requirements do not apply.

For volumes of new chemicals imported or manufactured in Canada between 100 kg and 1,000 kg in one calendar year, a company provides a New Substances Notification Package, for which there are minimal requirements

These include the name, the CAS number, trade names or synonyms, the material safety data sheets, intended use of the substance, contact information of other government agencies that have been notified of the manufacture or import, and all information in respect of the substance that is relevant to identifying hazards to human health and the environment and that is in the person's possession. No toxicity information is explicitly required.⁵²

These requirements apply to all substances new to Canada at the 100 kg level, with the exception of chemicals on another list, known as the Non-Domestic Substances List (NDSL). The NDSL list is a list of chemicals in use internationally, and the threshold for notifying the government of the use of Non-DSL substances is 1,000 kg per year.

Where companies have submitted this data, the Ministers of Health and Environment are effectively deemed to have assessed the information 5 days after the notification for substances not on the DSL or the NDSL, or 30 days after the notification for NDSL substances. In effect, a chemical is presumed to be acceptable, and is permitted to enter into Canadian commerce.

Quantities between 1,000 to 10,000 kilograms

More data and longer assessment periods are required for chemicals not on the DSL or the NDSL that will be imported or manufactured above 1,000 kg for substances but at volumes of less than 10,000 kg per year.⁵³ At this level, the notification package includes all the data required for chemicals under 1,000 kg plus basic data on toxicity, such as physical and chemical data, acute toxicity and mutagenicity testing, as well as exposure information, including whether the chemical will be used in products for children. NDSL substances provide the same data at a threshold level of 10,000 kg per year.

The assessment period for substances manufactured or imported in this volume range is 60 days. Again, companies can go ahead with marketing and using the new substance once the 60 day period is completed unless notified otherwise.

⁵² *New Substances Notification Regulations*, Schedule 4.

⁵³ NSNR, Schedule 5.

Quantities over 10,000 kilograms

Above 10,000 kg imported or manufactured annually, data requirements are expanded to include skin irritation and skin sensitization testing, repeated dose toxicity and additional mutagenicity testing.⁵⁴ The regulations also require companies to submit “all other information and test data” that apply to environmental and human health hazards that they possess. For these chemicals, an assessment period of 75 days applies. NDSL substances notifiers are required to provide this information only if they are predicted to have high releases to the aquatic environment or if the public may be significantly exposed to these substances.

Under the regulations, it is possible that the time periods allowed for assessments under the regulations may elapse before Health Canada and Environment Canada finish the assessment. In this case, Environment Canada may request an extension to complete the assessment. When the Minister asks for additional information, the substance is not allowed to be manufactured or imported until the new information is submitted and the 90 day assessment period takes place. However, if the time legally allocated for the review period expires with no request for information, the manufacturer or importer is allowed to bring it on to the market whether the assessment is complete or not.

In general, even at the highest volumes of production or use, the NSNR do not require data that would determine whether new substances have certain hazardous properties, such as neurodevelopmental toxicity or endocrine disruption.

Environment and Health Canada, in their assessments, do modelling to determine toxic characteristics of new chemicals. This gives the regulators some information on the persistence, bioaccumulative and toxic properties of these chemicals, such as carcinogenicity. New substances are assessed on the basis of risk, and are not eliminated or restricted based on their hazardous properties. *Therefore, these properties – persistence, bioaccumulation or toxicity – do not automatically result in prohibition of these chemicals from the Canadian market.*

What action can the government take with respect to new chemicals?

Environment Canada has five major options after reviewing the notification packages for new substances:⁵⁵

1) It can approve the proposed introduction of the substance onto the Canadian market with no conditions;

⁵⁴ NSNR, Schedule 6.

⁵⁵ CEPA, Section 84 and 85.

- 2) It can impose a Significant New Activity Notice (SNAc) whereby companies are allowed to proceed with proposed activities but would have to re-notify if other activities are considered;
- 3) It can prohibit the manufacture or import of a substance;
- 4) It can request further information to be submitted to complete the assessment of the substance; or,
- 5) It can impose conditions which are measures to address identified risks.

If no concerns have been raised with respect to a chemical's use at the highest quantity levels and the government decides that no risk management is required, a new substance can be used by any manufacturer or importer with no further notification or data required.

Of the 550 notifications for new chemicals annually, Environment Canada has prohibited the introduction of substances only 6 times in 14 years.⁵⁶

If the Minister applies a prohibition on the manufacture or importation of a substance, this prohibition expires two years after it is imposed. Should the government extend the prohibition, a notice of the proposed regulation must be published in the *Canada Gazette*. The proposed regulation replaces the prohibition.

The most recent prohibitions under the NSNR were imposed on four fluorotelomer-based substances proposed for use in 2004. Four prohibition notices were published on these substances. They were found to contribute to the formation of perfluorinated carboxylic acids (PFCAs). PFCAs, suspected of being bioaccumulative and subject to long-range transport, are found extensively throughout Arctic biota, and are associated with adverse effects in animals. In addition, breakdown products of fluorotelomer-based substances also lead to the formation of PFCAs.

A proposed regulation to amend the *Prohibition of Certain Toxic Substances Regulations, 2005* that would replace the prohibition on these substances was released June 17, 2006.⁵⁷ The proposed regulation prohibited the manufacture and use of the four fluorotelomer-based substances in Canada, but allowed its use in imported products. Although the prohibition would address a problem of direct discharges from industrial uses, they do not address the end of life exposures that would result, such as chemicals leaching from disposed products in landfills. The amendments to the regulation have yet to be finalized.

A more frequent response to substances of concern is the imposition of SNAc Notices.

⁵⁶ Personal communications with Bernard Madé, Director, New Substances Division, Environment Canada, July 14, 2008.

⁵⁷ Government of Canada, *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (Four New Fluorotelomer-based Substances)*, C. Gaz.I, 140 no. 24 (June 17, 2006). See canadagazette.gc.ca/partI/2006/20060617/html/regle1-e.html.

If the government determines through its assessment of a new chemical that a substance does not pose a risk when used for a particular use but may pose one under other circumstances, it puts a “significant new use activity” (SNAc) flag on the substance. Environment Canada imposes about 16 SNAcs each year on different substances. Companies wishing to use a substance subject to a SNAc will have to re-notify the government under the NSNR.

When a substance is suspected of being toxic or capable of becoming toxic, conditions may be imposed to mitigate any risk to human health or the environment. Conditions allow the manufacture or importation of a substance with restrictions. Types of restrictions on the substance include: the volume allowed, the physical form (e.g., must be imported as a plastic pellet), the use, or the disposal of the substance. The notifier is obliged to abide by the conditions imposed on the substance. These Ministerial conditions are published in the *Canada Gazette*, Part I. Substances that have conditions imposed on them are not eligible for addition to the DSL. Environment Canada imposes approximately 6 to 8 conditions per year.

For new substances that are found to be persistent, conditions may be placed on them that allow their use provided that there are no releases to the environment. For new substances that Health Canada determines may be carcinogenic, conditions may be placed on the substance that would limit the amount of exposure to the public based on a risk assessment.

Between 2000 and 2006, 46 SNAcs were imposed on chemicals and polymers and 60 ministerial conditions applied to new substances. In 2007, 12 SNAcs were applied to chemicals and polymers.

How are nanomaterials evaluated in Canada?

Nanotechnology is a technological process whereby products or substances are engineered on a scale of one to one hundred nanometers. One nanometer is one billionth of a metre in size – approximately one hundred thousand times smaller than the cross section width of a strand of human hair.⁵⁸

Although the IJC Multi-Board Work Group has not identified nanomaterials on the list of substances of emerging concern, it has been included in this report because there is a general lack of scientific evidence about important aspects of nanotechnology, such as associated human health risks, environmental fate, bioaccumulation, exposure routes, and the risks it poses for sensitive species and ecosystems.

In addition, published scientific studies suggest that there is cause for concern. For example, a recent study found that mice exposed to carbon nanotubes have the same toxic response as those exposed to asbestos, suggesting that, as with asbestos exposure, humans who inhale sufficient quantities of carbon nanotubes could be at risk of

⁵⁸ Canadian Institute for Environmental Law and Policy, *Discussion Paper on a Policy Framework for Nanotechnology*, (March 2007) p.1.

developing mesothelioma.⁵⁹ Another study demonstrated that silver nanomaterials – used extensively for a variety of antimicrobial applications – pose potential hazards in aquatic animals.⁶⁰

A particular concern is the growing use of nanomaterials as ingredients in cosmetic and personal care products. For example, nanoparticles of titanium dioxide are increasing in popularity as ingredients in sunscreens and cosmetics. Because of their extremely small size, nanomaterials may be able to enter the body and react in different ways than larger particles. Yet, there are no requirements in Canada for the assessment for many of these nanomaterials and their effects in the environment and on human health because they are already on the DSL. Titanium dioxide is a suspected carcinogen, and at least one animal study showed how nanomaterials spur the generation of biologically active molecules that can damage cells by inducing oxidative stress and potentially damage the brain.⁶¹

Nanoparticles may find their way into the Great Lakes due to the increasing number of products such as sunscreens, stain-resistant clothing, cosmetics, and sporting goods containing nanomaterials that are being used and manufactured in Canada.

The Woodrow Wilson Center's nanotechnology-based Consumer Products Inventory lists more than 800 manufacturer-identified nanotechnology-based electronic, cosmetic, automotive, and medical consumer products that are currently on the market.⁶² In Canada, approximately 80 companies are marketing products with nanomaterials.⁶³

There is currently no comprehensive regulatory framework to address nanomaterials in Canada.

Only new substances, such as carbon nanotubes, are governed by the NSN regulations. An Advisory Note was posted by Environment Canada in June of 2007 to manufacturers or importers of nanomaterials that are not on the CEPA DSL and whose nanoscale forms have “unique structures or molecular arrangements,” stating that these materials are subject to the NSNR.

However, there is no information publicly available as to how many nanomaterials have been evaluated through the NSNR process. Companies which use nanoform versions of

⁵⁹ Bethany Halford, “Nanotube Inflammation: Long, Thin Carbon Structures Exhibit Asbestos-like Pathogenicity in Mice,” *Chemical & Engineering News*, 86 no. 21, (May 26, 2008), 9. Accessed at: pubs.acs.org/cen/news/86/i21/8621notw4.html; Anonymous, “Space Elevators, Tennis Racquets, and Mesothelioma,” *The Lancet Oncology*, 9 no. 7, (July 2008), 601. Accessed at: hesa.etui-rehs.org/uk/dossiers/files/The%20Lancet%20Nano.pdf.

⁶⁰ Michael Berger, “Problematic new findings regarding toxicity of silver nanoparticles,” (June 6, 2008). Accessed at: www.nanowerk.com/spotlight/spotid=5966.php.

⁶¹ Thomas Long, et al., “Titanium Dioxide (P25) Produces Reactive Oxygen Species in Immortalized Brain Microglia (BV2): Implications for Nanoparticle Toxicity,” *Environmental Science & Technology*, 40 no. 14 (2006), 4346-4352.

⁶² The Project for Emerging Nanotechnologies, (2009). Accessed at: www.nanotechproject.org/inventories/consumer/

⁶³ Canadian Institute for Environmental Law and Policy, *Update on a Framework for Canadian Nanotechnology Policy: A Second Discussion Paper*, (March 2008) p.2.

substances that are already on the Domestic Substances List are not required to notify the government. As a result, there are few notifications under the regulations for nanomaterials.

For those nanomaterials that have been screened under the NSNR, Environment Canada has informed companies that the SNAc provisions of CEPA may apply where appropriate – an approach which has been used five times as of mid-2008.

Environment Canada is considering a proposal for how to regulate these substances. Environment Canada and Health Canada are considering specific data requirements under the NSNR for nanomaterials. Similarly, consideration is being given to using the SNAc provisions of CEPA to require notification of nanoscale forms of substances already listed on the DSL.

Non-Domestic Substances List

The second point of entry for new substances is through the Non-Domestic Substances List.

The Non-Domestic Substances List (NDSL) is comprised of those substances that are not on the Domestic Substances List, but are in use internationally. These substances are also subject to NSNR requirements. However, substances on this list benefit from reduced information requirements under the NSNR than would be required for a “brand new” substance being introduced in Canada.

The NDSL is primarily based on the U.S. *Toxic Substances Control Act* (TSCA) inventory, and includes substances which have been on the TSCA inventory for at least one year. The TSCA inventory is estimated to include about 56,000 substances. The NDSL is usually updated semi-annually, and includes new substances introduced into the United States under TSCA.

Substances that are on the NDSL are assigned to lower tier requirements under the *New Substances Notification Regulations*, even though manufacturers or importers notify Environment Canada that they will be using volumes that would normally require more toxicity data. This means, for example, that data and assessment time frames are the same for chemicals on the NDSL that will be introduced into Canada at volumes above 10,000 kilograms (Schedule 5) as they are for new chemicals above 1,000 kilograms (Schedule 4).⁶⁴ Companies are required to submit any data that are relevant to the assessment of the chemical, the U.S. EPA assessment under TSCA and whether any risk management measures were imposed.

⁶⁴ Schedule 4, which applies to high volume NDSL substances, requires minimal information as part of the notification packages given to government, while Schedule 5, which applies to substances new to Canada and not on either the DSL or the NDSL, has significantly more data requirements.

However, TSCA does not set out any specific data requirements for the acceptance of new chemicals into commerce. It is estimated that for 85% of the new chemicals being introduced into the American market, there are no health test data.⁶⁵

A 2005 Government Accountability Office report stated that:

TSCA does not require chemical companies to test new chemicals for toxicity and to gauge exposure levels before they are submitted for review and according to EPA officials, chemical companies typically do not voluntarily perform such testing.⁶⁶

The harmonized approach between U.S. and Canada hinders Canada's ability to effectively assess new substances entering Canada by lowering the bar for chemicals already on the U.S. market. Chemicals at higher volumes of importation or use that are on the TSCA inventory and the NDSL do not have to meet the same criteria as other chemicals that are not on the DSL. This provides an avenue for chemicals of concern to find their way into the market and into the Great Lakes with less data than would otherwise be required by the NSNR.

How much public participation is there in the new substances program?

In contrast to the processes established for assessing existing chemicals, the government has not established a protocol that would allow the public an opportunity to review or participate in the government's new chemicals approvals. Government assessments of new chemicals are not made public.

Furthermore, there is no public notification of new chemicals introduced into the Canadian market, except in the exceptional cases where the government decides to impose conditions on their use or significant new activity flags. Information in the *Canada Gazette* is published only if a determination is made that a new chemical is toxic and restrictions or prohibitions are placed on it. The latter was the case for two industrial chemicals and 4 new fluorotelomer-based substances.

Conclusion

Although the NSNR are the primary gateway through which most new chemicals must pass, the regulations are not stringent enough to ensure that chemicals being introduced onto the market today will not emerge as future substances of concern. There is considerable value in having regulations that require both notification and data for substances proposed for use in Canada, and these regulations provide the government with an inventory of new substances along with some basic data which are not necessarily available for substances on the original Domestic Substances List. However,

⁶⁵ U.S. Government Accountability Office, "Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage its Chemical Review Program," (June 2005), 11.

⁶⁶ *Ibid.*

there are also significant gaps in the current policies that can result in new substances becoming substances of emerging concern in the Great Lakes.

Gaps identified with new substances

Gap #1: There is a lack of data required for new substances.

- There are no data requirements for health and environmental screening at the lowest tier of volume for new substances entering the Canadian market. This may affect the government's ability to know the potential persistent and bioaccumulative hazards associated with these chemicals.
- Companies are not required to submit important environmental and health-related data under the NSNR. Data on carcinogenicity, neurodevelopmental toxicity and endocrine disruption are not specifically required under any schedule or for even the highest volumes of new chemicals being introduced. The government, however, does have the authority to request this information.
- There are no explicit requirements that data on persistence and bioaccumulation be submitted to the government as part of the notification packages, except for results of a biodegradation study and the octanol/water partition coefficient.
- There are no data requirements for chemicals being introduced into the United States and this lack of data for chemicals approved in the United States may allow chemicals to enter the Canadian market with less data than that required for new Canadian substances at the same volume.

Gap #2: New substances are not prohibited from entering the Canadian market, even though they may exhibit certain hazardous properties, and may become chemicals of emerging concern in the Great Lakes.

- The NSNR do not prohibit the entry of persistent, bioaccumulative and toxic chemicals to Canada on a consistent basis. Although the *Persistence and Bioaccumulation Regulations* under CEPA are considered during the assessment process, chemicals having properties of persistence and bioaccumulation are not necessarily refused entry to the Canadian market. They may be subject to conditions, which would limit the use or release of some persistent and bioaccumulative substances but would not ban or eliminate them completely. Because of this, the goals of the program are not consistent with the GLWQA.

Gap #3: The NSNR do not adequately address nanomaterials, which are beginning to be widely used in consumer products.

- The NSNR are not being used to determine the health and environmental impacts of a new generation of nanomaterials being rapidly introduced into the market, if they are versions of already existing chemicals. These regulations did not anticipate the development of nanoparticles and do not have schedules in place that would require data on their impacts.

Gap #4: Once the notification period has elapsed, new substances may enter the Canadian market, whether the assessment has been completed or not if the government does not ask for an extension of the timeframe.

- The government is required to finalize its decision on evaluations within a specified timeframe prescribed in the NSNR. If the government is unable to complete its assessment, the chemical may be introduced in Canadian commerce. It is important to note, however, that to date, the government has completed its assessments of notified substances within the legislated timeframes.

Gap #5: After a substance has entered the market, there are no monitoring requirements and little follow-up to ascertain whether new chemicals are having negative impacts on the environment and human health.

- The government does not require companies to develop a testing protocol for new substances that would be shared with the government, and allow government or independent scientific monitoring of new substances in the environment;
- There is no systematic monitoring of new substances in the environment after their introduction on the Canadian market to enable governments to understand if new substances are creating a concern, with particular emphasis on substances for which conditions have been imposed;
- Substances, which haven't been screened under the new substances program, can still enter the Canadian market in finished products if they meet the definition of a "manufactured item." For example, the proposed regulation to add four fluorotelomer based substances to the Prohibition of Certain Toxic Substances, 2005 in 2006 included an exemption for imports of finished products that may contain the prohibited substances.⁶⁷

Gap #6: There is a lack of public engagement and transparency in the assessment of new substances.

- Unlike existing substances where assessments are made public and include a public comment period, assessment results under the NSNR are not public unless conditions or SNACs are applied.

⁶⁷ Government of Canada, *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (Four New Fluorotelomer-based Substances)*, C. Gaz.I, 140, no. 24 (June 17, 2006). See canadagazette.gc.ca/partI/2006/20060617/html/regle2-e.html.

2.4 Pharmaceuticals and Personal Care Products

Many pharmaceuticals, antibiotics and ingredients in personal care products, such as synthetic musk fragrances, have been found in Canadian municipal treatment plant effluents, surface waters and drinking water.⁶⁸ One study, looking at 15 southern Ontario sewage treatment plants, found that ibuprofen, cholesterol drugs and triclosan were present in untreated water samples taken near sewage treatment plants in the Great Lakes.⁶⁹ The concentration of ibuprofen, often used as an anti-inflammatory drug, was also detectable in the treated drinking water of almost all the water treatment plants using the Great Lakes as a source of drinking water. Similarly, many veterinary medicines and animal care products have been found in agricultural watersheds.⁷⁰

Although it has been known for twenty years that pharmaceuticals and personal care products are being released into the environment, it is only in the last 10 years that scientists have had the analytical methods to identify and quantify their presence.⁷¹ As a result, pharmaceuticals and personal care products are now being recognized as a widespread source of water pollution. They are considered to be chemicals of emerging concern because of their ubiquitous presence near heavily populated areas of the Great Lakes and the large amounts coming from sewage treatment plants.

How do these chemicals find their way into the Great Lakes?

Pharmaceuticals can enter the water supply when people pass trace amounts of unmetabolized medications through their urine and into the sewage treatment system, or when unused medications are disposed of down the sink or into the toilet by individuals, hospitals or long-term care facilities. They can also enter the Great Lakes through direct discharges from pharmaceutical plants. This problem is aggravated by the increasing use of prescription drugs and personal care products.

Drugs have also been shown to contaminate sewage sludge, which is often applied to farmers' fields, and which in turn can contaminate the agricultural runoff into lakes and rivers. Similarly, farm animals excrete veterinary drugs, including hormones and antibiotics into fields, and the residues may eventually make their way into rivers and lakes. In addition to being found in municipal sewage and manure that are managed as

⁶⁸ *Ibid*, p.8.

⁶⁹ Mark R. Servos, et al., "The Presence of Selected Pharmaceuticals and Personal Care Products in Drinking Water in Ontario Canada," *Water Quality Research Journal of Canada*, 42 no. 2 (2007), 130-137.

⁷⁰ Health Canada, et al., "Workshop Proceedings, Pharmaceuticals and Person Care Products in the Canadian Environment: Research and Policy Directions," (March 5-7, 2007).

⁷¹ Health Canada, et al., "Workshop Proceedings, Pharmaceuticals and Person Care Products in the Canadian Environment: Research and Policy Directions," (March 5-7, 2007).

wastes or applied to fields, these chemicals have also been detected in aquaculture wastes.⁷²

Some pharmaceuticals and some ingredients in personal care products, such as musk fragrances, are persistent.⁷³ However, most pharmaceuticals or substances like phthalates, which are used in a wide range of personal care products, are not classified as persistent but are continually present in the water supplies around sewage treatment plants because they are constantly being emitted and replaced because of their widespread use.

How are these products regulated?

Pharmaceuticals, personal care products and veterinary drugs are all governed by the *Food and Drugs Act* (F&DA). The Act itself is directed at controlling the sale, advertising and labelling of food, drugs, cosmetics and medical devices, with different regulations setting out more specific rules for categories of products. These category-specific regulations have varying requirements and criteria for product safety. They include the *Cosmetic Regulations*, *Food and Drug Regulations*, *Medical Devices Regulations*, *Novel Foods Regulations* and *Natural Health Products Regulations*.

The concerns about substances approved under the F&DA are not limited to pharmaceuticals, veterinary drugs and ingredients in cosmetics and personal care products, however. Other products governed under this Act that may have an environmental impact are novel foods, such as foods containing genetically modified organisms, food additives, biologics, genetic therapies and radiopharmaceuticals, constituents of medical devices and natural health products.

As the government stated in its “Issue Identification Paper” with respect to all substances approved under the F&DA:

There is mounting evidence that some of these chemicals have the potential to induce adverse health effects in non-target species and possibly humans when chronically exposed to low levels. Effects of concern include disruption of development and reproduction (i.e. endocrine disruption) in exposed species and their offspring, as well as the enhancement of antibiotic resistant bacteria. There is great uncertainty on the potential long-term human health and ecological health consequences that may be resulting from continuous low-level exposure to these substances, especially in sensitive life states and populations.⁷⁴

⁷² It should be noted that some aquaculture products such as pesticides used to control sealice on salmon farms, are assessed under the *Pest Control Products Act*.

⁷³ U.S. Environmental Protection Agency, “Pharmaceuticals and Personal Care Products (PPCPs): Frequently Asked Questions.” Accessed at: www.epa.gov/ppcp/faq.html.

⁷⁴ Health Canada, “Issue identification Paper: Environmental Assessment Regulations,” p.11.

As noted above, pharmaceuticals and ingredients in personal care products have been detected in municipal sewage, agriculture and aquaculture wastes and have raised concerns about their potential to have adverse effects at chronic low levels and concerns about antibiotic resistance. Less is known about the other categories of products. The government in its “Issue Identification Paper” indicates that food additives and genetically modified organisms in the environment are not likely to pose a high risk to the environment, but there is a need for a much better understanding of their potential impact. Biological drugs, because of their instability, are considered unlikely to be a threat to the environment, while medical devices are generally disposed of in landfills or treated as hazardous waste.

Products approved under the F&DA and its regulations, such as pharmaceuticals and veterinary drugs, are evaluated prior to being licensed for sale for their effectiveness and safety. For cosmetics, there is no pre-market testing. However, the Cosmetics Division does maintain The Cosmetic Ingredient Hotlist (Hotlist), which is a list of prohibited and restricted cosmetic ingredients in Canada. The Hotlist has mandatory notification of each product’s formulation to Health Canada which is checked against Hotlist restrictions. Cosmetics or personal care products are defined as substances or mixtures “manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and include(s) deodorants and perfumes.”⁷⁵ Cosmetics do not include products that have a therapeutic claim such as sunscreens, which are considered drugs.

How are environmental effects evaluated?

Prior to 2001, none of the products regulated under the F&DA were assessed for their impact on the environment. However, as of September 2001, the government determined that all new products under this legislation will be subject to NSNR, and Health Canada became responsible for conducting environmental risk assessments on any new F&DA products. These assessments were done in accordance with the requirements of the NSNR under CEPA (See section 2.3). At the same time, environmental assessment regulations that would be more appropriate for F&DA approved products are being developed by Health Canada.

Between 2001 when these products became subject to the NSNR and 2007, approximately 400 new substance notifications were submitted to the Environmental Assessment Unit of Health Canada.⁷⁶ The majority of these notifications have been for cosmetic ingredients (62%), while pharmaceuticals made up 21% of all the notified substances.

As noted in the previous section under New Substances, the NSNR were developed to apply to industrial chemicals and polymers. They were not developed to screen

⁷⁵ *Food and Drugs Act*, Section 2.

⁷⁶ Andrew Beck, Head, Environmental Assessment Unit, Health Canada, “Abstract in the Pharmaceuticals and Personal Care Products in the Canadian Environment: Research and Policy Directions Workshop Proceedings,” (Niagara-on-the-Lake: Health Canada, March 5-7, 2007).

substances in products regulated under the F&DA, such as pharmaceuticals or genetically modified organisms. A significant problem with the application of these regulations to substances in F&DA products is the trigger levels established under the NSNR.

The NSNR are based on a tiered system of data requirements, with lower volumes of chemicals being required to offer the least data to the government. Many of the substances in F&DA products do not meet the lowest trigger levels that would require notification and data submission under the NSNR. Of the notifications that have been made for F&DA products under the NSNR, the majority are for the first level, a level that does not require any information on their environmental fate, distribution or effects.

This means that ingredients in cosmetics could be persistent, bioaccumulative and inherently toxic, or have the potential to be carcinogenic, mutagenic or toxic to reproduction. If they fall below the second level for NSNR, there are no requirements for data that would alert the government to potential hazardous properties and identify chemicals of emerging concern.

As a result, the government has recognized that the requirements of the NSNR are not rigorous enough for F&DA substances in products, and new regulations are necessary. Other limitations that must be considered for F&DA products are the types of fate and effects data that are needed for these products, and the uncertainty associated with the use of modelling.⁷⁷

The process for developing more appropriate regulations for new substances regulated under the F&DA was initiated in September 2001, when Health Canada announced its intention to develop environmental assessment regulations.

Subsequently, an Environmental Assessment Working Group was established in 2006 as part of the consultation on the regulations.⁷⁸ However, 7 years have elapsed since the government announced its intentions, and the environmental assessment regulations have still not yet been developed.

The regulations, once they are finished, will be the key vehicle through which *new* substances in products regulated under the F&DA are screened for persistence, bioaccumulation and toxicity. In addition to the regulations, Health Canada is looking at best practices in the management and disposal of F&DA regulated substances, such as take-back programs for pharmaceuticals.

What is the In-Commerce List?

Like the existing chemicals that were listed on the DSL, there is a similar group of chemicals in commerce that are primarily used in F&DA-regulated products. These substances have been in use for many years but were not listed on the DSL and, as a

⁷⁷ *Ibid.*

⁷⁸ Personal communication with Neil Tolson, Head, In-commerce Branch, Health Canada, and Jackie Sitwell, Director, New Substances Assessment and Control Bureau, Health Canada on July 22, 2008.

result, have not been categorized according to their persistent and bioaccumulative properties.

This is because it was initially assumed that CEPA was directed only at industrial chemicals.⁷⁹ However, substances could only be exempted from CEPA requirements if they were assessed under another federal Act or regulation that provides for the same procedures. These are listed as exempted Acts under CEPA. Since the F&DA did not provide for pre-notification and assessment of substances, as required by CEPA, the F&DA is not an exempted Act. This led to the government's decision to apply the NSNR to substances regulated under the F&DA.

Likewise, since it was assumed until 2001 that substances under the F&DA were not subject to CEPA, many substances in F&DA-regulated products were not placed on the DSL, which listed all substances in commerce in Canada between January 1, 1984 and December 31, 1986.

As a result, many substances in veterinary drugs, pharmaceuticals, personal care and natural health products were not listed on the DSL and prior to 2001, when they became subject to SNR, none were evaluated for their effects on the environment. These included about 9,000 chemicals that came onto the market between 1987 and September 13, 2001. The toxicity, and environmental and health impacts of these are unknown.

Health Canada as the lead agency, in collaboration with Environment Canada, has been working for several years now to bring these chemicals into the regulatory system, as required under CEPA. They have divided their efforts into four strategic categories.

The first category being investigated by Health Canada consists of about 600 to 800 substances that were not captured on the DSL, even though they were on the market and being used in F&DA regulated products between January 1, 1984 and December 31, 1986. These are active substances in pharmaceuticals and veterinary drugs, which were identified by Health Canada from its databases. These substances were considered eligible for addition to the DSL since they were on the market at the same time the DSL was being compiled.

The second category, and largest group, includes substances that were not included in the gap between the time the DSL was completed and the time when the NSNR were applied to F&DA products. These are substances that were licensed and came *onto the market* between January 1, 1987 and September 13, 2001. Approximately 9,000 of these chemicals, now known as the "In-Commerce" List, were not originally assessed under the NSNR requirements. There are only 3 pieces of information for each of these substances:

⁷⁹ Personal communications with Neil Tolson, Head, In-commerce Branch, New Substances Division, Health Canada and Jackie Sitwell, Director, New Substances Division, Health Canada, July 22, 2008.

the CAS name, the CAS registration number and an alternate name.⁸⁰ No information is available on use patterns, chemical structures of estimated annual volumes.

For these chemicals, Health Canada is developing a process similar to the categorization process used for DSL substances that will be applied to these substances. It is collecting basic information needed to determine the potential hazards of these substances. Categorization was used to determine which chemicals were persistent or bioaccumulative and inherently toxic.

A third category includes the substances *submitted to Health Canada for approval* prior to the introduction of the NSNR, but not yet approved. These are being treated the same as the second category.

The fourth, and last, category contains substances introduced on the market after September 13, 2001. These are the substances that are being evaluated under the NSNR.

What happened to chemicals in F&DA-regulated substances that are on the DSL?

Not all substances regulated under the F&DA were omitted from the DSL. As mentioned previously, some chemicals used in these products are also used as industrial chemicals, and were captured by the DSL. Because of this, they were also categorized under CEPA, and assessed for their persistent, bioaccumulative and inherently toxic properties.

Several have already been identified under the categorization process as chemicals of high priority to the government, and sent out as part of the Industry Challenge, discussed in Section 2.2. An example is hydroquinone. Hydroquinone is used in industrial applications and in personal care products. It was categorized as a high hazard chemical, and sent out in the first batch of chemicals of the Challenge under the Chemicals Management Plan. It was found to be CEPA toxic because it was identified as a non-threshold carcinogen for which there potentially would be harm at any level of exposure, and a threat to human health.

There were 110 notifications of cosmetic products containing hydroquinone filed by industry with Health Canada under the *Cosmetic Regulations* of the F&DA, primarily in manicure preparations and hair dyes, at concentrations ranging up to 3%. Health Canada's Drug Product Database lists 34 marketed products containing hydroquinone. It is also found in 3 licensed natural health products, and is used as a stabilizer in two registered pesticides, and in rubber processing, food processing, for paints, varnishes, motor oils and fuels, as well as in the photographic industry. Health Canada is intending to put further restrictions on hydroquinone on the Cosmetic Ingredient Hotlist.

As a result of its designation as a CEPA toxic substance, a management plan has been proposed for hydroquinone. The risk management plan does not propose any action for

⁸⁰ Neil Tolson, Head of In-Commerce Substances Unit, Health Canada, "Abstract in the Pharmaceuticals and Personal Care Products in the Canadian Environment: Research and Policy Directions Workshop Proceedings," (Niagara-on-the-Lake: Health Canada, March 5-7, 2007).

the use of hydroquinone in the adhesives sector, the photographic sector or its use in pest control products. It deems all these exposures negligible or low concentrations, even though the document says that “there may be a probability of harm at any level of exposure.”

Health Canada does propose two measures for F&DA-regulated products.⁸¹ It proposes regulating natural health products containing hydroquinone as prescription drugs. For its use in cosmetic products, Health Canada proposes to use the Hotlist, which sets out restrictions and prohibitions on the use of certain chemicals in cosmetics, for further restrictions.

The Hotlist is one of the management tools being used for high hazard substances in cosmetics. The Hotlist already stipulated that hydroquinone is not permitted in products to be applied on the skin or on mucous membranes, including skin lightening products. Health Canada is proposing to add restrictions on the concentrations of hydroquinone in hair dyes and artificial nail systems.

The Hotlist is largely adopted from the restrictions and prohibitions established in the European Union’s Cosmetics Directive, but it is unclear whether North American manufacturers or importers abide by the limits on the Hotlist. Notification of a cosmetic’s formulation is a mandatory requirement for sale in Canada, and the Hotlist is used to check against the formulation of every cosmetic product sold in Canada. However, Health Canada still allows the use of carcinogens in cosmetics if it determines that consumer exposures are limited.

⁸¹ Environment Canada and Health Canada, *Proposed Risk Management Approach for 1,4-Benzenediol (Hydroquinone)* Chemical Abstract Service (CAS) Registry Number: 123-31-9, (July 2008). Accessed at: www.ec.gc.ca/substances/ese/eng/challenge/batch1/batch1_123-31-9_rm.cfm.

Case Study: Triclosan

Triclosan has been detected in the Great Lakes, specifically in waste and surface waters from the Detroit River. It is an example of a chemical that has become a common ingredient in personal care products and a common contaminant in sewage systems, without any assessment of its environmental or health impacts.⁸²

Triclosan is a synthetic substance that is used in hospital and health care settings for controlling bacteria and germs, as well as in personal care products. The use of triclosan has exploded in the past 20 years, as it became an increasingly popular ingredient in antibacterial soaps, deodorants, skin cleansers, lotions, creams, toothpastes, detergents, cosmetics, fabrics for clothing, to plastics and house paint.⁸³

Despite its popularity, however, there is little information to demonstrate that the use of triclosan in personal care products or household cleaning products has provided added health benefits or protection from bacterial contamination. The U.S. Centers for Disease Control concluded that “antibacterial soaps are not necessary in everyday use, and washing hands with ordinary soap and warm water is an effective way to prevent home infections.”⁸⁴

Triclosan has been identified as a high production volume substance with 1 million pounds used or manufactured in the U.S.⁸⁵ Monitoring data shows it is frequently detected in aquatic environments close to sewage treatment plant outflows.

Because triclosan has industrial applications as well as cosmetic uses, triclosan was on the Domestic Substances List and included in the categorization exercise. However, there are at least three CAS numbers for triclosan included in the DSL. The different categorization results contribute to confusion on triclosan, and how it should be assessed and controlled.

DSL chemical name	CAS No.	Persistence*	Bioaccumulation*	Inherent toxicity*
Triclosan	64111-81-5	Yes	Yes	Yes
Phenol, 5-chloro-2-(2,4-dichlorophenoxy)-	3380-34-5	Yes	No	Yes
Urea, N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl)-	101-20-2	Yes	No	Yes

* according to Environment Canada’s categorization criteria

Triclosan (CAS no. 64111-81-5) met the criteria for persistence, bioaccumulation and inherent

⁸² Keri Hornbuckle and Carolyn Persoon, *Bibliography of Emerging Chemicals of Concern in the Great Lakes*, Prepared for International Joint Commission, (2008).

⁸³ Control and Prevention (CDC), *National Report on Human Exposure to Environmental Chemicals Centers for Disease*, (December 2007). Accessed at: www.cdc.gov/exposurereport/pdf/factsheet_triclosan.pdf.

⁸⁴ *Ibid.*

⁸⁵ Green Media Toolshed, *Pollution in Your Community*, (2005). Accessed at: www.scorecard.org.

toxicity, and was categorized as a high priority substance. Under the Chemicals Management Plan (CMP), it was identified for assessment under Batch 11 under the Industry Challenge. The government conducted a survey on all substances considered high priority in 2006 to determine whether the substance was currently in the Canadian market. No industry response was received for triclosan. This makes it difficult to know if Canadian manufacturers are using it or not, or whether triclosan is primarily found in imported products.

In contrast, the other two triclosans were not expected to be assessed under the current Industry Challenge, and no surveys were conducted under section 71 of CEPA. Both these substances are persistent and inherently toxic. Although they may be included in the medium or low priority groups, these two chemicals will not be subject to any assessment for several years. In addition, it is unclear how the results of the assessment that will be completed on the first triclosan will affect the assessment or possible management of the other two triclosans identified under categorization.

Some restrictions are already in place on the first triclosan. It is listed under the Cosmetic Hotlist (CAS no. 3380-34-5) with defined permitted concentrations equal to or less than 0.03% in mouthwash and 0.3% in other cosmetic products. The Hotlist also defines specific conditions for the use of triclosan including impurities of specific substances, labelling requirements, and specific manufacturing data to be submitted. However, it is unclear whether there are products in Canada that exceed the requirements identified on the Hotlist, or whether even with these limits in place, triclosan is widely dispersed in the aquatic environment.

The case of triclosan raises several important issues with respect to the Great Lakes:

- Are there other similar chemicals that have yet to be identified?
- Should a class approach be considered for triclosan even though not all substances were found to be persistent, bioaccumulative and toxic?

Another issue that arises with triclosan is the need to identify chemicals of emerging concern as a special group of chemicals that could be assessed more quickly and in a way that would give greater weight to their impacts on the Great Lakes. This approach would also give the government an avenue to ensure that toxic substances are not replaced with equally or more hazardous substances.

Gaps identified with pharmaceuticals and personal care products

Gap #1: Many substances regulated under the *Food and Drugs Act* have never been assessed for their potentially toxic effects on the environment and human health.

These include chemicals that were in use at the time the DSL was compiled that were not captured on the DSL and, therefore, not categorized as to their persistence, bioaccumulation or inherent toxicity. It also includes new substances in products regulated under the F&DA that do not meet the triggers for notification or for providing the government with toxicity data. Although the government is addressing this oversight, these substances, particularly pharmaceuticals, veterinary drugs and chemicals in personal care products, may have properties that are damaging to the environment and

possibly to human health at chronic low levels of exposure. This group of chemicals may include chemicals that are currently, or in the future, emerging concerns in the Great Lakes.

Gap #2: The *New Substances Notification Regulations* are not adequate to assess consumer and pharmaceutical products for either environmental or health impacts.

Since the development of environmental assessment regulations is proceeding at a very slow pace, the NSNR are being applied by the government to any new substances in F&DA products that are manufactured or imported into Canada. The proponent is required to submit data based on the volume used, manufactured or imported.

However, for many of the substances in products regulated under the F&DA, such as personal care products, human and veterinary drugs, or natural health products, the annual manufacture or import volumes for each individual company that would trigger notification or trigger the requirements of higher schedules, which provide for toxicity data to be submitted, are not likely to be reached until several years after their approval for sale when the yearly amount of use increases.⁸⁶ This means that many of these substances would be in use and active in the environment before the volumes of their use reached the levels that would require notification under the NSNR. Therefore, the data that would be required to assess their potential for such adverse effects as persistence and bioaccumulation are not legally required to be submitted for evaluation to the government, and these substances would not be assessed until many years after their introduction on to the market.

Gap #3: There are currently no federal laws or programs that would effectively control the disposal of F&DA regulated products.

As Hornbuckle and Persoon outlined in their bibliography, scientific studies have detected a number of pharmaceuticals and chemicals related to personal care products in the nearshore Great Lakes. A major source of these chemicals is sewage treatment plant discharges and agricultural runoff. However, there is little consensus as to how these problems should be addressed. For example, although Health Canada is discussing best practices in pharmaceutical take-back programs, there are currently no effective national or provincial programs controlling the disposal of unused pharmaceuticals or veterinary drugs that would prevent them from entering the Great Lakes.

Many of the assessments conducted on chemicals under Batch 1 noted that possible routes of exposure to some chemicals may be as a result of such disposal methods as deposit in landfills. However, assessment reports did not include potential exposure estimates for substances that may be disposed in landfills as part of a consumer product. Nor were estimates provided on rates of leaching of substances from landfills.

⁸⁶ Health Canada, "Issue identification Paper: Environmental Assessment Regulations," p. 13.

Gap #4: Unlike industrial chemicals, small doses of these chemicals may have a significant impact on the environment and wildlife.

Substances controlled under the F&DA, such as pharmaceuticals, are designed to be biologically active at low doses and may enter the aquatic environment through the sewer systems or through runoff after farm fields are treated with sewage sludge and manure. This fact suggests that triggers for evaluation based on volumes is not an appropriate approach to assessing products regulated under the F&DA. In the environmental screening proposed for new substances in products, such as drugs and personal care products, the government needs to consider setting lower trigger levels, and assessing the effects of continual discharges that potentially result in chronic low-level exposures to humans and aquatic organisms.

Gap #5: The timelines to address pharmaceutical products and to develop environmental assessment regulations are too long.

Since 2001, seven years after the announcement of these regulations, there are still no proposed regulations that would give Health Canada the authority to screen substances in products regulated under the F&DA, and that would improve on the current new substances regime.

Furthermore, the government has known for many years now about the problems with the In-Commerce List of 9,000 chemicals, which have not yet been assessed. Yet, the government is still developing a process for categorizing these chemicals comparable to the categorization process applied to the DSL. Because of this, the task of identifying high hazard chemicals from the In-Commerce List has been slow, and leaves a potentially undetermined number of chemicals without assessment or management of their risks.

Gap #6: There is a lack of public accountability in the NSNR process, which affects the substances in food and drug products currently being assessed under this regime.

Similar comments were noted under the New Substances section of this report. They are applicable here. There is relatively little data required at the lower volumes of use, and there is no public notice or comment on new chemicals evaluated under these regulations.

Gap #7: There are limitations to a risk-based approach of evaluating substances in food and drug products, and more generally all new substances.

Since the government undertakes a risk-based approach for these chemicals as well as for industrial chemicals, management regimes are decided based on demonstrating harmful effects, the potential for exposure and determining the level of risk. As a result of this approach, substances with hazardous properties are still allowed for use in Canada based on a calculation that the risk of the substances is within certain acceptable limits. This means that toxic chemicals, such as carcinogens and endocrine disruptors, are allowed in products such as cosmetics and other personal care products. Such is the case with

hydroquinone which was restricted, rather than completely prohibited, for use in products. In contrast to the European Union where carcinogens, mutagens and reproductive toxins are prohibited from use in cosmetics, Canada has no general prohibition against their use as ingredients. The difference is that the European Union has made a decision on their use in cosmetics based on the hazardous properties of the chemical, rather than on an assessment of the risk.

2.5 Pesticides

A variety of potentially harmful pesticides are being found in the Great Lakes Basin, often in relatively high concentrations. Some of these, such as Chlorothalonil, a widely-used fungicide, and Dacthal, a phthalate herbicide have been identified as chemicals of emerging concern.⁸⁷

In Canada, all pest control products sold or used are subject to the provisions of the *Pest Control Products Act* (PCPA). The PCPA is listed in Schedule 2 of the *Canadian Environmental Protection Act* (CEPA) as a statute which meets the requirements, meaning that pest control products subject to its provisions are not subject to the notification requirements for new substances under CEPA and that the *Pest Control Products Act* offers equivalent procedures.⁸⁸

The PCPA, revised in 2002 and in force as of 2006, is the principle statute governing pesticides and controlling their use in the Canadian environment. This revised Act addressed many of the significant concerns raised regarding the old PCPA, and includes new provisions codifying policies regarding the assessment of risks to children, aggregate pesticide exposure from all sources, and the assessment of groups of pesticides with common mechanisms for toxicity. It requires greater application of the precautionary principle, mandatory re-evaluation of older pesticides, and greater public access to information used in the pesticide registration process. Its goals are also more protective, in that the Minister's main objective in implementing the Act is to prevent unacceptable risks to people and the environment from pest control products.

Pesticides are applied intentionally because of their specific hazardous properties in regard to target organisms. The approach to assessment of active ingredients in pesticides differs in this regard from the processes for assessing industrial chemicals.

Although the focus of this report is the federal framework for assessing and managing pest control products, it is important to note that some provinces also control pesticides. For example, Quebec's new Pesticide Code, 2006 prohibits the use of 100 pesticide products registered for use in the rest of Canada. Similarly, the Ontario Ministry of the Environment enforces a provincial regulatory scheme, which is set out under the *Pesticides Act* and Regulation 914. These provincial laws restrict the sale, use, transportation, storage, and disposal of pesticides in the province.⁸⁹ The Ontario Pesticides Advisory Committee is also reviewing pesticide products and recommending

⁸⁷ Keri Hornbuckle and Carolyn Persoon, *Bibliography of Emerging Chemicals of Concern in the Great Lakes*, Prepared for the International Joint Commission, (2008).

⁸⁸ CEPA, ss. 81(6)(a).

⁸⁹ Note: On June 18, 2008, Bill 64, the proposed *Cosmetic Pesticides Ban Act, 2008* received Royal Assent. This Act amends the *Pesticides Act* by prohibiting the use and sale of pesticides which may be used for cosmetic purposes, subject to certain exceptions such as uses related to agriculture and forestry, and a conditional exception for golf courses.

their classification into one of six categories – based upon toxicity, bioaccumulation and mobility in the environment – designed to control sale and use.

How are pesticides evaluated for risk and toxicity?

The PCPA applies to all products in Canada which claim to have a pest control use. This includes not only active ingredients, but also adjuvants,⁹⁰ formulants,⁹¹ and contaminants.⁹² Though many products have both pest control and non-pest control uses, the PCPA regulates only the pest control uses of these products.

The Act establishes a general requirement that pest control products be registered for use. The burden of proof is placed upon an applicant to show the acceptability of the health and environmental risks and the value, including the efficacy, of the pest control product at issue.⁹³ Health and environmental risk assessments focus on both toxicity and the potential level of exposure of a pest control product, which includes knowledge of chemical and fate properties. The evaluation can take between two weeks to over a year. Generally, it takes between two and two and a half years for a regulatory decision to be made with regard to a new active ingredient.

The Pest Management Regulatory Authority (PMRA) is the Health Canada agency responsible for administering the PCPA. In addition, where applicable to products regulated under the PCPA, the PMRA also implements the federal government's Toxic Substances Management Policy (TSMP), which applies to all toxic substances and substances of concern subject to federal regulation that are released into the environment.

The PMRA's evaluation focuses on toxicity as well as potential routes and pathways of exposure. The PMRA takes a three-step risk assessment and risk management approach to the registration process:

- (1) screening to ensure format, content, and fee requirements have been met,
- (2) review of the data provided to demonstrate a substance's safety and value, and
- (3) making a decision as to whether or not registration should be granted.

What is the framework for assessing new pesticides?

Pesticides are assessed according to their risks, value, and effectiveness. In addition to the toxicity analysis described above, the assessments focus on a product's effectiveness

⁹⁰ Registration Requirements for Adjuvant Products, Regulatory Directive 93-15. Accessed at: www.pmra-arla.gc.ca/english/pdf/dir/dir9315-e.pdf.

⁹¹ Formulants Program, Regulatory Directive 2004-01. Accessed at: www.pmra-arla.gc.ca/english/pdf/dir/dir2004-01-e.pdf.

⁹² Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product, Regulatory Directive 98-04. Accessed at: www.pmra-arla.gc.ca/english/pdf/dir/dir9804-e.pdf.

⁹³ PCPA, s. 7(6).

in the management of pest problems and its resulting environmental, health, and/or economic benefits. To show a product's value, an applicant must provide scientific information about its effectiveness for its intended purposes. Where a product is used on crops, an applicant must also provide information regarding its safety for the host plant species in relation to which it is to be used.

The human health risk assessment for pesticides is a combination of both toxicity and exposure assessments. Factors considered by the PMRA when it is evaluating (or re-evaluating) the health risks of a given product include exposure, cumulative effects, different sensitivities of vulnerable groups, and potential pre- and post-natal exposure and toxicity.

With regard to cumulative effects, the health reviews on pesticides performed by the PMRA include assessments of potential long-term (cumulative) exposure. Risk assessments of pest control products are based on the most sensitive effects observed in the overall toxicity database. The broad toxicology database examined for each pesticide includes studies on acute, short-, and long-term exposure, as well as studies that examine the potential for causing cancer, studies to determine the potential for causing birth defects or reproductive effects (including the effects of exposure from breast milk), and studies to assess pre- and post-natal development, including endocrine effects. Additionally, the PMRA has published guidance for identifying pesticides that have a common mechanism of toxicity for human health risk assessment.⁹⁴

Registrants must provide a range of toxicity studies as well as data characterizing potential exposure for the PMRA's human health risks assessment. The Agency requires that toxicity studies assess potential adverse effects on a variety of species from single-, multiple-, lifetime, or multi-generation exposure to a given active ingredient, as well as end-use product formulations. Such studies may include, acute toxicity studies, short-term toxicity studies, long-term toxicity and carcinogenicity studies, genetic toxicity studies, reproductive and developmental toxicity studies, metabolism and toxicokinetics studies, teratology studies, and reproductive and developmental toxicity studies. The PMRA may also review and consider epidemiological evidence, general scientific knowledge, and general scientific knowledge.

Where the PMRA views a pesticide as possibly neurotoxic, immunotoxic, or endocrine disrupting, the Agency can require that registrants submit studies that evaluate developmental neurotoxicity, immunotoxicity, and/or endocrine disruptor potential.

The portion of the PMRA's human health risk assessment dealing with potential exposure specifically addresses, sensitive populations and life stages, including infants, children, and women of child-bearing age. If the PMRA has no concerns regarding a product's estimated exposure, it may be registered and label directions will indicate the appropriate use instructions to minimize exposure.

⁹⁴ Science Policy Notice SPN2001-0. Accessed at: www.pmra-arla.gc.ca/english/pdf/spn/spn2001-01-e.pdf.

To conduct its environmental risk assessment, the PMRA requires that applicants submit information pertaining to environmental fate and environmental toxicology.

“Environmental fate” refers to what happens when the pesticide enters the environment, including concentrations to which “non-target” plant and animal life may be exposed, while “environmental toxicology” refers to the hazards posed by the pesticide to “non-target” plant and animal life.

To assess environmental fate, the PMRA reviews data on the proposed use pattern, and considers the product’s physical and chemical properties, transformation products, mobility studies, and field studies. To assess environmental toxicology, the PMRA evaluates data on lethal and sublethal effects in acute and chronic toxicity laboratory tests, effects on non-target terrestrial species, and effects on non-target aquatic species.

According to the PMRA, environmental risk is most frequently mitigated through label statements that specify the rate, site, frequency and mode of application, as well as buffer zones between the treatment area and sensitive areas. Cumulative effects on non-target organisms from the various active ingredients that may be individually applied to a treatment site during a growing season are not taken into consideration in the environmental risk assessment.

Pesticides are screened for inherent toxicity and persistence and bioaccumulation using the federal government’s TSMP criteria,⁹⁵ which are the same as those used for CMP. Like CMP, these thresholds may not identify a number of potentially harmful substances that are identified by other jurisdictions.

As an example of the number of applications for registration of new products received annually by the PMRA and the nature of the decisions made in regard to these applications, during the 2007-2008 fiscal year, the PMRA completed 425 applications to register new products. Of these applications, 358 (approximately 84%) were approved, while the remaining 67 applications were rejected or withdrawn. Of the 358 new products registered, 42 products (approximately 12%) had conditions placed upon their registration.⁹⁶

Persistence and Bioaccumulation

Persistence Criteria

Data requirements for active ingredient submissions are based on intended use, and are described in the PMRA’s Use-Site Category (USC) tables, which can be found on the Agency’s website. Studies required by the PMRA to determine persistence include those addressing the transformation of a given active ingredient in aerobic soil, anaerobic soil, and aerobic aquatic

⁹⁵ Environment Canada, *Toxic Substances Management Policy*. Criteria outlined for persistence and bioaccumulation. These criteria are similar to the CMP criteria as well as *Persistence and Bioaccumulation Regulations* under CEPA. Accessed at: www.ec.gc.ca/toxics/TSMP/en/criteria.cfm.

⁹⁶ Personal email correspondence with Robert Martin, Pest Management Regulatory Agency, dated October 29, 2008.

(water and sediment) environments, and anaerobic aquatic studies.

In these studies, applicants are required to determine the time it takes for one half of the initial concentration of the parent to transform or degrade, so that a half-life ($t_{1/2}$) or disappearance time (DT50) can be determined. Guidelines for these studies are published by the U.S. EPA and the OECD, and all studies are to be compliant with good laboratory practices. In most cases, terrestrial field dissipation studies in Canada or relevant U.S. locations are also required to determine persistence under field conditions.

Persistence is classified in accordance with the following scheme for soil and natural water:

Class	Estimated Time for 50% Disappearance (Months)
Non-Persistent	< 0.5
Slightly Persistent	0.5 – 1.5
Moderately Persistent	1.5 - 6
Persistent	> 6

Half-lives are also used in drinking and groundwater modelling. The more persistent a compound, the more potential there is for it to leach.

Bioaccumulation Criteria

With regard the PMRA’s assessment of a product’s bioaccumulation, a bioconcentration study is required with fish if the $\log K_{ow}$ – that is, the partitioning coefficient between octanol and water – is ≥ 3 . Like the persistence analysis described above, this requirement is based on intended use.⁹⁷

A point of concern for both environmental and human health, in addition to the high thresholds described above, is the fact that even where a product is found to be persistent and/or bioaccumulative according to the high TSMP/CMP threshold, the application for registration will not necessarily be denied. Rather, the registration may be approved, subject to conditions. In fact, according to the PMRA, it would be rare for registration to be refused based solely on persistence or bioaccumulation, unless a substance was persistent, bioaccumulative and toxic.⁹⁸ In such a case, the active ingredient would be assessed against the TSMP “Track 1” criteria.⁹⁹

Under the TSMP, a Track 1 substance is one that is persistent, bioaccumulative, CEPA-toxic or equivalent, and predominantly human-caused. The Plan calls for these

⁹⁷ Personal correspondence with Robert Martin, Regulatory Information Officer of the PMRA dated October 10, 2008.

⁹⁸ Personal correspondence from Robert Martin, Pest Management Regulatory Agency dated October 10, 2008.

⁹⁹ TSMP Track 1 substances targeted for virtual elimination. Accessed at: www.ec.gc.ca/toxics/TSMP/en/track1.cfm.

substances to be virtually eliminated, as opposed to “Track 2” substances, which are subject to life-cycle management to prevent or minimize releases to the environment.¹⁰⁰

With respect to the implementation of the TSMP, if a new product contains an active ingredient or a formulant which is found to be a Track 1 substance, then the risks would generally be considered unacceptable and the product would not be registered.¹⁰¹ However, the Directive then lists a number of conditions under which a Track 1 pesticide would be registered. Such conditions include exceptional circumstances or if the product offers a significant reduction in health or environmental risks over those posed by an existing product registered for the same use. Then, the new product would be registered for one year, and limitations and conditions could be imposed.

Much of the same conditions would apply for a new product which contains a Track 1 substance as a contaminant or impurity, except that these are given five year registrations. The situation is less stringent for an existing pesticide product that contains an active ingredient that is a Track 1 substance. There is no statement that the risks are unacceptable, but only that this would help guide priorities for re-evaluation and the search for reductions. Virtual elimination is seen as a long-term goal requiring a common sense approach.¹⁰²

These policies are now being put into practice. For example, the widely-used pesticide endosulfan was found to meet all the criteria of persistence, bioaccumulation, anthropogenic source, and CEPA toxic, making it a Track 1 substance under the TSMP. The PMRA found that “[c]ontinued use of products containing endosulfan would result in the entry of a Track 1 substance into the environment.” Therefore, the preliminary risk assessment proposes additional consultation “to develop an appropriate management strategy in accordance with the long-term goal of virtual elimination.”¹⁰³ In the meantime, however, a number of pest control products containing endosulfan are still registered for use in Canada.¹⁰⁴

How are new pesticides managed after their approval?

Generally, registration is granted for a term of five years, subject to renewal. Renewal involves submitting a range of fairly basic product information, including a notice of pending expiry of the product’s registration, an application form requiring basic information about the product, its use, and the registrant, and information regarding labelling practices. A term will be less than five years in situations where the PMRA determines the risks or value of the substance should be evaluated sooner.

¹⁰⁰ TSMP Track 2 substances are managed through a life cycle management approach. Accessed at: www.ec.gc.ca/toxics/TSMP/en/track2.cfm.

¹⁰¹ The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy, Regulatory Directive 99-03. Accessed at: www.pmra-arla.gc.ca/english/pdf/dir/dir9903-e.pdf.

¹⁰² Regulatory Directive DIR99-03, *ibid*.

¹⁰³ PMRA Preliminary Risk and Value Assessments of Endosulfan, (2007). Accessed at: www.pmra-arla.gc.ca/english/pdf/rev/rev2007-13-e.pdf.

¹⁰⁴ See pr-rp.pmra-arla.gc.ca/PR_SOL/PUBLIC_REGISTRY.LBL_RESULTS.

To further the objective of preventing unacceptable risks to human health and the environment, the PMRA can specify conditions of registration which may include:

- maximum residue limits in or on human food;
- methods for disposing of the pest control product and empty packages;
- methods for detoxifying or neutralizing the product in water, air or soil, or any other surfaces;
- conditions relating to its manufacture, handling, storage, transport, import, export, packaging, distribution, use or disposal, including conditions relating to its composition;
- labelling requirements;
- the period for which the registration or amended registration is valid; and
- product safety information which must be provided to workplaces.¹⁰⁵

What public accountability is there for pesticides?

After the Minister makes a decision regarding an application for registration, there is a 60 day period within which a person may file a notice of objection to the decision, at which point the Minister may decide to establish a panel to review the decision and recommend whether it should be confirmed, reversed, or varied.¹⁰⁶ The Minister is to consider whether the notice of objection raises “scientifically founded doubt” regarding the product’s evaluation, and whether it would be useful to get the advice of scientific experts to address the concerns raised in the notice. Those appointed to the Panel would have to have a relevant scientific background.

An important component of the revised PCPA is the PMRA’s public registry, which contains non-confidential information regarding pesticides. It includes all publicly available information on currently registered products and incidents of pesticide residues in food.¹⁰⁷

What post-market monitoring is done?

The PRMA’s focus when applying the PCPA is on assessing and managing risk, rather than preventing harm, which is due to inherent toxicity and the cumulative effects of exposure to approved pest control products. It has a program to monitor compliance with registration conditions, and may impose penalties such as suspension, cancellation, use restrictions or the phasing out of a pest control products for violation of such conditions.

The PMRA does not do monitoring beyond compliance activities. Rather, Environment Canada has the primary role in monitoring of pesticide residues in the environment. The Agency works with other federal agencies and departments with surveillance and monitoring programs, and receives monitoring data on pesticides in various media. The

¹⁰⁵ Reg. S.O.R. 206-124, s. 8 (r), (j) and (h), PCPA sections 8(1) and 8(3).

¹⁰⁶ PCPA, ss. 35(1)-(3).

¹⁰⁷ The registry is available at: www.pmra-arla.gc.ca/english/pubreg/pubreg-e.html.

PCPA sets out requirements for mandatory and voluntary incident reporting, and requires that registrants provide annual sales data.

What is the framework for existing pesticides?

In addition to the approval and registration of new active ingredients, the PMRA is also required to re-evaluate active ingredients already on the market. Re-evaluation is subject to the same standards and procedures described above pertaining to new products.

Unlike industrial chemicals, pesticides have always been subject to some form of regulatory evaluation and an approval process prior to being allowed for use. However, as of the mid 1990s, of the hundreds of pesticide active ingredients registered in Canada (translating to thousands of pesticide products), over 75% had not been evaluated according to up-to-date scientific methods to assess human or environmental impacts. Many had registrations that were based on information that was up to 10, 20 or even more than 30 years old.

The PMRA re-evaluation program applies to pest control products registered before January 1, 1995 and requires that all such products undergo re-evaluation by the end of 2009. After a slow start, the agency has completed re-evaluations of nearly 75% of those pesticides in the re-evaluation program. Of the 285 active ingredients re-evaluated, 93 were either discontinued or phased out by registrants, or are in the discontinuation process. Nine have been phased out or are proposed for phase-out, 166 have been accepted, or are proposed for continued use with modifications to allowable terms of use, and 17 were accepted for continued use with no change in regulatory status.

In addition to the process for re-evaluating products registered prior to January 1, 1995, the PMRA re-evaluates pesticides on a 15 year cycle, including those registered after 1995. Also, where a pest control product is approved for use, the Minister can initiate a re-evaluation if there has been a change in the information required or the procedures used for the evaluation of health or environmental risks posed or the value of products of the same class or kind.¹⁰⁸

In addition to re-evaluations, the Minister can also initiate a special review of a product where its health or environmental risks or its value are unacceptable, or where a member of the public has requested that such a review take place.¹⁰⁹ These special reviews also require the Minister of Health to apply the precautionary principle – that is, where there is some evidence of harm to human health or the environment, a lack of scientific uncertainty should not be used to postpone actions aimed at protecting the environment and human health.

A special review is required where another OECD member country prohibits all uses of an active ingredient for health or environmental reasons. However, it would still be possible for such a special review to result in the conclusion that Canadian registrations

¹⁰⁸ PCPA, s. 16(1).

¹⁰⁹ PCPA, s. 17(3).

will not follow the OECD member's ban. In Canada, approximately 60 active ingredients, used in over 1,100 pesticide products, are banned by other OECD countries.¹¹⁰ The PMRA has decided not to launch special reviews of these substances because many of them are subject to re-evaluation requirements.¹¹¹

¹¹⁰ David Suzuki Foundation Request for Review, (June 28, 2006). Accessed at: www.davidsuzuki.org/files/WOL/June_28_06_Pesticides.pdf.

¹¹¹ Response from the Pest Management Regulatory Authority (PMRA) to the Request for Special Review from the David Suzuki Foundation. Accessed at: www.pmra-arla.gc.ca/english/pdf/rev/rev2007-09-e.pdf.

Case Study: Lindane

On March 15, 1999 the PMRA announced it was initiating a special review of pest control products containing Lindane – an insecticide commonly used for agricultural purposes, but banned in 50 countries, and withdrawn from agricultural use in the U.S. in 2006. The decision to conduct the review was based upon, concerns raised internationally and nationally about Lindane’s persistence and human health effects and the signing by Canada and a number other states of an international protocol on persistent organic pollutants under the Convention on Long-Range Transboundary Air Pollution of the UN’s Economic Commission for Europe.

In March of 2005, the Commission on Environmental Cooperation (CEC) released a draft action plan to reduce or eliminate the use of Lindane in North America in one decade. The final version of the plan was released on November 30, 2006, containing recommendations aimed at reduction and elimination initiatives.¹¹² The *Great Lakes Water Quality Agreement* sets specific objectives for persistent toxic substances in Annex I of the agreement including maximum levels for the concentration of Lindane in water and edible portions of fish.

Lindane is listed under the Protocol on Persistent Organic Pollutants (POPs) to the Convention on Long-range Transboundary Air Pollution under the UN Economic Commission for Europe as a POP with restricted uses. Furthermore, Lindane was recently reviewed by the POPs Review Committee established under the *Stockholm Convention on Persistent Organic Pollutants* for possible listing under Annex A of that Convention. Based on its work, the POPs Review Committee has recommended the addition of Lindane to Annex A, which means it would be subject to elimination.¹¹³ Based on decisions made at the Fourth Conference of the Parties under the Stockholm Convention, lindane (along with its isomers, alpha hexachlorocyclohexane and beta hexachlorocyclohexane) was added to Annex A.¹¹⁴

Based on its special review, the PMRA determined that the occupational and health risks posed by Lindane were unacceptable and that it was necessary to phase-out the product’s use by means of voluntary discontinuation of sales and the suspension of registrations. The only registrant that did not give notice of intent to discontinue sales of Lindane-containing products requested the establishment of a Review Board after its registrations were suspended. On January 10, 2005 the Board began its hearing to examine the PMRA’s registration decisions. On August 17, 2005 the Board released its decision, recommending that the PMRA “reconsider potential opportunities for mitigating its concern for health related issues associated with the use of Lindane” and that it seek input from interested parties when doing so.¹¹⁵

¹¹² *The North American Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane (HCH) Isomers*. Accessed at: www.cec.org/files/PDF/POLLUTANTS/LindaneNARAP-Nov06_en.pdf.

¹¹³ United Nations Environment Programme and Stockholm Convention Secretariat, *Stockholm Convention on Persistent Organic Pollutants* web site. Accessed at: chm.pops.int/Convention/POPsReviewCommittee/RecommendationsofthePOPRC/tabid/440/language/en-US/Default.aspx.

¹¹⁴ Accessed at: chm.pops.int/Convention/Media/Pressreleases/COP4Geneva9May2009/tabid/542/language/en-US/Default.aspx. Also accessed at: www.iisd.ca/download/pdf/enb15174e.pdf

Note: Lindane was added to Annex A with one specific exemption for pharmaceutical use for control of head lice and scabies as second line treatment.

¹¹⁵ PMRA, *Report of the Lindane Board of Review*, (August 17, 2005). See www.hc-sc.gc.ca/cps-spc/pubs/pest/_corp-plan/report-lindane-rapport/index-eng.php.

Since the Board's role is advisory, the Minister of Health is not obligated to act on its recommendation. However, on April 26, 2006 the PMRA announced that a follow-up review of Lindane had been initiated.

Despite the known human health and environmental risks of Lindane, and despite the fact that it has been banned in 50 countries – including Canada – for agricultural uses, a number of over-the-counter lotions and shampoos used for scabies and lice treatment containing the substance are still on the market in Canada. The National Association of Pharmacy Regulatory Authorities has classified it as a Schedule 2 substance, meaning that “professional intervention from the pharmacist at the point of sale and possibly referral to a practitioner” is required.

Concerns about the health and environmental impacts from use of Lindane are increasingly being raised internationally. For instance, California announced a ban on Lindane-containing products in 2002, due to concerns about its presence in wastewater and the human health risks of pharmaceuticals containing it. The state estimated that 22 million litres of water were affected by each treatment of Lindane-based product that was washed down the drain. Lindane became virtually undetectable in California's water supply within a few years of the ban. Several Great Lakes States are considering similar bans.

Gaps identified in the *Pest Control Products Act*

Gap #1: The *Pest Control Products Act* does not prevent the approval and use of harmful pesticide products in the Great Lakes Basin.

- One reason for pesticides emerging as a concern in the Great Lakes Basin is that the approach set out under the PCPA is not sufficiently precautionary in nature. The registration and re-evaluation processes should be focused on precaution and hazard, rather than on a risk analysis of products viewed in isolation.

Gap #2: Pesticides with the properties of persistence and bioaccumulation may still be approved for use in Canada.

- Although pesticides are screened for persistence and bioaccumulation using the federal government's TSMP criteria, as is the case with the CMP, these thresholds may not identify a number of potentially harmful substances identified by other jurisdictions with more rigorous thresholds.
- Even where a product is found to be persistent and bioaccumulative according to the TSMP or CMP threshold, the application for registration will often be approved, subject to conditions.

Gap #3: Registrants are not automatically required to provide the PCPA with information regarding a pest control product’s developmental neurotoxicity, immunotoxicity, and/or endocrine disruptor potential.

- This information is generally required by the PMRA only where existing studies show that a given product may have these effects. However, this information is important in evaluating the potential toxicity of pesticides, including their impacts on the Great Lakes.

Gap #4: Monitoring for pesticides in the Great Lakes Basin is not adequate for detecting emerging chemicals.

- Like the *New Substances Notification Regulations*, no protocols are developed when a new pesticide is submitted for approval. This means that the government must develop its own protocols and long lead times exist between the development of testing protocols and the identification of a specific pesticide as a problem.
- In addition to the lack of protocols, no post-approval monitoring beyond compliance measures is required that would indicate whether new pesticides are having environmental effects in the Great Lakes.

Gap #5: Though the PMRA has a program to encourage manufacturers in Canada to register reduced-risk products available in the United States, there is no explicit mechanism in the PCPA that requires evaluation of the use of less hazardous and non-hazardous alternatives.¹¹⁶

- Even when there is an active ingredient already approved on the market for the same application, there is no mechanism in place to require the use of the safer ingredient. Rather, the Minister merely has the option, in accordance with regulations, if any, to take into account information regarding the risks and value of other pest control products that are registered for the same use when evaluating or re-evaluating a product.¹¹⁷ Given the seriousness of the human health and environmental risks caused by many pest control products, and specifically given the presence of a number of chemicals of emerging concern in the Great Lakes Basin resulting from pest control activities, voluntary initiatives are insufficient to achieve the goal of requiring that industry adopts safer use alternatives.

¹¹⁶ The PMRA, in coordination with the U.S. EPA and Mexican regulatory agencies, established the Joint Review Program for Reduced-Risk Chemicals in 1996 under the NAFTA Technical Working Group on Pesticides to facilitate the registration of “reduced risk” pesticides – i.e. those which have lower risks, however slight, than registered pesticides with the same use pattern. Under this initiative, reduced risk pesticides undergo an expedited review.

¹¹⁷ PCPA ss. 7(9) and 19(4).

2.6 Findings based on Canadian Analysis

This examination of Canada's laws and policies governing chemicals, including emerging chemicals, in the Great Lakes has led to the following findings:

1. The goals of the *Great Lakes Water Quality Agreement* will not be achieved under the current approach on substances of emerging concern.

The International Joint Commission has stated that if a chemical is persistent, toxic and bioaccumulative, a process for banning or sunseting its use should be undertaken. This is consistent with the *Great Lakes Water Quality Agreement's* philosophy of zero discharge and virtual elimination for persistent toxic substances into the Great Lakes. The approach to persistent toxic substances is well defined. It is "the policy of the Parties [Canada and United States] that: The discharge of toxic substances in toxic amounts be prohibited and the discharge of any or all persistent toxic substances is virtually eliminated."

However, these broad, bold and visionary goals for the Great Lakes are at risk from the weaknesses of the Canadian government's programs to assess and control chemicals. Although CEPA includes references to pollution prevention, virtual elimination and the precautionary principle in its preamble, limited progress has been made in advancing towards these principles. Even less progress has been made towards the bolder vision of the *Great Lakes Water Quality Agreement's* goal of zero discharge.

The analysis in this report demonstrates that the current approach for identification, screening and assessing substances has not resulted in significant progress to virtually eliminate the input of persistent toxic substances, as stated in the GLWQA, Annex 12. The strategy under the current federal Chemicals Management Plan will not fully achieve the principle for regulatory control or prevention of persistent toxic substances expressed in the GLWQA Annex 12 -- "the philosophy adopted for control of inputs of persistent toxic substances shall be zero discharge."¹¹⁸

Persistent chemicals are still being approved for use, manufacture, import, sale, storage and disposal in the Great Lakes under CEPA's new substances program, the *Food and Drugs Act* and the *Pest Control Products Act*. Existing chemicals found by the government to be both persistent and bioaccumulative but which are not inherently toxic do not meet the categorization criteria and therefore are screened out of further action under CMP. Persistent and toxic chemicals are considered medium or low priority and so will not be assessed or managed until 2020.

2. Chemicals, which find their way into the Great Lakes, are not prohibited from entering the market solely on the basis of hazardous properties, such as

¹¹⁸ *Great Lakes Water Quality Agreement*, Annex 12 – Persistent Toxic Substances 2(a) (ii).

persistence or bioaccumulation, under the current legislative and policy framework.

Chemicals that have undesirable hazardous properties are generally not prohibited or restricted from manufacture or use in the Great Lakes Basin as a result of the reliance on a risk-based approach to chemicals management. Although the federal government has used persistence, bioaccumulation and inherent toxicity to identify chemicals of concern from the 23,000 existing chemicals, the assessments rarely lead to prohibitions or rigorous control programs. Furthermore, new chemicals with these hazardous properties are not automatically prevented from entering the Canadian market. Similarly, substances that show carcinogenicity, reproductive and developmental toxicity or mutagenicity do not result in an automatic prohibitive or restrictive approach. Management decisions rely on demonstrating their presence in Canadian commerce, the scope of their use, mode of release to the environment, and determining their potential risk to human health and environment.

The legal obligations set out in CEPA to categorize the Domestic Substances List were directly focused on identifying chemicals for purposes of further assessment activities. As a ground breaking initiative, the categorization process was designed to take action on these substances in an expeditious manner by allowing for faster assessments and accelerated risk management discussions. The release of the Chemicals Management Plan, specifically the Industry Challenge, has yet to result in substantial action to prevent many persistent toxic substances from use, manufacture, import, sale, storage, and disposal.

Of the 31 chemicals found to be persistent, bioaccumulative and inherently toxic under categorization in Batch 1-3 of the Industry Challenge, 24 were subsequently found to be not CEPA “toxic.” This means that 77% of the P/BiTe chemicals originally identified by categorization will not have a risk management scoping document. Although these chemicals may emerge in the future as persistent or bioaccumulative problems for the Great Lakes, the government will not develop proposals to manage them. Six of the 24 P/BiTe chemicals rejected as CEPA toxic were subject to SNAc provisions.

3. Efforts to control persistent and bioaccumulative substances need to emphasize up-stream prevention. A preventive and upstream approach to persistent toxic substances is rarely applied under the current framework.

Substances found to be persistent, bioaccumulative and inherently toxic should be targeted for action. A greater emphasis should be placed on pollution prevention, virtual elimination as defined by the GLWQA and interpreted through Annex 12, substitution of safer chemicals and changes in production that would completely eliminate persistent and bioaccumulative substances. The government programs are not driven to attain a high-level of pollution prevention that includes finding safer alternatives or processes; rather, they still favour end-of-pipe controls and best management practices. Therefore, the current CMP approach needs to move upstream and emphasise pollution prevention and safer alternatives.

The full scope of management tools including the use of pollution prevention planning, prohibitions, and virtual elimination have not been utilized for these persistent toxic substances. The case studies detailed in this report demonstrate that emerging chemicals are entering the Great Lakes and are likely to continue to be released, despite regulatory programs. Management regimes for these substances do not consistently take into account the full life cycle of the substance, which would include consideration and evaluation of breakdown products and by-products created in the manufacturing process, end products and disposal methods, including the potential leachate from products containing toxic substances.

4. The decision-making process for regulating toxic substances in Canada has flaws that allow toxic chemicals to enter the Great Lakes and to potentially become emerging problems.

The Chemicals Management Plan attempts to bring together many of the different regulatory programs governing chemicals. It also tries to address the problem of using chemicals which lack health and safety data. A cornerstone of the CMP, the categorization process was a ground breaking attempt to prioritize 23,000 chemicals using environmental and health criteria. While all these actions were long overdue, unfortunately the CMP has some significant flaws in decision making and implementation. These flaws result in many emerging chemicals continuing to enter the Great Lakes.

Decisions made by the federal government on chemical management for existing chemicals are affected by a number of critical factors:

- a) Reliance on outdated and inaccurate list of chemicals (so not all chemicals are covered, and incorrect conclusions possible on use, exposure and risk management tools);
- b) Use of different criteria to determine environmental properties such as toxicity, persistence and bioaccumulation so that chemicals considered persistent under GLWQA and under REACH are not considered persistent under Canada's categorization and CMP criteria;
- c) The decision that only chemicals that meet all three environmental criteria of persistence, bioaccumulation and inherent toxicity are considered for high priority action;
- d) Chemicals that are both persistent and bioaccumulative fail to meet environmental categorization criteria and so no further action is taken;
- e) Chemicals that meet only one environmental criterion are not considered for further action. Many emerging chemicals only meet one environmental criteria;
- f) Rapid screening approaches have become a large off ramp for many PiTe and BiTe, resulting in no further action for large numbers of chemicals that meet environmental categorization criteria;
- g) Endocrine toxicity is not considered as an end point in health assessment;

- h) Analogues are regularly used for decisions on PBiT, instead of requiring experimental data on the targeted chemical;
- i) Lack of government transparency in disclosing reasons for changing decisions on persistence, bioaccumulation and inherent toxicity based on industrial data submitted;
- j) Lots of emphasis on chemical screening, few strong actions to drive reductions in chemicals;
- k) Reliance on SNAc provisions as a method of chemical control; and
- l) The quality of some available data is unknown or low.

The categorization process and the subsequent risk management plans have brought home the fact that often very little is known about chemical use. The DSL information is 20 years old, consumer product formulations are constantly changing, and so estimating exposure is often difficult. However, in a risk-based system such as the Chemicals Management Plan, errors in exposure can lead to errors in prioritization of chemicals and selection of less effective risk management tools.

5. There is no one program in Canada that identifies, assesses and controls substances of emerging concern. This results in confusing overlaps, and environmental screening processes that differ depending on whether the chemical is in industrial use or in a consumer product, drug or in a pesticide.

Currently, different statutes are responsible for assessing, managing or regulating substances in Canada depending on their end-use. Industrial chemicals may be assessed and managed under CEPA. However, if these chemicals have a pesticidal use, another statute will outline the assessment and management regime.

There is a lack of clarity and co-ordination between the major federal statutes that govern toxic chemicals. Although CEPA is the principle statute for managing toxic chemicals, many potentially toxic chemicals are also licensed for use under the *Food and Drugs Act* and the *Pesticide Control Products Act*. Although new chemicals are licensed under the *Food and Drugs Act*, the screening tools currently in place are not appropriate to identify all substances that need further action, a fact the government has recognized.

Many pharmaceuticals and cosmetic ingredients that are introduced into commerce do not meet the trigger levels for government notification, or do not meet trigger levels that would require the submission of toxicity data under the NSNR.

In addition, more than 9,000 existing chemicals, known as the In-Commerce list, have never been categorized as to their persistence, bioaccumulation or inherent toxicity. Very little is known about the potential for these substances to have an impact on the environment. The government has recognized this gap, and over the past seven years has begun to initiate a process to collect information and establish a regime for assessing priority substances.

Currently, there is no environmental screening for nanomaterials in Canada; instead the government is relying mainly on the *New Substances Notification Regulations* to evaluate nanomaterials. With hundreds of nanomaterials and products already in the market, the ability of the process to verify safety of these substances or products will be a significant challenge to the regulatory system in the coming years. This is a major shortcoming, since nanomaterials are already being recognized by non-governmental organizations as chemicals of emerging concern.

There is environmental screening for pesticides. However if a chemical is found to be PBiT, this does not necessarily mean it will not be used. Although these properties are considered during the evaluation process before pesticides are licensed, Canada currently allows the use of several pesticides that have been found to be PBiT. Some of these pesticides may find their way into the Great Lakes and result in exposure to non-target aquatic organisms.

Furthermore, the Great Lakes agencies and other levels of government that are responsible for the implementation of Great Lakes activities on toxic management may not be well integrated into the federal approach. The lack of coordination between statutes, departments, levels of governments and agencies may contribute to identification of priorities that do not reflect the needs of the Great Lakes.

6. Timelines for developing and implementing management activities are too long.

The government programs are based on long timelines that result in continuing releases of toxic chemicals into the Great Lakes. For example, the time that elapses between the identification of a chemical as likely to be CEPA-toxic, its assessment and the development of a management program can take up to ten years. This is in contrast to the 75 day period that the government allows for assessing the suitability of a new chemical coming on to the market and imposing conditions, if necessary.

Even under the Chemicals Management Plan, despite the shortened timelines of almost a year to complete the screening level risk assessment for high priority chemicals, for substances proposed to be toxic under CEPA, the government is required to follow the timeframes for developing management options and implementation of management tools, which could be up to 42 months as prescribed in CEPA.

For the 2,600 chemicals considered medium priority, it will be more than a decade (2020) before risk management options are proposed, let alone implemented.

Similarly, seven years have passed since the government announced its intentions to develop environmental assessment regulations for F&DA regulated products in 2001. There has also been considerable delay in the program to categorize the 9,000 chemicals in F&DA products that were not captured on the DSL.

While pesticides undergo much more rigorous upfront testing than industrial chemicals, controls and management of pesticides occur at a substance by substance basis after significant risk assessment activities have been undertaken. The timeframe for completing these assessments are not prescribed. This results in long periods where potentially harmful pesticides are being assessed while at the same time they continue to be used. Furthermore, should special reviews be conducted on active ingredients, the time required to complete these reviews is extensive. For example, the lindane special review was begun in 2001 but its follow-up assessment has yet to be completed.

7. Effective public engagement in decision making is limited.

The public's involvement in protecting the Great Lakes ecosystem, along with timely scientific research, contributed significantly to goals set out in the *Great Lakes Water Quality Agreement*.

Although the information gathered through the CMP is accessible to the public, there is a lack of public accountability and limited involvement in other aspects of the toxic chemical framework. There is no public notification of new chemicals and the assessments are not published, as they are for existing chemicals. Only those new substances, which receive specific ministerial conditions or SNACs, are published in the *Canada Gazette*. Under the *Food and Drugs Act*, public engagement does not exist in development of a management regime, although assessments of substances would be addressed under CEPA. There is no tracking or public awareness of nanomaterials technology or products. There is a general lack of public awareness about the problems of drugs and personal care products that results in unnecessary health and environmental exposures.

8. Monitoring programs need to look for emerging chemicals more aggressively, and monitoring results need to lead to chemical reduction. Guidelines for analyzability need to be a requirement for chemical approval.

Although monitoring has not been discussed in this report, it is important to note that the monitoring programs in the Great Lakes are not able to keep pace with the number of new and emerging chemical problems. The government does not require companies to submit analytical testing protocols that would allow post-market monitoring of chemicals in the Great Lakes. A great deal of expense and a considerable burden is placed on government scientists to develop methods to monitor and to detect chemicals that have been developed and placed on the market. Given the number of substances that are found in Canadian commerce and the number of new substances that are introduced into the market each year, it is impossible to monitor for all substances. Once a substance is detected in the Great Lakes, the impact to the environment and human health has already occurred. The emphasis of the monitoring program to date has been on substances that may require additional government and industry action.

The evidence gathered through monitoring programs for substances to the Great Lakes has not always resulted in specific actions aimed at protecting the Great Lakes Basin.

Rather, the emphasis has been on information gathering and priority setting for the purposes of conducting assessments. The current framework does not provide an effective mechanism to respond to the findings of monitoring programs without first completing risk assessments on substances.

PART 3 – United States Analysis and Findings

This section presents an analysis of U.S. federal, regional, state, and local policies regarding chemicals of emerging concern, including: (1) a discussion of the relationship between federal and state policy in the United States; (2) an overview of the inventory of policies and programs identified at the federal, regional, state, and local levels; (3) a detailed review of important federal statutes, policies and programs relevant to chemicals of emerging concern in the Great Lakes Basin; and (4) an analysis of their strengths and weaknesses with regards to identification, characterization, and control and prevention of chemicals of emerging concern. While there are no specific U.S. laws addressing “chemicals of emerging concern,” we have focused on how existing chemicals laws and policies address them. Based on these sections and interviews with key stakeholders, we provide a critical summary of lessons learned for enhancing policies with regards to characterization and prevention of chemicals of emerging concern in the Great Lakes Basin.

As noted in the introduction, the chemicals of emerging concern in the Great Lakes span several legislative and jurisdictional boundaries. No single piece of policy or agency addresses the different types of chemicals of concern. While we examine these policies in the traditional, jurisdictional manner, we also discuss the significant limitations of this approach for control and prevention of these chemicals of emerging concern from entering the Basin and ways to advance a more comprehensive approach to prevention of chemicals of emerging concern in Section 3.5. *It is important to reiterate that our focus is on policies and programs that address rapid identification, characterization, control and prevention of chemicals of emerging concern and not on policies that would manage emissions or waste of such materials.* These other laws include the Clean Water Act (CWA), the Safe Drinking Water Act (SDWA), the Clean Air Act (CAA) and the Resource Recovery and Conservation Act (RCRA). An analysis of such policies would be beyond the scope of this report, and, as noted previously, most media specific policies such as air and water emissions regulations tend to address industrial emissions of contaminants and not dispersive ones from products. While our focus has been on product-oriented policies, some media specific policies may be relevant for addressing emerging chemicals of concern, such as waste disposal bans for materials, such as lead in electronics, or air regulations to achieve air quality in a specific area through restrictions on a specific volatile chemical used in industrial and consumer applications.

3.1 Federal-State Relationship in U.S. Environmental Policy

Historically, U.S. environmental policy is based on a model of “cooperative federalism” that is characterized by the participation of several governments in cooperative legislative or administrative action. Most of the U.S. environmental laws establish a framework in which the federal and state governments work together to protect health and the environment from the adverse effects of pollution-generating activities by both private

and public entities. In general, the federal government is responsible for promulgating standards while the states have the primary authority to implement the standards promulgated by the federal government. Further, in most instances, the states have the authority to adopt standards that are more stringent than applicable federal standards.¹¹⁹

As a result, state (and often local) governments play an important role in U.S. environmental policy. Chemicals regulation is no exception to this. In addition to implementing federal environmental laws, states and localities often address many environmental issues on their own, without a federal mandate. State and local officials, closer to the environmental and economic concerns of their residents than those of federal officials, possess the local knowledge and expertise needed to solve environmental problems, which are often local or regional in nature. For example, at the local level, health, environmental and hazardous waste management officials address all categories of chemicals (waste management tends and waste water treatment tends to be a locally managed activity) and view chemicals policy as encompassing a broad range of concerns, not only industrial chemicals. States and localities also play a key role in policy innovation and in experimenting with new approaches to environmental protection, especially with respect to issues where federal action has failed to adequately address local concern. States and localities have an ability to establish policies and programs that transcend jurisdictional boundaries, addressing more than one category of chemicals of emerging concern. For example, the City of San Francisco's Precautionary Principle Ordinance requires the city to identify safer alternatives to materials of concern, regardless of the material type. Many state pollution prevention programs, such as the Massachusetts Toxics Use Reduction program, engage in source reduction activities for numerous materials types, such as industrial chemicals, pesticides, and nanomaterials. Nonetheless at a regional level, jurisdictional boundaries can still be challenging, for example, when Great Lakes states differ in policies regarding a particular chemical or water quality criteria. Any future discussion about regional policy regarding chemicals of emerging concern will need to explore harmonization across the Great Lakes states and provinces.

3.2 Review of Inventory of Policies and Programs Pertaining to Chemicals of Emerging Concern in the Great Lakes Region

In this section, we provide a synopsis of the database of policies and programs pertaining to identification, characterization and management of chemicals of emerging concern in the Great Lakes Region. This database of enacted legislative and executive branch legislation, policy and programs was compiled using searches of legislative databases, interviews with key informants, and web-based policy research. These sources were searched using a series of search terms related to identification, characterization, and management of industrial chemicals, pesticides, pharmaceuticals, and engineered nanomaterials. Searches were conducted of local, state, federal, and international policies

¹¹⁹ Robert Glicksman, "From Cooperative to Inoperative Federalism: The Perverse Mutation of Environmental Law and Policy," *Wake Forest Law Review*, 41 (2006), 719-803.

and programs that would affect inputs of chemicals of emerging concern in the Great Lakes region.

Our research efforts identified 237 currently enacted statutes, policies and programs that address chemicals of emerging concern in the Great Lakes Region. These include international (9), federal (30), regional (4), state (105) and municipal (89) statutes, policies and programs. Each of these levels is described in more detail below. Given the challenges of policy research, we expect that this database is incomplete and recommend efforts to fill any gaps in its contents. Further, the synopsis provided does not include most media specific policies or an analysis of the efficacy of the myriad of local, state and federal policies which were beyond the scope of this project. However, some of the most relevant policies and programs are reviewed in detail in the following sections. The database demonstrates a large number of often uncoordinated policies that could address chemicals of emerging concern.

International

Our database highlights nine international efforts that may address chemicals of emerging concern. Most of these are voluntary commitments, while others (such as the Stockholm Convention), have been signed but not ratified by the United States. These efforts also include bi-national efforts to address chemicals in the Great Lakes specifically as well as broader international efforts that may ultimately impact the Great Lakes Region. Overall, many of these efforts present more comprehensive approaches to chemicals management, focusing not on single classes of chemicals (industrial chemicals, pesticides, pharmaceuticals, etc.) but rather on chemicals of all types that exhibit certain properties (PBTs, POPs, endocrine disruptors). These efforts also employ a number of different policy strategies, including pollution prevention, chemical restrictions, prioritization, data collection, alternatives assessment, right-to-know, and product stewardship. The impact of such policies and programs depends on the extent to which they are implemented in the United States and Canada.

Federal

Our database highlights thirty federal efforts – legislation, policy, and programs - that may address chemicals of emerging concern. Most of these policies focus on single classes of chemicals (industrial chemicals, pesticides, consumer products, pharmaceuticals). There is no comprehensive and integrated approach to all chemicals and chemical classes. These efforts employ a number of different policy strategies, including pollution prevention, chemical restrictions, prioritization, data collection, alternatives assessment, green chemistry, product category regulation (i.e. consumer products), biomonitoring, environmental health surveillance systems, right-to-know, product stewardship, and environmentally preferable purchasing.

Some of these efforts also include federal attempts to establish and promote regional efforts in the Great Lakes. These efforts include the establishment of: an interagency task force to improve federal coordination on the Great Lakes; a regional collaboration for the

Great Lakes; monitoring programs to assess the health of the Great Lakes ecosystem; and criteria for states to use when setting water quality standards for certain pollutants.

Regional

Our database highlights four regional efforts that address chemicals of emerging concern. These efforts establish frameworks for coordinated action in the Great Lakes Region. Some of these efforts specifically address toxic substances, while others create forums that could discuss and address chemicals of emerging concern in the future.

State and Municipal

Our database highlights 105 state and eighty-nine municipal efforts that may address chemicals of emerging concern. These include efforts on: industrial chemicals, pesticides, pharmaceuticals and nanomaterials. Efforts on each of these chemical classes are discussed in more detail below.

Industrial Chemicals

A number of different policies' strategies have been employed in the Great Lakes states, at both the state and municipal level, with regards to industrial chemicals.

Seven Great Lakes states (IL, IN, MI, MN, NY, OH, and WI) have implemented pollution prevention policies and programs—multi-pollutant, multi-media strategies that shift the focus from end-of-pipe regulation to reduction of pollution at the source. These policies and programs encourage changes in production processes, product, or raw materials to reduce, avoid, or eliminate the use of toxic or hazardous substances or the generation of hazardous byproducts. Some states simply have aspirational goals for pollution prevention, while others have voluntary or mandatory pollution prevention programs that provide technical assistance and outreach to businesses.

A number of Great Lakes states and municipalities have implemented single chemical restrictions, policies that ban or significantly restrict certain chemicals or uses of chemicals. Four Great Lakes states (IL, MI, MN and NY) have banned pentabrominated diphenyl ether and octabrominated diphenyl ether. Seven Great Lakes states (IL, IN, MI, MN, NY, PA and OH) and 19 municipalities (IL(1), MI(3), MN(3), NY(2), WI(10)) have enacted legislation that bans or significantly restricts the use of mercury products. Three Great Lakes states (IL, MI, and MN) and one municipality (WI) have enacted legislation that bans or significantly restricts the use of lead. One Great Lakes state (MN) and two municipalities (IL and NY) have enacted legislation that bans the use of bisphenol A in certain children's products. One Great Lakes state (NY) has restricted the use of chromated copper arsenate.

Six Great Lakes states (IL, IN, MI, MN, OH and WI) and two municipalities (NY(2)) have enacted multiple chemical policies that regulate groups or classes of chemicals, rather than just one chemical. The legislation enacted in Minnesota requires the

prioritization of chemicals of high concern and priority chemicals in children's products. The legislation enacted in Illinois, Indiana, Michigan, Ohio and Wisconsin regulates "hazardous substances." The municipal resolutions in Erie County, New York and Buffalo, New York encourage the reduction of pollution from PBTs, encourage the purchase of products that do not contain PBTs, and stimulate the development of alternatives to PBTs.

A number of Great Lakes states and municipalities have implemented policies that regulate categories of products. These types of policies include regulating chemical use in products, encouraging the use of less toxic products and labeling/disclosing chemicals in products. Five Great Lakes states (IL, MN, NY, PA, and WI) have enacted toxics in packaging laws that prohibit the sale or distribution of packaging containing intentionally added cadmium, lead, mercury, and hexavalent chromium, and set limits on the incidental concentration of these materials in packaging. Two Great Lakes municipalities (IL and NY) have enacted legislation that bans the use of bisphenol A in certain packaging. Three Great Lakes states (IL, MI and MN) and one municipality (MN) have enacted legislation that regulates children's products or toys. Three Great Lakes States (IL NY, and WI) and four municipalities (IL(1), MN(1), and NY(2)) have implemented policies that require state, county, or municipal facilities to purchase and use environmental cleaning products. Illinois and New York have also enacted legislation that requires schools to purchase and use environmentally preferable cleaning products. Two Great Lakes states (MI and MN) have enacted legislation to regulate lead in jewellery.

Two Great Lakes states (IL and MN) have enacted biomonitoring legislation that establishes programs to assess human biologic specimens (blood, urine, breast milk, fat tissue) to characterize the levels of human chemical exposure. One Great Lakes state (IL) has established a program to collect, compile, and correlate information on public health and hazardous substances.

One Great Lakes state (MI) has issued an executive directive on green chemistry that encourages the research, development and the implementation of innovative chemical technologies that accomplish pollution prevention, promotes the use of chemical technologies that reduce or eliminate the use or generation of hazardous substances during the design, manufacture and use of chemical products, and encourages the use of safer chemical alternatives.

Six Great Lakes states (IL, IN, MI, MN, NY and PA) and 8 municipalities (IL(1), MN(2), NY(3), and OH(2)) have enacted environmentally preferable purchasing policies that require or encourage more environmentally preferable state and local government purchasing decisions for a wide range of products.

A number of Great Lakes states and municipalities have enacted product stewardship legislation, especially with regards to electronic waste and mercury-added products. Four Great Lakes states (IL, MN, NY and PA) and one municipality (NY) have enacted legislation providing for the management of obsolete electronics, since many of these products contain toxic components. Six Great Lakes states (IL, IN, MI, MN, NY, and

WI) and eight municipalities (NY(1) and WI(7)) have enacted legislation providing for collection and recycling programs for products containing mercury

One Great Lakes state (MI) has begun to take Great Lakes-specific action on a number of issues, including toxic chemicals. In August 2008, Michigan released a draft “Framework for Restoring and Protecting Michigan’s Great Lakes,” which attempts to prepare and begin implementation of an action agenda to restore, remediate and protect the Great Lakes. With regards to toxics, the framework sets a goal of virtual elimination for the release of, and exposure, to persistent toxic substances in the Great Lakes Basin ecosystem. In addition, it outlines short-term and long-term actions for mercury, dioxins and furans, PCBs, lead, pesticides, and emerging persistent toxic substances to meet the goal of virtual elimination.

The Great Lakes states and municipalities are continuing to move forward on the policy strategies outlined above and in addition, have proposed more comprehensive efforts for managing industrial chemicals, especially in products.

The Great Lakes states are continuing to pursue a variety of single chemical restrictions, including: decabrominated diphenyl ether (IL, MI, MN, and NY); bisphenol A (IL, MI, NY and PA); lead (IL, IN, MI, MN, and NY); mercury (IL, MI, NY, OH, PA, and WI); chromated copper arsenate (MN); perchloroethylene (NY); and chlorinated solvents (NY). The Great Lakes states are also continuing to pursue a number of multiple chemical policies, which include policies that focus on: priority chemicals (IL, IN, MI, NY, PA, and WI); toxic substances (MI); and xenoestrogens (PA). New York legislators are discussing broad chemicals policy reform legislation that focuses primarily on toxic substances.

The Great Lakes states are also pursuing additional policies that regulate categories of products including: consumer products (MN) children’s products (IL, IN, MI, MN, NY, PA, and WI), cosmetics (IL, MN and NY), cleaning products (IL, MN and NY) and packaging (NY). The legislation proposed to regulate children’s products includes restrictions on phthalates (IL, IN, MN, NY, and PA) and bisphenol A (IL, MI, MN NY, and PA), lead (IN and NY) and toxic substances (MI). Additionally, children’s product legislation proposed in Illinois, Indiana, Michigan, Pennsylvania, and Wisconsin seeks to designate priority chemicals of concern and regulate these chemicals in children’s products. The proposed legislation in these states also: provides the state with the ability to collect information about chemical use in children’s products; requires the identification of safer alternatives; and requires substitution where safer alternatives exist.

Further, the Great Lakes states and municipalities are also continuing to pursue additional efforts with regards to: green chemistry (MN), pollution prevention (NY which recently established a pollution prevention institute and PA); biomonitoring (IN); environmental health tracking (NY); product stewardship (framework legislation-MN; electronics-IL, IN, MI, NY, PA, WI; mercury-MI, MN, NY; and chromated copper arsenate-NY); environmentally preferable purchasing (Minneapolis, MN and NY); and the precautionary principle (Ann Arbor, MI and NY).

Pesticides

States and municipalities in the Great Lakes Region regulate pesticides in a number of different ways. Each Great Lakes state regulates pesticides under FIFRA (through EPA authority) and their own pesticide laws, usually through their agricultural departments or pesticide bureaus. States are required to license pesticide applicators, provide pesticide applicator training, collect use data in some instances, and are responsible for enforcement.

States may place more or less restrictive requirements on pesticides than EPA. For instance, States can require the registration of pesticide and inert ingredients that are exempt from FIFRA 25b (minimum risk products). States can also add additional uses and restrictions to the label.

Several states in the U.S. have passed laws restricting pesticide use in and around schools and requiring integrated pest management (IPM). IPM is a method for addressing the root cause of pest infestations primarily through non-chemical methods. Pennsylvania has a model school integrated pest management (IPM) program.

With regards to the municipal regulation of pesticides, all of the Great Lakes states have pre-emption laws that prohibit local governments from restricting the use, sales and distribution of pesticides. However, these pre-emption laws do not restrict a municipality from curtailing its own municipal use of pesticides and several municipalities have passed ordinances or bylaws calling for organic land care or integrated pest management in buildings and on grounds under their jurisdiction. In another example, on January 1, 2005 officials in Dane County, Wisconsin, which consists of 61 municipalities, passed a precedent-setting county-wide ban on the use of phosphorus containing synthetic lawn fertilizers due to pollution impacts to local lakes. This is significant because it has the ability to impact pesticide usage by restricting a major product used on lawns - “weed and feed” type product that contain a combination of fertilizers and pesticides.

Great Lakes states and municipalities have taken a number of additional actions on pesticides including: restricting pesticide use, implementing notification requirements, and promoting integrated pest management. Two Great Lakes states (IL and NY) and eighteen municipalities (IL(2), MI(2), MN(11), OH(2) and WI(1)) have enacted legislation that requires notification of certain pesticide applications. Five Great Lakes States (IN, MN, NY, PA and WI) have enacted legislation that places restrictions on pesticide applications in schools and requires notification when pesticides are used in schools. Two Great Lakes states (IL and NY) have enacted legislation that places restrictions on pesticide applications at day care facilities and requires notification when pesticides are used in these facilities. Four Great Lakes states (IL, MN, NY and PA) and two municipalities (MN(2)) have enacted legislation that requires or encourages the use of integrated pest management strategies as alternatives to pesticides. Twelve municipalities (IL(2), NY(9), OH(1)) have placed restrictions on pesticide use and encouraged the use of integrated pest management strategies.

Pharmaceuticals

States and municipalities in the Great Lakes Region are just beginning to discuss options for dealing with pharmaceuticals in water supplies and to take action on these issues. The impacts of pharmaceuticals are particularly local as water treatment systems may not effectively remove all of these contaminants. Currently, these discussions and actions have focused around product stewardship options for pharmaceuticals, especially take-back options for unused, unwanted or outdated pharmaceuticals.

One Great Lakes state (IN) has taken action on this issue. Indiana has established pharmaceutical disposal procedures, which instructs all individuals to refrain from pouring unwanted medications down a drain or flushing them down a toilet. Instead, it suggests that individuals contact local solid waste management districts for disposal guidance or follow certain steps for disposal in the regular trash. Indiana has also passed legislation that requires the board of pharmacy to establish procedures to ensure that pharmacies may return expired prescription drugs to drug wholesalers and manufacturers. In addition, eight municipalities in the Great Lakes Region (IL(4), IN(1), OH(1) and WI(2)) have begun to implement pharmaceutical take-back programs. These programs range from establishing year-round drop-off sites for unused, unwanted or outdated pharmaceuticals to periodic take-back events. Four Great Lakes states (IL, MN, PA and WI) have proposed legislation that would establish pharmaceutical take-back programs.

Nanomaterials

Currently, no state or municipality in the Great Lakes region has enacted a statute, policy or program that deals with engineered nanomaterials.

Despite this, discussions around environmental and health regulatory issues related to nanotechnology have begun in Wisconsin. Wisconsin has established an ongoing multi-agency working group and published a white paper specifically to address the preparedness of its chief environmental agency (Department of Natural Resources) to address nanotechnology risk regulatory issues. The multi-agency working group is developing nanotechnology risk scenarios that are likely to confront Wisconsin in upcoming years, and discussing coordinated cross-agency policy strategies for addressing these potential risks proactively. In addition, in December 2007, a Wisconsin legislator initiated an effort to work with state environmental and health agencies to develop a policy that would require a registry of what nanomaterials are being produced by industries in the state, at what levels, and other critical information necessary to address potential risks of nanotechnology developments.¹²⁰

¹²⁰ Maria C. Powell, Martin P.A. Griffin and Stephanie Tai, "Bottom Up Risk Regulation? How Nanotechnology Risk Knowledge Gaps Challenge Federal and State Environmental Agencies," *Environmental Management*, 42 no. 3 (September 2008), 426-443. Accessed at: www.springerlink.com/content/j453163328217214/.

Table 1: A Summary of Policies and Programs Relevant to Chemicals of Emerging Concern in the Great Lakes

LEVEL OF POLICY/PROGRAM	DETAILED OVERVIEW OF CURRENTLY ENACTED POLICIES/PROGRAMS
International	<ul style="list-style-type: none"> • 9 Policies/Programs • Most are voluntary commitments. • Includes bi-national efforts to address chemicals in the Great Lakes specifically as well as broader international efforts that may ultimately impact the Great Lakes Region. • Focus on chemical properties rather than chemical class (i.e. industrial chemicals, pesticides, pharmaceuticals, etc.). • Employ a number of different policy strategies, including pollution prevention, chemical restrictions, prioritization, data collection, alternatives assessment, right-to-know, and product stewardship.
Federal	<ul style="list-style-type: none"> • 30 Policies/Programs • Focus on single classes of chemicals (i.e. industrial chemicals, pesticides, consumer products, pharmaceuticals, etc.). • Employ a number of different policy strategies, including pollution prevention, chemical restrictions, prioritization, data collection, alternatives assessment, green chemistry, product category regulation, biomonitoring, environmental health surveillance systems, right-to-know, product stewardship, and environmentally preferable purchasing. • Some attempts to establish and promote regional efforts in the Great Lakes.
Regional	<ul style="list-style-type: none"> • 4 Policies/Programs • Focus on frameworks for coordinated action in the Great Lakes Region.
State/Municipal	<ul style="list-style-type: none"> • 105 State Policies/Programs; 89 Municipal Policies/Programs • <u>INDUSTRIAL CHEMICALS</u> <ul style="list-style-type: none"> • <i>Pollution Prevention</i>—Seven Great Lakes states (IL, IN, MI, MN, NY, OH, WI) have implemented multi-pollutant, multi-media strategies that shift the focus from end-of-pipe regulation to reduction of pollution at the source. • <i>Single Chemical Restrictions</i>—Four Great Lakes states (IL, MI, MN, NY) have banned pentabrominated diphenyl ether and octabrominated diphenyl ether. Seven Great Lakes states (IL, IN, MI, MN, NY, OH, PA) and 19 municipalities (IL(1), MI(3), MN(3), NY(2), WI(10)) have enacted legislation that bans or significantly restricts the use of mercury products. Three Great Lakes states (IL, MI, and MN) and one municipality (WI) have enacted legislation that bans or significantly restricts the use of lead. One Great Lakes state (MN) and two municipalities (IL and NY) have enacted legislation that bans the use of bisphenol A in certain children’s products.

LEVEL OF POLICY/PROGRAM	DETAILED OVERVIEW OF CURRENTLY ENACTED POLICIES/PROGRAMS
State/Municipal (cont.)	<ul style="list-style-type: none"> • <u>INDUSTRIAL CHEMICALS</u> (cont.) <ul style="list-style-type: none"> • <i>Multiple Chemical Policies</i>—Five Great Lakes states (IL, IN, MI, OH, WI) have enacted legislation that regulates "hazardous substances" and two municipalities (NY(2)) have enacted policies that encourage the reduction of pollution from PBTs. One Great Lakes state (MN) has enacted legislation that requires the prioritization of chemicals of high concern and priority chemicals in children's products. • <i>Regulation of Product Categories</i>—Five Great Lakes states (IL, MN, NY, PA, WI) have enacted toxics in packaging laws. Two Great Lakes municipalities (IL, NY) have enacted legislation that restricts bisphenol A in certain packaging. Three Great Lakes states (IL, MI, MN) and one municipality (MN) have enacted legislation that regulates children's products or toys. Three Great Lakes states (IL, NY, WI) and four municipalities (IL(1), MN(1), NY(2)) have implemented policies that require state, county, or municipal facilities, and in some cases, schools, to purchase and use environmentally preferable cleaning products. Two Great Lakes states (MI, MN) have enacted legislation to regulate lead in jewelry. • <i>Biomonitoring</i>—Two Great Lakes states (IL, MN) have enacted biomonitoring legislation. • <i>Data Collection</i>—One Great Lakes state (IL) has established a program to collect, compile, and correlate information on public health and hazardous substances. • <i>Green Chemistry</i>—One Great Lakes state (MI) has issued an executive directive on green chemistry. • <i>Environmentally Preferable Purchasing</i>—Six Great Lakes states (IL, IN, MI, MN, NY, PA) and eight municipalities (IL(1), MN(2), NY(3), OH(2)) have enacted environmentally preferable purchasing policies. • <i>Great Lakes Specific Action</i>—One Great Lakes state (MI) is beginning to prepare and implement an action agenda to restore, remediate and protect the Great Lakes. • <u>PESTICIDES</u> <ul style="list-style-type: none"> • <i>Notification Requirements</i>—Two Great Lakes states (IL, NY) and 18 municipalities have enacted legislation that requires notification of certain pesticide applications. • <i>Restriction/Notification Requirements</i>—Five Great Lakes states (IN, MN, NY, PA, WI) have enacted legislation that places restrictions on pesticide applications in schools and requires notification of when pesticides are used in schools and two Great Lakes states (IL, NY) have enacted legislation that places restrictions on pesticide applications at day care facilities and requires notification when pesticides are used in these facilities.

LEVEL OF POLICY/PROGRAM	DETAILED OVERVIEW OF CURRENTLY ENACTED POLICIES/PROGRAMS
State/Municipal (cont.)	<ul style="list-style-type: none"> • <u>PESTICIDES</u> (cont.) <ul style="list-style-type: none"> • <i>Restriction of Pesticide Use</i>—12 municipalities have enacted legislation that places restrictions on pesticide use and encourages the use of integrated pest management strategies. • <i>Promotion of Integrated Pest Management</i>—Four Great Lakes states (IL, MN, NY, PA) and two municipalities (MN(2)) have enacted legislation that requires or encourages the use of integrated pest management. • <u>PHARMACEUTICALS</u> <ul style="list-style-type: none"> • <i>Pharmaceutical Disposal Procedures</i>—One Great Lakes state (IN) has established pharmaceutical disposal procedures. • <i>Take-Back</i>—Eight municipalities in the Great Lakes Region have begun to implement pharmaceutical take-back programs. • <u>NANOMATERIALS</u> <ul style="list-style-type: none"> • No state or municipality in the Great Lakes Region has enacted a statute, policy, or program that deals with engineered nanomaterials, although discussions around environmental and health regulatory issues related to nanotechnology have begun in one Great Lakes state (WI).

3.3 Review of Federal Policies Regulating Chemicals of Emerging Concern

In this section, we provide a detailed overview of the key pieces of federal legislation and policy/programmatic efforts that could be applied in identifying, characterizing, and decision-making on chemicals of emerging concern in the Great Lakes. We analyze the extent to which these policies and programs support these goals. Given the current jurisdictionally defined approach to addressing these chemicals, we examine policies and programs with regards to each individual chemical group. Additional details of policies regarding industrial chemicals and consumer products, as well as case studies on specific Great Lakes chemicals of emerging concern are included in Appendices B-D. In the next section, we explore the broader implications of these policies and general themes with regards to limits, challenges, and opportunities to advance more prevention-oriented approaches to chemicals of emerging concern in the Basin.

The laws regulating chemicals of emerging concern are complicated and, in places, unclear as to requirements and responsibilities of government agencies and industry. However, in general the hazards/risks (excluding end of pipe emissions) of these substances are regulated by four sets of statutes: (1) for industrial chemical substances, the *Toxic Substances Control Act*; (2) for pesticides the *Federal Insecticide Fungicide and Rodenticide Act* (FIFRA), the *Federal Food Drug and Cosmetics Act* (FFDCA) and the *Food Quality Protection Act* (FQPA); (3) for consumer products, the *Consumer Product Safety Act* (CPSA) and the *Federal Hazardous Substances Act*; and (4) for cosmetics and drugs, the *Federal Food Drug and Cosmetics Act* (FFDCA). They are

regulated by three different agencies: the US Environmental Protection Agency (EPA); the Federal Food and Drug Administration (FDA), and the Consumer Product Safety Commission (CPSC). The EPA regulates the testing and manufacture of industrial chemical substances and their risks in use and disposal as well as the testing and safety of pesticides; the FDA regulates pharmaceuticals (though not end of life) as well as chemical substances (including pesticides) in food, cosmetics, and food contact materials (lunch boxes or ceramics); and the CPSC oversees chemical exposures to consumers from consumer products.

At this point in time, there is no comprehensive regulatory structure for engineered nanomaterials and they are thus being addressed in an ad hoc manner using existing regulatory structures. The US EPA has assumed administrative and programmatic leadership at this point (with the National Institutes for Occupational Safety and Health examining workplace health and safety questions). Similarly for pharmaceuticals and personal care products in the environment, there is less clear federal leadership with the US Geologic Survey and the EPA assuming responsibility for monitoring these contaminants in water supplies, and the US EPA leading limited policy discussions to date.

The laws noted above provide the framework for the discretionary voluntary and mandatory program initiatives that are implemented by the various agencies. By far, the EPA has undertaken the most extensive program initiatives in the areas of industrial chemicals, engineered nanomaterials, and pesticides. Further, the laws it implements, the TSCA, FIFRA, and FQPA are likely the most important with regards to chemicals of emerging concern. As noted in the introduction, we have focused in this report on product-based laws that address the inherent toxicity of materials and source reduction. The role of media-specific laws, such as the *Clean Water Act* and *Safe Drinking Water Act*, which focus on minimizing exposures to materials once in the environment, have not been analyzed as these tend to address industrial emissions of materials, when most of the identified chemicals of emerging concern reach the Basin from product-based emissions. Clearly, there is an important need for such laws as a “safety net” when and if chemicals of concern enter the environment; however given the preventive vision and goals of the Great Lakes Water Quality Agreement, our focus in this report is to provide advice for policies that would avoid these materials entering the Great Lakes Basin in the first place.

The Role of Monitoring

Prior to examining individual laws, it is useful to examine the role of monitoring as none of the federal laws on the various types of chemicals have monitoring requirements and few, if any, of the state laws require monitoring. There is no coordinated national monitoring scheme for the various types of chemicals of emerging concern. Some programs, such as the Center for Disease Control’s biomonitoring effort, examine some of the industrial and pesticide chemicals of emerging concern. Also, the U.S. Geological Survey has undertaken numerous national and state level surface water monitoring studies to understand the levels of various chemicals of emerging concern (pharmaceuticals, pesticides, personal care products, etc.) in surface waters. Nonetheless,

it is unclear if and how the results of these programs are integrated into policy decision-making. Based on our interviews with experts in the region, it appears that the Great Lakes Region has one of the most sophisticated and advanced monitoring frameworks in the nation, which may be in part due to *Great Lakes Water Quality Agreement* mandates.

Nonetheless, even in the cases where there are coordinated monitoring efforts, there is an ad hoc connection at best between monitoring and actual characterization and risk management decisions on chemicals. There is no clear, consistent basis by which chemicals are chosen for monitoring. Further, analytical methodologies do not exist for many types of contaminants and contaminant types and the development of such methods can be costly. The process of monitoring is expensive and as such only a small number of the thousands of high production or high concern substances can be examined at any time. Monitoring may not be necessary for all substances given their physical properties and use patterns, though criteria for determining this are unclear. Finally, the extent to which monitoring is used to understand the efficacy of policy interventions is unclear.

Several types of monitoring are important with regards to Great Lakes chemicals of concern. We discuss those relevant to the U.S. Canada has much more extensive monitoring programs that appear to be policy linked:

Great Lakes Regional Monitoring. There are several data and monitoring programs around the Great Lakes documenting the health of the air, beaches, wildlife, and habitats of the lakes, their tributaries, and watersheds. Several of these programs use GIS or real-time data generation to provide ready access to researchers. Perhaps in response to these potentially duplicative initiatives, the Great Lakes Commission has developed a Great Lakes Monitoring Inventory to make public and raise awareness around environmental monitoring programs in the Great Lakes. This searchable database allows users to track environmental monitoring programs focused on land use and contaminants in air, water, soil, sediments, and wildlife in the states and provinces bordering the Great Lakes.¹²¹

Several programs are managed jointly between Canada and other jurisdictions. For example, the Integrated Atmospheric Deposition Network (IADN) was established to respond to Annex 15 of the GLWQA. This program is managed jointly by the US and Canada and focuses on air and precipitation. Under this program, its focus is on persistent Bioaccumulative Toxic Pollutants (PCBs), ozone/Criteria Pollutants, hazardous air pollutants (HAPs), and air emissions in the Great Lakes. The findings of this program inform the activities on toxic substances in the Great Lakes under the Canada-Ontario Agreement as well as under the Bi-national Toxics Strategy signed in 1997 between the US and Canada.¹²²

Additionally, on even years, US EPA and Environment Canada host a State of the Lake Ecosystem Conference (SOLEC). These conferences provide an opportunity to share information about the health of the Great Lakes and improve decision making and

¹²¹ Great Lakes Commission website, "Data and Monitoring." Accessed at: www.glc.org/monitoring/.

¹²² U.S. Environmental Protection Agency website, "Great Lakes Monitoring." Accessed at: epa.gov/grtlakes/monitoring/air2/index.html.

environmental management between the two countries.¹²³ SOLEC focuses on an overarching set of ecosystem health indicators that can build on indicators for specific areas of concern.

The *Great Lakes Water Quality Agreement* also committed the US and Canada to draft Lakewide Management Plans (LaMPs) to determine which contaminants to the Great Lakes lessen their water quality, and to work collaboratively on policies necessary for their restoration.¹²⁴

The Great Lakes National Program Office (GLNPO) coordinates the interests of those in the US considered stakeholders in the health and management of the Great Lakes waters. The GLNPO facilitates the development and implementation of a comprehensive management approach to the Great Lakes focused on ecosystem health. Data collected by the office is available for public review.¹²⁵

Biomonitoring. The CDC's Environmental Public Health Tracking Program has been documenting the prevalence of toxic substances in the human body for 30 years, through the National Health and Nutrition Examination Surveys NHANES.¹²⁶ CDC sees the goal of the program as providing the data necessary to evaluate and ultimately prevent diseases related to environmental factors.¹²⁷ While NHANES was originally a periodic program, in 2001, the program became a continuous survey of the U.S. population. The program now tests a random sample of 5000 individuals from the average U.S. population every two years (from 15 sites) for nearly 200 chemicals in human sera. The collection of samples is combined with a health examination. The data are used for several purposes including: establishing reference ranges for comparison, identifying at risk populations (by gender, age, geography or socio-economic class), recognizing time trends in exposures, and identifying priority exposures.¹²⁸

¹²³ U.S. Environmental Protection Agency website, "State of the Lakes Ecosystem Conference." Accessed at: www.epa.gov/solec/.

¹²⁴ U.S. Environmental Protection Agency website, "Lake Superior Lakewide Management Plan (LaMP 2004)." Accessed at: www.epa.gov/glnpo/lakesuperior/2004/.

¹²⁵ U.S. Environmental Protection Agency website, "About the Great Lakes National Program Office." Accessed at: epa.gov/greatlakes/about.html.

¹²⁶ Centers for Disease Control website, "National Environmental Public Health Tracking Program." Accessed at: www.cdc.gov/nceh/tracking/biomonitoring.htm.

¹²⁷ Centers for Disease Control website, "National Environmental Public Health Tracking Program, Linking: Hazards, Exposures, and Health Effects." Accessed at: www.cdc.gov/nceh/tracking/biomontrack.htm.

¹²⁸ Ken Sexton, Larry L. Needham and James L. Pirkle, "Human Biomonitoring of Environmental Chemicals," *American Scientist*, 92 (2004), 38-46. Accessed at: www.cdc.gov/biomonitoring/pdf/AS_article_biomonitoring.pdf.

As part of the program, the US Geological Survey recently published an assessment of the quality of drinking water taken from private wells in 16 states which looked for 11 contaminants potentially found in wells which are of concern for human health.¹²⁹

The State of California recently passed biomonitoring legislation to track chronic disease and environmental exposures statewide to discover what patterns may emerge for conditions suspected to be linked to environmental factors.¹³⁰ The State of Minnesota has established an Environmental Health Tracking Program which requires the state to conduct biomonitoring of communities, pregnant women, and minors on a voluntary basis. The state of Illinois passed a biomonitoring feasibility act to examine approaches to designing a state program. The New York State (NYS) biomonitoring program, funded by multiple sources, is a pilot scale biomonitoring program examining contaminants in drinking water and health outcomes. The state has also initiated a community-based health and nutrition examination to examine environmental contaminants in human sera. Other Great Lakes states have programs for tracking exposure to heavy metals in children and adults.

Emissions/Waste Monitoring (TRI). Under the *Community Planning and Emergency Right to Know Act*, EPCRA, facilities manufacturing more than 25,000 lbs per year of some 650 chemicals are required annually to submit data on chemical emissions and waste generation to the Environmental Protection Agency. This data is compiled into the Toxics Release Inventory Database and gives an indication of larger, industrial sources of emissions. For certain PBT chemicals, thresholds for reporting were reduced to as low as 0.1 grams (for dioxins).¹³¹ The TRI has been credited with being a strong stimulus for industrial process pollution prevention efforts. However, in recent years there have been proposals to reduce reporting under TRI which have been strongly opposed by the states. In addition to Toxics Release Inventory Reporting, under EPCRA Section 312, firms storing extremely hazardous substances are required to report to their Local Emergency Planning Committee stored amounts of those chemicals. These data are generally not compiled into publicly available databases like the TRI. Additionally, data on process safety and possible worst case accident scenarios collected under the *Clean Air Act* S. 112 Risk Management Plan Rule, is not publicly collected but could provide important data on accidental emission and pollution prevention opportunities to firms and regulators.

Two Great Lakes states, Minnesota and New York, as a result of mercury products legislation belong to the Interstate Mercury Education and Reduction Clearinghouse

¹²⁹ U.S. Geological Survey website, "Summary of U.S. Geological Survey Data on Domestic Well Water Quality for the Centers for Disease Control's National Environmental Health Tracking Program." Accessed at: pubs.usgs.gov/sir/2007/5213/.

¹³⁰ Centers for Disease Control website, "National Environmental Public Health Tracking Program: Policy and Legislation." Accessed at: www.cdc.gov/nceh/tracking/policy.htm.

¹³¹ U.S. Environmental Protection Agency, "PBT Final Rule Summary." Accessed at: epa.gov/tri/lawsandregs/pbt/pbtrule-sum.pdf.

(IMERC),¹³² which compiles data on mercury use in products and allows for tracking such uses for reduction and substitution and could serve as a model for data collection for tracking chemicals in products in the region.

Industrial Chemicals - The *Toxic Substances Control Act*

Passed in 1976, the *Toxic Substances Control Act* regulates the entry and use of industrial chemical substances into commerce and authorizes the Environmental Protection Agency to take actions to prevent risks from such substances. It is the only statute that authorizes EPA to regulate industrial chemicals in the broadest possible way, from outright banning of chemical substances to testing and labeling requirements.¹³³ TSCA's provisions apply differently to new and existing chemicals. A "new chemical substance" is defined in TSCA Section 3 as "any chemical substance which is not included in the chemical substance list compiled and published under [TSCA] section 8(b)." This list, called the "TSCA Inventory," is a list of all toxic substances in commerce since 1977 (or since January 1, 1975 in some cases). This list currently consists of approximately 81,000 substances, though the number of substances used in commerce today is likely less.¹³⁴ Those substances that have come on the market since the establishment of the TSCA inventory amount to approximately 5% by volume of the chemicals on the market today¹³⁵ (See Appendix B for an in-depth overview of TSCA and EPA's voluntary programs under its Office of Pollution Prevention and Toxics).

Approximate Number of Existing Chemicals in TSCA Inventory (October, 2003)

Number of non-polymeric organics > 10,000 pounds/year	9,000
Number of non-polymeric organics < 10,000 pounds/year	41,800
Number of inorganic substances	3,200
Polymers	27,600
Number of new chemicals added to original Inventory via Commenced Pre-manufacture Notifications (in totals above)	18,100

TSCA is an extremely complex act that covers only industrial chemicals and excludes pesticides, food additives, drugs, cosmetics and preparations. It regulates both

¹³² Northeast Waste Management Officials Association website, "About the Interstate Mercury Education and Reduction Clearinghouse (IMERC)." Accessed at: www.newmoa.org/prevention/mercury/imerc/about.cfm.

¹³³ Nicholas Ashford and Charles Caldart, *Technology Law and the Working Environment*, (Washington, DC: Island Press, 1997).

¹³⁴ Under the EPA's Chemical Assessment and Management Program (CHAMP), EPA will be reviewing the TSCA inventory to "reset" it, removing chemicals no longer in commerce.

¹³⁵ U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics, "Overview: Office of Pollution Prevention and Toxics Programs," (December 24, 2003).

manufacturers and processors (including importers). The main components of the Act, which is implemented by the federal government and not the states, include:

- It allows EPA to regulate toxic substances in a broad way from outright bans to labelling (Section 6)
- It authorizes EPA to require industry to test old and new substances (Section 4)
- It permits EPA to exercise regulatory control over the introduction of new chemicals at pre-manufacture stage (Section 5)
- It contains wide reaching recordkeeping and reporting requirements (Section 8)

It should be noted that the *Pollution Prevention Act* of 1990, while non-regulatory in nature, extended these TSCA goals by establishing a national policy that pollution should be prevented or reduced at the source whenever feasible and that emissions and safe disposal of contaminants into the environment should be a last resort. This vision is critical to many of the voluntary programs (see below) that have been implemented by the EPA's Office of Pollution Prevention and Toxics (OPPT), which is in charge of TSCA implementation.

The underlying purpose and goals for TSCA lies in its Congressional Intent and in Section 2 of the Act. Congressional drafters noted that:

“the most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest.”¹³⁶

While TSCA Section 2 notes that:

“It is the policy of the United States that: adequate data should be developed with respect to the effect of chemical substance and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;

And adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment;

Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of the Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.”

¹³⁶ United States Congress - Staff House Committee on Interstate and Foreign Commerce, 94th Congress 2nd Session. 1976, *Legislative History of the Toxic Substances Control Act*, (Washington, DC: Government Printing Office, December 1976).

The key sections of TSCA include:

- Section 4: Compels the EPA Administrator to require the testing of chemical substances or mixtures, new or existing, if 1) there are insufficient data to make an unreasonable risk determination and testing is necessary; and 2) the chemical substance or mixture may present an unreasonable risk or the chemical will be produced in substantial quantities and either may enter the environment in substantial quantities or lead to significant or substantial human exposure. Testing requirements can be imposed through regulatory channels or binding consent orders with manufacturers, allowing more flexibility in test methods.
Section 5: Prohibits the manufacture, processing, or import of a “new chemical substance” or “significant new use” of an existing substance unless a pre-manufacture notification (PMN) is submitted to EPA at least 90 days before the commencement of manufacture or processing. The PMN contains information on the chemical identity, physical characteristics, processing and use, and available toxicity data. During this 90-day period, EPA reviews (primarily on the basis of structure activity data) the chemical’s human and environmental risks and exposures, examining the data submitted in addition to other information. EPA can then request more data, prohibit or limit manufacture, or halt the review process (using regulatory powers or binding consent orders). This process is currently being considered the main approach for addressing new engineered nanomaterials. Under Section 5, EPA can issue Significant New Use Rules that would require any new use to be subject to the PMN process when concerns are raised about new uses or increased production of a substance.
- Section 6: Authorizes the EPA to issue regulations to address the risks of existing substances if “there is a reasonable basis to conclude that . . . a chemical substance or mixture . . . *presents or will present an unreasonable risk of injury to health or the environment* [emphasis added]. . . using the least burdensome requirements” that are necessary to address that risk. Such regulations can be issued immediately when a threat of harm is imminent.
- Section 8: Authorizes EPA to promulgate rules that require chemical manufacturers, processors, and distributors to maintain records and make reports on chemicals and mixtures. This includes requirements to submit health and safety studies, provide immediate notice of “substantial risks,” and maintain records of adverse health effects for 30 years. This section allows EPA to issue rules to collect production and use information as well as information on disposal and byproducts. This includes the Inventory Update Rule, which generates an inventory every five years of non-polymeric chemicals produced or imported into the United States over 25,000 lbs. Additionally, under TSCA Section 9, EPA is required to consult with other agencies if the statutes they implement may reduce or eliminate unreasonable risks.

Voluntary Initiatives Under the EPA Office of Pollution Prevention and Toxics

The US EPA has been a world-wide leader in advancing voluntary chemicals testing, characterization, and safer chemicals initiatives. These initiatives have generally proven quite successful and have been driven by several factors: (1) the ability to go beyond legal requirements; (2) the ability to engage multiple stakeholders in developing solutions; (3) their often lower cost and resourcing needs; and, importantly, (4) the administrative burdens associated with many of the TSCA requirements (discussed in the next section).¹³⁷ These voluntary initiatives of the EPA Office of Pollution Prevention and Toxics fall into two broad categories – (1) programs on enhanced chemical testing, assessment, and characterization; and (2) programs on safer product design (these programs are outlined in greater detail in Appendix B). Additionally, in some cases individual companies or sectors, in response to regulatory demands elsewhere or consumer pressure are characterizing and publishing information on chemical hazards or seeking alternatives to some of the identified chemicals of concern. These industry initiated programs, such as those of Walmart, SC Johnson, Nike, Dell and other companies (such as the pharmaceutical sector) can be exceptionally effective means to advance understanding of chemical hazards and a transition to more environmentally-benign materials.¹³⁸ We do not cover such initiatives in this report, but note their importance in preventing chemicals of concern from entering the Great Lakes Basin.

1. *Programs on enhanced chemical testing, assessment, and characterization.* In 1998, following studies on the lack of data on high production volume (HPV) chemicals, those used over one million pounds per year, EPA initiated its Chemical Right to Know Initiative. This program started with the High Production Volume Chemicals Challenge Program, designed to collect screening level toxicity data on some 2800 chemicals manufactured or imported in quantities over one million lbs per year; and the Voluntary Children’s Chemical Evaluation Program, established to characterize risks to children from certain high production volume chemicals. However, more recently as a result of obligations resulting from the US-Canada-Mexico Security and Prosperity Partnership, the EPA has initiated the Chemicals Assessment and Management Program (ChAMP) to obtain toxicological data on mid-production volume chemicals. Both the HPV and ChAMP programs involve hazard screening of chemicals to prioritize substances for further testing, risk assessment or risk management actions. The ChAMP program is currently EPA’s most active effort on industrial chemicals assessment and management.

2. *Programs on Safer Product Design.* EPA has initiated several programs designed to ensure that safer chemicals come to market and that safer alternatives are available to chemicals identified as higher concern. These world renowned programs include: (1)

¹³⁷ Voluntary Programs, coupled with regulatory structures, can provide a strong framework for advancing prevention (see Steffen Hansen, and Joel Tickner, “The Challenges of Adopting Voluntary Health, Safety and Environment Measures for Manufactured Nanomaterials. Lessons from the Past for More Effective Adoption in the Future,” *Nanotechnology Law and Business* 4 (2007), 341-359).

¹³⁸ The Lowell Center for Sustainable Production coordinates the Green Chemistry and Commerce Council, a network of approximately 75 firms dedicated to advancing the application of green chemistry and design for environment in process and product design. Accessed at: www.greenchemistryandcommerce.org.

Sustainable Futures, which includes training and support to chemical designers to enhance consideration of toxicity and safer process and product chemistry at the chemical design stage; (2) Pollution Prevention Partnerships, designed to engage companies (and often sectors or user groups of chemicals) and those using chemicals in reducing pollution at the source; (3) Design for Environment, designed to engage stakeholders in finding safer product design options and overcoming challenges to their implementation; and Green Chemistry, which helps reward and support design of inherently safer chemistries. EPA's Great Lakes National Program Office and regional offices have initiated several voluntary pollution prevention initiatives that have successfully shown economic and ecosystem benefits.

Analysis of Federal Policy on Industrial Chemicals – TSCA and its Implementation

Many of the early federal environmental protection statutes contained bold and far-reaching chemicals management goals and policies, such as the *Clean Water Act's* goal of clean water bodies by 1986. However, in practice, and despite great progress in improving environmental quality (as noted in the introduction) many of these bold goals have never been attained. TSCA has been hindered by high burdens on government that limit EPA's authority to take action on chemicals of high concern. The limitations of TSCA have been broadly described elsewhere over the last twenty years.¹³⁹ These can be categorized in the following ways (these limitations are further outlined in Appendix B):

Unequal Treatment of “New” and “Existing” Chemicals. Scientifically there is no difference between existing and new chemicals. Yet when TSCA came into force in 1979, chemicals on the market at that time were allowed to be automatically placed on the TSCA inventory of existing substances. For these chemicals, which make more than 90% by volume of the chemicals on the market today, there are no automatic testing or review requirements. While this does not mean that those chemicals have received no testing or government scrutiny in the US or elsewhere, EPA has a high legal and administrative burden placed on it to restrict existing chemicals under TSCA Section 6, which has led to only a small number of chemical restrictions over the past 30 years.

As a result, EPA has had to rely primarily on voluntary initiatives on chemicals management, such as the consent agreement for the phase out of the Penta and Octa Brominated Diphenyl Ethers and the Voluntary PFOA stewardship program (see case study). While important, these initiatives have focused on a small number of chemicals and only ones where there was significant legal pressure (for example restrictions in Europe) or market and legal pressures (concerns about PFOA and fines being issued to DuPont for failure to report significant risks)

¹³⁹ Richard Denison, 2007, *Not That Innocent: A Comparative Analysis of Canadian, European, and U.S. Policies on Industrial Chemicals*, (Washington, DC: Environmental Defense); Government Accountability Office, 2007, *Chemical Regulation: Comparison of U.S. and Recently Enacted European Approaches to Protect Against the Risk of Toxic Chemicals*, (Washington, DC GAO-07-825); Michael P. Wilson, Daniel A. Chia, and Bryan C. Ehlers, 2006, *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation*, (Berkeley, CA: California Policy Research Center, University of California)

None of the industrial chemicals outlined in the Persoon and Hornbuckle database as chemicals of emerging concern in the Great Lakes have been subject to regulatory restrictions under Section 6 of TSCA, with the exception of PCBs (restricted in the original TSCA legislation). This does not mean that they have not been subject to testing requirements or emissions restrictions. Also, some of these, PBDEs, PFOS, other brominated flame retardants and nonylphenol ethoxylates have been subject to voluntary programs with industry. Still others, such as short chained chlorinated paraffins, chlorinated flame retardants, and synthetic musks, which have been identified as chemicals of concern in other jurisdictions (such as the European Union), have received little, if any voluntary or regulatory attention under the law.

For new chemicals, EPA has significant authority to ensure chemicals are safer at the pre-manufacture state (before any commercial manufacture has occurred). Through informal negotiation with manufacturers and provision of tools and training to chemical designers, EPA provides strong signals to manufacturers as to the types of chemicals that might present an unreasonable risk and types of chemicals and synthesis pathways that will reduce risks. These tools have provided invaluable resources to chemical designers. However, if risks are not identified in the short 90 day pre-manufacture review, the manufacturer or importer is free to manufacture or import the substance with the burden on EPA to request further testing or limit manufacture. EPA only uses its authorities to issue Significant New Use Rules on limited occasions. The higher burdens placed on the agency once a chemical comes to market are particularly problematic when new chemicals replace high volume existing chemicals, such as polybrominated diphenyl ethers.

Limited Toxicological and Use/Exposure Information on Chemicals in Commerce.

Numerous studies over the past 30 years have noted that most industrial chemicals in commerce lack some basic information about their toxicity and uses/exposure. Further, such information often does not get shared along supply chains. Important regulatory and voluntary efforts have been undertaken over the past 10 years to fill in many of these gaps, such as the Inventory Update Rule revisions, the High Production Volume Challenge and the Chemical Assessment and Management Program. Some like the HPV challenge have been very successful. However, there are many limitations in these efforts, such as: remaining data gaps and poor quality of some of the data received; the slow speed of application of the data to decision-making on chemicals; the limited range of substances covered under the programs; the overprotection of confidential business information which inhibits the ability of states, chemical users and the public to use data in decision-making; and the lack of a regulatory backbone to ensure that voluntary initiatives are implemented comprehensively.

Slow and Burdensome Chemical-by-Chemical Risk Assessment and Risk Management

Processes. The challenges EPA faces in exerting its authority to issue risk management regulations for existing chemicals has been outlined above. These high burdens were not intended in TSCA's legislative history. TSCA was written at a time when concerns about chemicals tended to focus on large facility level emissions, where scientific demonstration of risks is a relatively simple process. However, demonstrating risks when

exposures are product-based and disperse and toxicological effects may be at lower doses or subtle in nature presents many scientific challenges that increase the burden of demonstrating unreasonable risks. While chemical by chemical risk assessments for most chemicals is a laudable goal, in practice risk assessments can take years (for example EPA's risk assessment of trichloroethylene has taken almost 20 years) and while analysis is undertaken, there is an implicit assumption that management actions are not necessary.

TSCA not only provides high burdens for restricting industrial chemicals in commerce, but also for the requirement of testing, whereby EPA must present some evidence of risk or significant use or exposure before requesting such testing. In both the testing and risk management cases, generally these burdens must be met on a chemical by chemical basis unless the chemical is part of a chemical category under TSCA section 26.

EPA does have the capacity, however, to rapidly screen and prioritize actions on chemicals of concern on a more expedited basis. For example, the mid-production volume chemical assessment under ChAMP is expected to take until 2012, using a process that has been employed to screen over a thousand new chemicals per year and make risk management decisions for almost 30 years. Despite this capacity, there are few guidelines or clear processes as to how the EPA makes decisions as to which chemicals are of concern, which are higher or lower priority or when prevention options are needed. While the new HPV and ChAMP programs aim to collect and screen basic toxicological and very limited exposure data, there is little indication as to how EPA will use this information in decision-making, including affirmative or no action decisions.

Disincentives to safer chemicals and products. The grandfathering of existing chemicals, with concomitant limited regulatory oversight could be viewed as a disincentive to bringing new, safer chemicals to market. While many new chemicals have been produced since TSCA entered into force, few have reached market prominence (many of the new chemicals, however, are lower production specialty chemicals). This may also be in part due to the fact that well-performing, cost-effective alternatives to existing chemicals do not currently exist. Further, only limited research funds have been invested in the design of safer chemicals and processes.

Despite these limitations, EPA has undertaken innovative efforts, through the Office of Pollution Prevention and Toxics to guide and support manufacturers and users of chemicals towards safer chemistries, chemical processes, and products. These programs focus on safer chemical and product design, as well as improvements in process design to eliminate unwanted contaminants and byproducts and reduce emissions and waste. Starting with the tools EPA provides to chemical designers, to sectoral pollution prevention initiatives, to partnership projects, such as the Furniture Flame Retardancy Project, to awards programs such as the Presidential Green Chemistry Awards, EPA has received multi-stakeholder and international praise for its efforts to promote safer chemicals and products. However, the impact and scope of these programs are limited by

small budgets compared to data collection and risk assessment activities. They have also been limited by the lack of a regulatory backbone to ensure broad application.¹⁴⁰

There is some momentum to reform TSCA after 30 years and pressure coming from the European Union's REACH initiative and consumer and market pressures. The proposed *Kid's Safe Chemicals Act* would require chemical manufacturers and importers to issue statements of safety for children for high concern chemicals, require phase-outs of some chemicals and invest in green chemistry. It is unclear when such an Act may be passed, however. Additional legislation has been proposed that would phase out the use of Bisphenol-a in children's products. The federal *Green Chemistry Research and Development Act* has been passed in the House of Representatives and is awaiting passage in the Senate.

The Role of State Industrial Chemicals Policy in Shaping Regional and Federal Reforms

Concerned about the lack of federal momentum on chemicals policy and the implications of new European Union policies such as REACH and the Restrictions on Hazardous Substances in electronics directive, several states have initiated broad chemicals policy reform discussions. These include Massachusetts, Washington, California, Oregon, Minnesota, New York, and Maine. These build on experience in pollution prevention and more recently single chemical restrictions policies, such as those on PBDEs and mercury. Michigan's Green Chemistry Executive Directive has been viewed as a model for linking prevention activities with economic development actions and is likely to be a focus in the near future. Further, states are beginning to coordinate and collaborate on chemicals identification, assessment, and alternatives assessment given the limited budgets they face and resources to complete such activities. These discussions have resulted in the formation of an Interstate Clearinghouse on Chemicals to compile data and coordinate discussions across states. Several Great Lakes states including Michigan, Minnesota, New York, and Illinois have been active in these broader chemicals policy reform debates and likely to play an active role in shaping any regional or federal reforms.

Chemicals in Consumer Products, Cosmetics, and Food Contact Applications (Other Than Pesticides)

Chemicals in consumer products including cosmetics and food contact applications are regulated under two sets of laws and agencies, as described below.

¹⁴⁰ Cheryl Hogue, "The Future of U.S. Chemical Regulation," *Chemical and Engineering News*, 85 no. 2 (January 8, 2007) 34-38. Accessed at: pubs.acs.org/cen/government/85/8502regulation.html.

The Federal Food Drug and Cosmetics Act

The FDA regulates chemicals in two consumer product categories: cosmetics and materials that have contact with food (such as water bottles, ceramics, or lunch boxes, and toys such as ovens). These product types are regulated in different ways by the agency.

Cosmetics. The FDA website succinctly summarizes the regulation of chemicals in cosmetics, stating, “FDA's legal authority over cosmetics is different from other products regulated by the agency, such as drugs, biologics, and medical devices. Cosmetic products and ingredients are not subject to FDA pre-market approval authority, with the exception of color additives...Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing.”¹⁴¹

In general, except for color additives and those ingredients which are prohibited or restricted from use in cosmetics by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic provided that the ingredient and the finished cosmetic are “safe,” as defined by the manufacturer, the product is properly labeled, and the use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces. Only 11 chemicals are restricted by FDA for use in cosmetics (many used as solvents or propellants).

In light of limited federal government oversight, the US FDA, along with the Cosmetic, Toiletry, and Fragrance Association and Consumer Federation of America founded the Cosmetics Ingredient Review (CIR) which “thoroughly reviews and assesses the safety of ingredients used in cosmetics in an open, unbiased, and expert manner, and publishes the results in the peer-reviewed scientific literature.”¹⁴² The CIR is not a regulatory body but is independent from the industry and reviews cosmetic ingredients according to a set of procedures. To date, the panel has reviewed a percentage of ingredients used in cosmetics. However, there is no guidance from the FDA as to the determination of safety or the methods of testing, for example multiple exposures or low dose exposures. The end of life considerations of cosmetic chemicals in the environment are not considered. Additionally, the results of the CIR are not linked to any regulatory process.

Food Contact Substances. Also known as indirect food additives, Food Contact Materials are substances used in food-contact articles (such as packaging or can linings) but are not intended to be directly added to food, including adhesives and components of coatings, paper and paperboard components and polymers. Under the 1997 amendments to the *Food Drug and Cosmetic Act*, manufacturers are required to submit food contact notifications to the FDA for new uses of food contact substances (including new food contact substances). Notification is not required for food contact substances that have prior regulations related to their use in contact with food or are considered “Generally Recognized As Safe” (a designation made by FDA, and in some cases, by industry that

¹⁴¹ U.S. Food and Drug Administration website, “FDA Authority Over Cosmetics.” Accessed at: www.cfsan.fda.gov/~dms/cos-206.html.

¹⁴² Cosmetic Ingredient Review, (2008). Accessed at: www.cir-safety.org/.

applies to many food contact substances). These notifications are reviewed by FDA with the manufacturer, and FDA can issue limits on the use of those substances and on the degree that such substances can leach from contact surfaces to food.¹⁴³ FDA has expedited procedures for food contact substances that are of low exposure potential (below 1.5 micrograms per person per day). Food items marketed with toys in them, such as cereals, are regulated by both the FDA and the CPSC. The FDA regulates the safety of the food, and the CPSC is responsible for the safety of the toy.

Consumer Product Safety Act and the Federal Hazardous Substances Act

The Consumer Product Safety Commission (CPSC) is charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products used in homes, schools, and recreation that pose a fire, electrical, chemical, or mechanical hazard, or can otherwise cause injury. To carry out its mission, CPSC administers several statutes passed by Congress, including two primary laws—the Consumer Product Safety Act and the Federal Hazardous Substances Act (additional detail on the provisions of these laws is included in Appendix C).

(1) The Consumer Product Safety Act (CPSA) of 1972 is an umbrella statute that consolidated federal safety regulatory activity relating to consumer products within the CPSC. The law defines the authorities of the CPSC and authorizes the agency to develop standards to reduce or eliminate unreasonable risks of injury associated with consumer products, to ban products if there is no feasible safety standard, and to pursue recalls for products that present a substantial hazard.

(2) The Federal Hazardous Substances Act (FHSA) of 1960 requires the labeling of hazardous household products that are toxic, corrosive, combustible, or otherwise hazardous, and that have the potential to cause substantial personal injury or illness as a result of reasonably foreseeable handling, use, or ingestion. The Act also allows the CPSC to ban certain products (called “banned hazardous substances” that are so dangerous that labeling is not adequate to protect consumers. For example, it specifically prohibits any toy or other article that is intended for use by children and that contains a hazardous substance if a child can gain access to the substance. The term hazardous substance is defined under the law as requiring strong toxicological evidence and evidence of exposure and firms generally make the determination as to whether a product contains a hazardous substance.

The laws authorize CPSC to undertake activities in product testing (though no pre-manufacture testing of products is required); to establish product safety standards, including voluntary industry initiated standards; to require labeling of products containing hazardous substances; and to issue recalls.

The *Consumer Product Safety Improvement Act* of 2008, makes the following amendments to the *Consumer Product Safety Act*: (1) it issues strict limits for lead

¹⁴³ U.S.FDA, “Inventory of Effective Food Contact Substance (FCS) Notifications,” (December 2008).

content of children's products (100ppm after 3 years); (2) it prohibits the manufacture, import or sale of any children's toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP); and (3) it makes any voluntary safety standard (including material bans) under the provisions of ASTM International Standard F963-07 *Consumer Safety Specifications for Toy Safety* (ASTM F963) a mandatory consumer product safety standard.

Analysis of Consumer Product Policies and their Implementation

As noted, under TSCA Section 9, EPA is required to consult with other agencies if the statutes they implement may reduce or eliminate unreasonable risks. With regards to consumer products and toys, the *Consumer Product Safety Act* and *Federal Hazardous Substance Act* contain several limitations that challenge the ability of the Consumer Product Safety Commission to act quickly on chemicals of emerging concern. These include:

Consumer Product Safety Laws require the CPSC to rely on voluntary product standards developed by industry groups when compliance with them would eliminate or reduce the risk of injury. While the new *Consumer Product Safety Improvement Act* makes these consensus standards mandatory, such standards tend to test for very few materials of concern, require few restrictions and, as they are negotiated, there is no expedited process for chemicals of emerging concern.

There are no pre-market testing requirements for chemicals used in consumer products, as is the case with industrial chemicals. While manufacturers are required to ensure their products are not hazardous or improperly labeled, defining a substance as hazardous is difficult due to the high scientific burdens imposed to list a substance as hazardous and subject to labeling requirements or restrictions. As such, very few substances have been listed as hazardous. Further, given the thousands of products CPSC is charged with regulating, and the lack of product content or toxicity data, it is virtually impossible for the agency to make safety determinations, particularly when the agency's budget is half of its original budget with only a small number of health scientists on staff.

To regulate or restrict a substance, the CPSC has to undergo a lengthy, costly, and time consuming process which requires balancing costs to manufacturers with benefits to health and application of the least burdensome requirements for industry. As a result of this cumbersome process with high burdens on the agency, few substances have actually been subjected to mandatory restrictions. CPSC depends on voluntary initiatives wherever possible. Because of these burdens, a focus on safety concerns (which are relatively easier to demonstrate) may actually cause countervailing chemical risks as the current debate over flame retardants demonstrates. Such trade offs may be avoided by focusing on alternatives that achieve flame retardancy function but reduce toxicity.

There are no federal consumer or food and drug restrictions on chemicals in cosmetic products; however, as a result of European Union regulations restricting or prohibiting

the use of carcinogens, mutagens, and reproductive (CMRs) toxicants in cosmetics, a coalition of environmental and public health organizations called the Campaign for Safe Cosmetics, has secured the commitment of more than 300 companies to eliminate CMRs in their products and go beyond European regulations.

As noted, several states have initiated consumer product based policies: for example on lead in children's products; on environmentally preferable purchasing; and on mercury products.

Pesticides

The U.S. federal authority and responsibility for regulating pesticides is granted through the following federal statutes:

- The *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) is the primary law that governs the registration, use, sale and distribution of pesticides in the U.S. It grants authority to the federal Environmental Protection Agency (EPA) to register pesticides, and prescribes labeling, testing, and other regulatory requirements to prevent unreasonable adverse effects on human health or the environment.
- Under the *Federal Food, Drug, and Cosmetic Act* (FFDCA), EPA establishes tolerances (maximum legally permissible levels) for pesticide residues in food.
- In 1996, the *Food Quality Protection Act* (FQPA) amended both FIFRA and FFDCA to enact a more protective pesticide regulatory framework. The FQPA was passed to address pesticide residue levels on food and to account for the special susceptibilities of children and infant exposures to pesticide residues. The FQPA required risk assessments of pesticides used on food and feed to consider aggregate exposures, cumulative risks of pesticides with similar mechanisms of toxicity, and to develop health based standards that were protective of children and infants (with a 10-fold additional safety factor). It required a reassessment of all existing pesticide tolerances, the amount of the pesticide that can legally remain in or on foods, and required periodic re-evaluation of registered pesticides.

Additional laws addressing the introduction of pesticides into waterways include:

- The *Clean Water Act* (CWA) designates uses, sets water quality standards for contaminants, and regulates the discharges of pollutants into the surface waters.
- The *Safe Drinking Water Act* (SDWA) authorizes EPA to set national health-based standards for drinking water to protect against both naturally-occurring and man-made contaminants that may be found in drinking water. It focuses on treatment and source water protection and applies to every public water system.

The EPA has the authority and responsibility for regulating pesticides under the federal statutes listed above (with the exception of the FFDCA). Both EPA and the states register a pesticide before its sale, distribution and use. Before registering a new pesticide or a new use for an existing pesticide, the manufacturer must submit a

registration application to EPA with data that meets certain scientific data and testing requirements to determine the pesticide hazard to humans, domestic animals, non-target species, as well as the environmental fate.

EPA must ensure that “the pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment.” The label is considered the law.

FIFRA Section 2(bb) defines “unreasonable adverse effects on the environment” as:
(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or
(2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the *Federal Food, Drug, and Cosmetic Act*.

The burden to demonstrate that a pesticide product satisfies the criteria for registration is at all times on the proponents of initial or continued registration.

A pesticide is considered ineligible for registration if it does not meet the safety standard for its intended use.

It is important to understand that a pesticide end product contains an active ingredient (the pesticide) and inert ingredients which can make up to 98% of the product. The registration process requires different levels of testing on the active ingredient and the end use product.¹⁴⁴ Acute toxicity and chronic toxicity testing are required for the active ingredient (though some types of testing – such as for endocrine disruption have not been required due to lack of consensus on testing methods despite many years of discussion). However, no chronic toxicity studies, such as carcinogenicity and developmental toxicity, are required for the end product. The emphasis for the end product is on acute studies to develop precautionary statements for the pesticide label.

There are more significant toxicity data requirements for skin applied pesticides, such as mosquito repellents.

In addition to effects on the target organism, hazards to non-target organisms are assessed to determine the pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. According to EPA, these tests include short-term acute, subacute, reproduction, simulated field, and full field studies. Only when laboratory tests suggest a high potential for possible adverse effects are simulated field data or field data required to determine the potential for chronic effects. Once again, a main purpose of the testing is to help determine the need for precautionary label statements to minimize potential harm to non-target organisms.

In addition, in accordance with FQPA, EPA requires the registrant to determine pesticide residue levels that will remain on food and environmental fate data to assess the presence

¹⁴⁴ See U.S. Code of Federal Regulations, *Protection of the Environment*, 40 CFR §158.300.

of widely distributed and persistent pesticides in the environment that may result in loss of usable land, surface water, groundwater, and wildlife resources.

An exception to the federal pesticide registration process are a group of exempt pesticides referred to as FIFRA (25)b that are considered “minimum risk” pesticides.

The *Food Quality Protection Act* (FQPA) of 1996 mandated a registration review program for pesticides, intended to respond to developments in risk assessment, policies and practices. Through the re-registration process pesticides are reassessed every 15 years to determine whether they meet the FIFRA standard. In the re-registration process EPA will put out a call for data when it finds data gaps in the information submitted by the applicant.

Under FQPA, EPA also must assess the cumulative risks of exposures to multiple pesticides that share a common mechanism of toxicity, or act the same way in the body. These cumulative assessments consider exposures from food, drinking water, and residential sources. EPA also incorporates regional exposures from residential and drinking water sources since this is the most appropriate way to account for the considerable variation in potential exposures across the country.

When a pesticide is found to pose risks of concern to humans or the environment, the Agency must address these risks. The options for addressing such risks include risk mitigation, determining that the risks are justified in light of the benefits of the pesticide, or initiating regulatory options to modify or cancel the registration. This could be, and often is, a change in use on the label.

In terms of other agencies responsibilities, the Department of Health and Human Services’ Food and Drug Administration and the U.S. Department of Agriculture enforce the pesticide residue tolerances required under the FQPA.

While not a regulating body, the U.S. Geologic Survey conducts a National Water Quality Assessment of pesticides in surface and ground waters, bed sediments and fish of the United States and maps some pesticide usage data.

Analysis of Pesticide Policies

Pesticides are in general more thoroughly tested than industrial chemicals and in many cases this testing has had important public health benefits. However, pesticide policies to date have not focused on the “service” or “function” being achieved through pesticide application and identification of safer, healthier ways to manage pests. Further, broad pesticide use almost inevitably results in disperse and non-point exposures, and toxicity testing may not be adequate to protect specific populations, such as pregnant women and small children. In general, this registration process identifies primarily the acute risks of pesticide formulations and mitigates impacts through label restrictions. Even for active ingredients, testing may have gaps. The process does not rapidly identify, assess or

respond to synergistic or cumulative impacts and species resistance issues that occur during the use or end life of pesticide products.

More specific gaps and issues are as follows:

1. Full pesticide product formulations are not tested. Pesticides consist of active and inert ingredients. The inert ingredient(s), which can make up 50-98% of the product, are for the most part undisclosed on the label (an exception-FIFRA 25b products fully disclose inert ingredients as a requirement). However, the majority of testing data is based on the active ingredient, not the full product (only some acute testing is required). Because of this, the toxicological implications of inert ingredients (which EPA estimates may be as many as 3,000 chemicals of varying toxicity and biologic activity) are often not considered in the registration process. Nonetheless, data indicate that such substances can increase the human or ecological toxicity of pesticide formulations as well as exposure (increasing uptake). For example, some formulations of glyphosate are 10–100 times more acutely toxic to fish than the active ingredient alone. In one study, a formulation of the fungicide vinclozolin, but not the active ingredient alone, caused fish to develop intersex gonads.¹⁴⁵ While EPA has undertaken efforts to assess the toxicity/risks of some inert ingredients, the ways in which these data will be used in the pesticide registration and review process is unclear.

2. Environmental data shows pesticides reaching the environment, wildlife and humans at levels of concern. There is no comprehensive environmental monitoring program to determine if risk predictions performed during the registration of pesticides are accurate. Data indicate the presence of many pesticides in surface and ground waters, human tissue and wildlife. The Persoon and Hornbuckle bibliography identifies several older and newer agricultural, home use (home use herbicides and insecticides and anti-microbials), public health use (methoprene) and personal use (DEET) pesticides in Great Lakes water and sediments. While the presence of pesticides in the environment, humans and wildlife do not provide clear evidence of significant risks, the presence of these bioactive substances raises concern, especially for benchmark exceedances. Their presence further indicates the need for prevention to avoid such exposures in the first place.

For example, the U.S. Geologic Survey (USGS) conducted a 10-year assessment of pesticides in surface and ground waters of the United States, the National Water Quality Assessment (NWQA).¹⁴⁶ Some of the key findings (1992-2001) are as follows:

- Pesticide compounds were detected >90% of the time in developed watersheds which were dominated by agricultural, urban, or mixed land use.
- Organochlorine compounds, most of which were restricted or phased-out before the study (such as DDT) were found in fish and bed-sediment from most streams in developed watersheds.

¹⁴⁵ See Caroline Cox and Michael Surgan, “Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health,” *Environmental Health Perspectives*, 114 no. 12 (December 2006), 1803-1806.

¹⁴⁶ See USGS website. Accessed at: water.usgs.gov/nawqa/.

- Concentrations of pesticides were higher than water-quality benchmarks for aquatic life and fish-eating wildlife in more than half of the agricultural and urban streams measured. Most urban streams (83%) had benchmark exceedances, mainly by the insecticides diazinon, chlorpyrifos, and malathion.
- Pesticides occurred in >50% of wells that sampled shallow groundwater beneath agricultural and urban areas.
- One or more pesticide compounds were detected in 33% of the deeper wells that tap major aquifers used for water supply.

These data show that pesticides are making their way into surface and ground waters from a range of diverse sources, raising concerns as to human and ecological health implications and the most effective means of exposure prevention.

3. Urban uses and water quality issues not adequately predicted or benchmarked. The NWQA data show that the current regulatory framework has not adequately predicted, or tracked the environmental impact of non-agricultural uses of pesticides. Pesticides used for non-agricultural uses such as in and around schools, homes, gardens, landscapes, and for public health, and personal uses of pesticides are contributing to unanticipated contamination in urban waterways.

Recently, researchers have discovered unanticipated hazards with the synthetic pyrethroid class of pesticides used widely for urban and agricultural pest control. Original registration data indicated that these bind to sediment and do not stay in the water column. However, researchers from the University of California, Berkeley, Southern Illinois University and the Central Valley Regional Water Quality Control Board (California) have found synthetic pyrethroids, such as bifenthrin, to be widespread at toxic levels to aquatic organisms in California's urban streams.¹⁴⁷

One of USGS's recommendations is for monitoring and benchmarks for synthetic pyrethroids and emerging pesticides. This example provides some evidence that current federal system is not structured to comprehensively monitor, evaluate, or respond quickly to identified risks.

4. The label is the law and often inadequately followed. Pesticides are approved for certain uses based on toxicological testing and exposure estimates. The premise of current laws is that acute risks to humans and the environment will be mitigated if the label precautions are followed. It is expected that users, both professional applicators and homeowners, will read the label and follow personal protections and specific conditions for use, such as wind, temperature, and distance of application from a water body. However, numerous law suits against major pesticide application companies show that labels are often not adequately followed. Terminix has entered into settlements with the states of New York, Connecticut, Kentucky, Pennsylvania, and Florida for pesticide

¹⁴⁷ Robert Holmes, "Statewide Investigation of the Role of Pyrethroid Pesticides in Sediment Toxicity in California's Urban Waterways," *Environmental Science and Technology*, 42 no. 18 (2008), 7003–7009,

application violations. Minnesota has also noted violations in how Terminix follows the label.¹⁴⁸

5. Product performance or efficacy is not tested on widely use pesticides. EPA only requires efficacy data for pesticides used in the public health area, including disinfectants used to control microorganisms, rodents, ticks, and mosquitoes that may directly or indirectly transmit diseases to humans. This means that pesticides that may serve no use due to species resistance or other factors can be widely used in commerce. There is no system for monitoring alerting users to trends in efficacy or species resistance.

The Agency will be developing a proposed rule in the future to address product performance data requirements for conventional pesticides and biochemical and microbial pesticides.¹⁴⁹

6. Limited mechanisms to rapidly identify and respond to individual pesticide risks. EPA relies on a 15 year re-registration process or petitions for special review to reassess risks for particular pesticides. When EPA or their Scientific Advisory Panel, or other entity, such as USGS identifies an unacceptable risk or violation of a standard, immediate protective actions are rarely taken, especially for workers and children. For instance, after unacceptable risks were identified with household uses of two of the commonly used organophosphate pesticides, chlorpyrifos (dursban) and diazinon, the products remained on the market for those uses for years through voluntary phase-out agreements with the manufactures.¹⁵⁰ As evidence increases related to the potential risks of entire classes of pesticides, for example organophosphates, the current system currently inhibits class-based approaches to responding to identified risks, but rather they are addressed in a resource intensive chemical-by-chemical manner.

Risk assessment and risk management processes for acting on pesticides of concern are slow and most often fraught with debates over acceptable exposures and uncertainties.

7. The fate of breakdown product(s) in the environment is not thoroughly investigated. The breakdown products, or degradates of active and inert ingredients, which can be more toxic than their parent compounds, are not assessed to the same degree as active ingredients.

8. Mixtures and synergistic effects are not well accounted for. According to the USGS, pesticides occur as mixtures of multiple pesticide compounds much more often than individually. Streams with developed watersheds contained ≥ 2 pesticide compounds $>90\%$ of the time, and ≥ 10 compounds $\sim 20\%$ of the time. While the science of studying complex mixtures is growing (particularly with the development of high throughput

¹⁴⁸ See www.consumeraffairs.com/news03/terminix_ny.html; and www.syx.com/emu/html/mn.html.

¹⁴⁹ See www.epa.gov/pesticides/regulating/data_requirements.htm#performance.

¹⁵⁰ See www.epa.gov/pesticides/reregistration/REDs/factsheets/chlorpyrifos_fs.htm and www.epa.gov/pesticides/reregistration/REDs/factsheets/diazinon_ired_fs.htm.

testing and genomics), these are rarely thoroughly considered in risk assessment activities in part due to the lack of defensible methodologies.¹⁵¹

9. Burden on local water supply and wastewater treatment facilities not adequately addressed or supported. The current framework burdens each state with setting standards, monitoring and treating for the myriads of pesticides, inert ingredients and breakdown products. Current drinking-, waste-, and storm water technologies were not designed to remove many pesticides and byproducts, nor do most local governments have resources to upgrade to the necessary technologies. For instance, the common antibacterial agent, triclosan, used in antibacterial soaps, deodorants, toothpastes, cosmetics, fabrics, plastics, and its analog, triclocarban, used in bar soaps, has been found by USGS to contaminate waterways in large quantities. In 2006, researchers at Johns Hopkins Bloomberg School of Public Health found that after people flush antibacterial agents down the drain, as much as 75% of triclocarban and 50% of triclosan can survive treatment at sewage plants. Even when removed from water during treatment, such contaminants end up in biosolids which may re-contaminate agricultural lands and end up in a non-point manner back in the water supply.¹⁵²

10. Professional training in alternatives is inadequately mandated. Under FIFRA, states are required to license pesticide applicators and provide training in pesticide use. In some states professional classes for continuing education credits and certification are available on alternatives, such as integrated pest management, but they are not required. This can promote a professional bias toward pesticide use and a lack of understanding and use of a tool-box approach where safer and more sustainable pest control methods are promoted.

While we have outlined numerous aspects of the current regulatory and policy framework for pesticides that limit the ability to rapidly identify and respond to emerging pesticide issues in the Great Lakes, there is a larger structural issue with the focus of the federal system. The current system does not focus on the long-term suppression of pest problems through the most economically and environmentally viable means. While there are many non-regulatory programs to promote the least-toxic methods of pest control in agriculture, public health, and the built environment, a majority of federal resources are focused on a chemical registration process. Given increasing data on health effects of pesticide exposure (both agricultural and home use), a prevention-oriented approach, using integrated pest management techniques, combined with enhanced testing and

¹⁵¹ See Caroline Cox and Michael Surgan, "Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health," *Environmental Health Perspectives*, 114 no. 12 (December 2006), 1803-1806.

¹⁵² D.W. Kolpin, E.T. Furlong, M.T. Meyer, E.M. Thurman, et al., "Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance," *Environmental Science and Technology*, 36 (2002), 1202-1211; A. Lindstrom, I.J. Buerge, T. Poiger, P. Berqvist et al., "Occurrence and Environmental Behavior of the Bactericide Triclosan and its Methyl Derivative in Surface Waters and in Wastewater," *Environmental Science and Technology*, 36 no. 11 (2002), 2322-2329; Johns Hopkins Bloomberg School of Public Health, "Sludge Recycling Sends Antiseptic Soap Ingredient to Agriculture," *Public Health News Center*, April 26, 2006. Accessed at: www.jhsph.edu/publichealthnews/press_releases/2006/halden_sludge.html.

broader assessment approaches could more effectively achieve the goals of pest management and health and ecosystem protection.

Engineered Nanomaterials

As previously noted, there is no comprehensive regulatory framework as of yet for the safety of engineered nanomaterials. At this point in time, engineered nanomaterials are being addressed using existing regulatory structures. Yet their ability to address the unique characteristics of engineered nanomaterials is unclear. For example, such materials are subject to new chemicals provisions (pre-manufacture notification) under TSCA, though there is little guidance as to testing needs or how these materials should be reviewed. EPA has established guidance for manufacturers to determine whether their engineered nanomaterial is subject to PMN requirements.¹⁵³ However, the US EPA has assumed administrative and programmatic leadership through the launch of the Nanoscale Materials Stewardship Program (NMSP) in January 2008. This voluntary program encourages the submission and development of information including risk management practices for nanoscale materials.

The NMSP contains a basic and an in-depth program. Under the basic program, participants are invited to voluntarily report available information on the engineered nanoscale materials they manufacture, import, process or use. These data include information on material characterization, hazard, use, potential exposures, and risk management practices. Under the in-depth program, participants will voluntarily develop data, including testing, over a longer time frame. The data and experience generated by the basic program will inform the types of in-depth data that need to be developed.

To date, twenty-eight companies and organizations have submitted data covering more than 122 nanoscale materials. Seven more companies have made commitments to the basic program and three for the in depth program. All non-confidential submissions are posted on the EPA's website as they become available.¹⁵⁴ Despite the level of participation and submissions noted by the EPA, most participating companies have submitted information on only a single nanomaterial. In addition, the extent of the information provided is exceedingly limited even where it is not claimed as confidential business information.¹⁵⁵

Although the EPA has not advanced a comprehensive regulatory framework to deal with engineered nanomaterials, it has applied established frameworks, namely TSCA and FIFRA, to nanomaterials on occasion.

¹⁵³ See www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf.

¹⁵⁴ U.S. Environmental Protection Agency website, "Nanoscale Materials Stewardship Program." Accessed at: www.epa.gov/oppt/nano/stewardship.htm.

¹⁵⁵ Environmental Defense website, Nanotechnology Notes blog post by Richard Denison, August 20, 2008, "Tired of Waiting [With Apologies to Ray Davies]." Accessed at: blogs.edf.org/nanotechnology/2008/08/20/tired-of-waiting-with-apologies-to-ray-davies/.

EPA has established procedures for firms to determine whether an engineered nanomaterial is subject to PMN requirements.¹⁵⁶ The agency has reviewed numerous pre-manufacture notices and has issued 5(e) consent orders on a number of occasions. A sanitized version of one carbon nanotube TSCA 5(e) consent order has also been publicly released.¹⁵⁷ The consent order addresses the manufacture of a multi-walled carbon nanotube (MWCNT) product from an undisclosed company. The order places several requirements on the manufacturer. Specifically, the manufacturer is required to: (1) deliver one gram of the MWCNT to EPA with a copy of the Material Safety Data Sheet for the product; (2) conduct a 90-day inhalation toxicity test in rats; (3) submit certain characterization data within six months after commencing full manufacture; (4) require its workers to wear protective gloves and clothing shown to be impermeable and NIOSH-approved respirators; (5) use the substance only for a particular use; (6) provide the nanomaterial only to entities that agree to the same use restrictions and worker protection conditions.¹⁵⁸ The consent order also provides the manufacturer with an opportunity to submit toxicity testing data under the NMSP as an alternative to the 90-day inhalation toxicity test in rats.¹⁵⁹ In addition, EPA concludes that "the information available to the Agency is insufficient to permit a reasoned evaluation of the human health effects of the PMN substance" and thus "that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health." On October 31, 2008, EPA published a notice in the Federal Register asserting that EPA generally considers carbon nanotubes to be chemical substances distinct from graphite or other allotropes of carbon listed on the TSCA inventory and may therefore be new chemicals under TSCA section 5. As a result, manufacturers or importers of carbon nanotubes must submit a pre-manufacture notice under TSCA section 5.¹⁶⁰

Further, EPA has promulgated significant new use rules (SNURs) for siloxane modified silica nanoparticles and siloxane modified alumina nanoparticles. This action requires persons who intend to manufacture, import, or process either of these chemicals for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity.¹⁶¹

In September 2007, EPA published a federal notice requiring products that emit silver ions or other antimicrobial substances to be registered as pesticides under FIFRA in response to the marketing of a "nanosilver" washing machine that claimed to kill

¹⁵⁶ See <http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf>.

¹⁵⁷ See www.nanolawreport.com/EPA%20Pre-manufacture%20Notice%20Number%20P-08-0177.pdf.

¹⁵⁸ Environmental Defense website, Nanotechnology Notes blog post by Richard Denison, October 9, 2008, "EPA;s Nano Consent Order, Part I: 'Sanitized' Transparency is Still Very Revealing." Accessed at: blogs.edf.org/nanotechnology/2008/10/09/epas-nano-consent-order-sanitized-transparency-is-still-very-revealing/.

¹⁵⁹ Nanotechnology Law Report website, blog post by John C. Moncia Jr. October 15, 2008, "EPA Consent Order for Multi-Walled Carbon Nanotubes." Accessed at: www.nanolawreport.com/2008/10/articles/epa-consent-order-for-multiwalled-carbon-nanotubes/.

¹⁶⁰ See www.epa.gov/fedrgstr/EPA-TOX/2008/October/Day-31/t26026.htm.

¹⁶¹ See www.epa.gov/fedrgstr/EPA-TOX/2008/November/Day-05/t26409.htm.

germs.¹⁶² However, EPA was clear that the notice is not intended to regulate nanotechnology as a whole. Thus, it is likely that the EPA will decide on a case-by-case basis whether it will require products containing nanosilver to be registered under FIFRA.

Analysis of Current Programs for Addressing Engineered Nanomaterials

Reports have noted the general lack of health and safety and exposure data on engineered nanomaterials and the relatively small proportion of national R&D funding dedicated to understanding such materials before being released into the environment. Despite this, there is increasing evidence of exposure, particularly in the workplace, and of potential hazards as new research indicates some materials, such as carbon tubes, may exhibit asbestos-like qualities. Little is known at this point about the end of life fate of such materials. It is clear that some uses – dispersive ones such as in creams or detergents – will result in higher exposures than others, such as carbon tubes in a tennis racquet.

EPA's Nanoscale Materials Stewardship Program is the first coordinated attempt at gaining basic information (but not regulating) engineered nanomaterials. However, it has been criticized for its inability to result in the health and safety data necessary to adequately protect human health and the environment. After asking for information already available to industry during a 6 month first phase, volunteers will not be asked for further information following this first submission for another two year's time. This timeline for data gathering will result in delayed action on properly regulating nanoscale materials which already can be found in many types of products on the market today. Moreover, EPA will not require that all information available for participating nanomaterials be turned over to the agency, or that participants justify why incomplete information is offered in such an instance. Additionally, participants are not required to let EPA know what data is missing on a material enrolled in the program, meaning that the agency will not know the full extent of data available or which data is unknown to industry. Lastly, critics point out that the United Kingdom initiated a similar program in 2007 which has been slow to attract participation.¹⁶³ Finally, there is no requirement or commitment under the program to ensure safety of engineered nanomaterials, a request originally made by an EPA advisory committee.

While the intent of the program is to provide the public with data on the potential production and use hazards of nanomaterials, EPA has yet to release any of the information generated as a result of the program. On the project's launch, EPA estimated it would collect data from 180 firms on 240 materials and that 15 firms would agree to participate in the "in depth" information generation portion of the initiative. As stated above, EPA has yet to see this type of interest from industry. Furthermore, many of these firms are all providing information on the same nanomaterial, and while EPA states that 68 nanomaterials in total are being evaluated by the program, it seems that one firm is

¹⁶² U.S. Environmental Protection Agency website, "Pesticide Registration: Clarification for Ion Generating Equipment." Accessed at: www.epa.gov/oppad001/ion_gen equip.htm.

¹⁶³ Environmental Defense Fund, "EPA's Voluntary Program for Nanomaterials Still Too Little, Too Late," Press release, January 28, 2008. Accessed at: www.edf.org/pressrelease.cfm?contentID=7564.

responsible for most of these materials, which are metal-based, and that a portion of the data is protected from public view as confidential business information.¹⁶⁴ As such, it appears that EPA has not succeeded in attracting volunteers to the program and that the firms that are participating do not represent the scope of nanomaterials currently being used in commerce. A report released in January 2009 indicates that the NMSP has yielded only little information on a small percentage of the engineered nanomaterials in use or development in the United States.¹⁶⁵

Pharmaceuticals

Pharmaceuticals are exclusively regulated under the FFDCFA, administered by the FDA. The FDA is required under the *National Environmental Policy Act* (NEPA) to consider the environmental impacts of approving human drug and biologics and animal drug applications as an integral part of its regulatory process.

FDA regulations specify that environmental assessments (EAs) or environmental impact statements (EISs) must be submitted as part of certain new human drug applications (NDAs); abbreviated applications; applications for marketing approval of a biologic product; supplements to such applications; investigational new drug applications (INDs); and for various other actions. In 1997, the FDA revised these regulations, cutting back the environmental side of the drug review process. As revised, the regulations provide for a number of categorical exclusions that exempt certain applications from submitting an EA or EIS. For example, an EA or EIS is not required where the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion. In addition, an EA or EIS is not required for substances that naturally occur in the environment (i.e. hormones).¹⁶⁶ However, the FDA considered requiring more tests for the possible environmental effects of drugs in 2002 after the USGS released its findings that more than 100 waterways in 30 states contained minute amounts of dozens of antibiotics, hormones, pain relievers, cough suppressants, disinfectants, and other products.¹⁶⁷ Despite this, there is no indication that the FDA has increased its environmental assessments of pharmaceuticals.

FDA regulations also specify that EAs or EISs must be submitted as part of the approval process for new and abbreviated animal drug applications. Much like the regulations pertaining to human drug and biologics applications, this regulation provides for a number of categorical exclusions that exclude classes of actions that individually or

¹⁶⁴ See www.commondreams.org/news2008/0728-10.htm.

¹⁶⁵ See U.S. EPA, "Nanoscale Materials Stewardship Program: Interim Report," (2009). Available at: www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf; and Environmental Defense Fund, "EPAs Voluntary Reporting Program Fails to Deliver Data Needed to Determine Safety of Nanomaterials, Report Shows," (January 13, 2009). Available at: www.edf.org/pressrelease.cfm?contentID=9094.

¹⁶⁶ U.S. Department of Health and Human Services, "Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications," (July 1998).

¹⁶⁷ Andrew C. Revkin, "FDA Considers New Tests for Environmental Effects," *New York Times Online*, March 14, 2002. Accessed at: query.nytimes.com/gst/fullpage.html?res=9B01E4D81339F937A25750C0A9649C8B63&sec=&spon=&pagewanted=1.

cumulatively do not significantly affect the quality of the human environment from the requirement to prepare an EA or EIS. In the case of animal drug applications, these categorical exclusions include applications for: naturally occurring substances; drugs intended for use in non-food animals; anesthetics that are individually administered; non-systemic topical and ophthalmic animal drugs; drugs for minor species; and drugs intended for use under prescription or veterinarian's order for therapeutic use in terrestrial species. Additionally, applications where the action does not increase the use of the drug are also exempt.¹⁶⁸

In addition, the EPA has begun to lead limited policy discussions on these issues. In 2007, the EPA, jointly with the White House Office of National Drug Control Policy (ONDCP) and the Department of Health and Human Services (HHS) released new guidelines for the proper disposal of unused, unneeded, or expired prescription drugs. The guidelines urge Americans to place unused, unneeded or expired prescription drugs in impermeable containers and throw the containers in the trash rather than flushing them down the toilet. It also encourages the return of unused, unneeded or expired prescription drugs to pharmaceutical take-back locations for safe disposal.¹⁶⁹

In 2008, the EPA outlined a four-pronged approach for addressing pharmaceuticals and personal care products (PPCPs) in water. The first prong, strengthening science, consists of several activities, including: the development of analytical methods to reliably detect PPCPs in water, wastewater, and biosolids; the funding of studies to better understand the potential sources and occurrence of pharmaceuticals in wastewater; and the investigation of key questions associated with exposure pathways, health, and aquatic life effects of pharmaceuticals in water. The second prong, improving public understanding, includes the development of a website focusing specifically on PPCPs in water designed to facilitate communication with the public. The third prong, building partnerships and promoting stewardship opportunities, focuses on strengthening collaborative efforts including: participating in the Pharmaceuticals in the Environment workgroup along with ten other federal agencies; supporting and promoting good stewardship efforts (e.g., state, local, regional, and private pharmaceutical collection efforts); and participating in the World Health Organization Task Force on PPCPs in drinking water. The fourth prong, taking regulatory action when appropriate, aims to use existing regulatory tools to minimize the amount of pharmaceuticals entering the waste stream. These efforts to date include: the investigation of pharmaceutical disposal practices of hospitals, long-term care facilities, hospices, and veterinary hospitals to identify best practices to minimize pharmaceutical discharges to water and the proposed evaluation of 104 contaminants to determine if national drinking water regulations are needed to protect public health. None of these initiatives focus on the redesign of pharmaceuticals so that they break down more easily in the environment or involve less potentially toxic chemistries.

¹⁶⁸ See The Code of Federal Regulations, *Food and Drugs*, tit. 21. Accessed at: www.cfsan.fda.gov/~lrd/cfr25-33.html.

¹⁶⁹ Office of National Drug Control Policy website, "Federal Government Issues New Guidelines for Proper Disposal of Prescription Drugs: What Every American Can Do to Prevent the Misuse of Prescription Drugs," Press release, February 20, 2007. Accessed at: www.whitehousedrugpolicy.gov/news/press07/022007.html.

Three pieces of federal legislation introduced in the current Congressional session seek to further develop and encourage the proper disposal of unused pharmaceuticals. The Safe Drug Disposal Act of 2009 (HR 1191) provides for the disposal of controlled substances by ultimate users and care takers through state take-back disposal programs and prohibits recommendations on drug labels for disposal by flushing and the Secure and Responsible Drug Disposal Act of 2009 (HR 1359) provides for take-back disposal of controlled substances in certain instances. In addition, the Drug Free Water Act of 2009 (HR 276) directs the EPA Administrator to convene a task force to develop recommendations on the proper disposal of unused pharmaceuticals.

Analysis of Current Policy Efforts to Address Pharmaceuticals in the Environment

Although science was not yet capable of detecting them, pharmaceuticals probably have been in the environment since their use began. Science caught up in the 1970s when the first traces of pharmaceuticals began to be found in the US and throughout Europe.¹⁷⁰ This fact, that pharmaceuticals are finding their way into the environment, and perhaps ultimately back to the human body, may be the most obvious critique of the way they have been regulated in the past. As previously noted, the US Geological Service found measurable amounts of pharmaceuticals and personal care products in 139 streams and rivers across 30 states.¹⁷¹ Findings such as these are causing some to ask the federal government to assign oversight of pharmaceuticals and their breakdown products to a specific agency.¹⁷² Moreover, because there are no standard setting limits on the amounts of pharmaceutical and personal care product ingredients in drinking water,¹⁷³ the public may be exposed to these now recycled contaminants with unknown consequences.

Pharmaceuticals are of particular concern because of their unique characteristics: they are being made in quantities comparable to those found in industry; they are designed to be biologically active and resist the very chemical processes that would degrade them in the environment; they are capable of inducing effects in varied species; they are capable of biological effects including chronic toxicity at very small doses; and they are being found at these small amounts in the environment around the world.^{174,175}

¹⁷⁰ Sharon Batt, "Full Circle: Drugs, the Environment and Our Health," Women and Health Protection Website. Available at: www.whtp-apsf.ca/en/documents/fullCircle.html.

¹⁷¹ Dana W. Koplan, Edward T. Furlong, Michael T. Meyer, E. Michael Thurman, Stephen D. Zaugg, Larry B. Barber, and Herbert T. Buxton, "Pharmaceuticals, Hormones and Other Organic Wastewater Contaminants in U.S. Streams 1999-2000: A National Reconnaissance." *Environmental Science and Technology*, 36 no. 6 (2002), 1202-1211.

¹⁷² Sabine Vollmer, "Looking at Drugs in Water." *The News and Observer Online*, November 12, 2008. Accessed at: www.newsobserver.com/business/story/1291129.html.

¹⁷³ The Groundwater Foundation website, "Pharmaceuticals and Personal Care Products: An Emerging Issue." Accessed at: www.groundwater.org/gi/docs_pack/fa13.pdf.

¹⁷⁴ O.V. Enick, and M.M. Moore, "Assessing the Assessments: Pharmaceuticals in the Environment," *Environmental Impact Assessment Review*, 27 (2007), 707-729.

¹⁷⁵ Sharon Batt, "Full Circle: Drugs, the Environment and Our Health," Women and Health Protection Website. Accessed at: www.whtp-apsf.ca/en/documents/fullCircle.html.

Pharmaceuticals and their metabolized compounds have longer half-lives than other regulated chemicals and take longer to break down in the environment. Because of this, and because newly added contaminants continually enter streams and rivers, they have the same effects on organisms that would be expected from persistent substances.¹⁷⁶ Once in the water these compounds combine into complex mixtures of substances, which is an important consideration for the health aquatic organisms constantly exposed to these pollutants.¹⁷⁷ Veterinary pharmaceuticals also contribute to the environmental load of pharmacologically active substances. Livestock are dosed with medicines or growth stimulants which are then excreted on the fields and pastures in which the animals live.¹⁷⁸ Rain water then washes this waste and its contaminants into surrounding watersheds. Evidence is beginning to mount about the potential for these pollutants to damage aquatic ecosystems. The water of Maine's Penobscott River was found to contain estrogen-like compounds which officials fear may have substantial consequences for the long-term health of reproductive systems in people and wildlife.¹⁷⁹

The regulatory breakdown in this instance comes from FDA's oversight of pharmaceuticals with more traditional toxicity endpoints in mind, as opposed to important newly emerging endpoints, such as the behavior of pharmaceuticals once they have been introduced into ecosystems.¹⁸⁰ Additionally, barring extraordinary circumstances, FDA categorically exempts the need for Environmental Impact Assessment for pharmaceutical used in animals which are not intended for food or pharmaceuticals for land animals¹⁸¹ because they are seen to have an insignificant effect on "the quality of the human environment."¹⁸² Perhaps in acknowledgement of the shortcomings of current FDA protocols, the US has begun an interagency effort to curb the amount of pharmaceuticals in the environment: FDA, EPA, US Geological Survey (USGS), Centers for Disease Control and Prevention, and National Oceanic and Atmospheric Administration (NOAA) have assembled a task-force focused on this issue.¹⁸³

¹⁷⁶ Christian G. Daughton, "Environmental Stewardship and Drugs as Pollutants," *The Lancet*, 360 (October 5, 2002), 1035.

¹⁷⁷ Christian G. Daughton, and Thomas A. Ternes, "Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?" *Environmental Health Perspectives Supplements*, 107 no. s6 (December 1999).

¹⁷⁸ O.V. Enick, and M.M. Moore, "Assessing the Assessments: Pharmaceuticals in the Environment," *Environmental Impact Assessment Review*, 27 (2007), 707-729.

¹⁷⁹ Testimony of David P. Littell, Commissioner, Maine Dept. of Environmental Protection to the Subcommittee on Water and the Environment of the House Committee on Transportation and Infrastructure, (September 18, 2008).

¹⁸⁰ Christian Daughton, and Thomas Ternes, "Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?" *Environmental Health Perspectives*, 10 no. s6 (December 1999).

¹⁸¹ Charles Erikson, "Environmental Assessment for Veterinary Pharmaceuticals," (Presented by Charles Erikson, U.S. Food and Drug Administration Center for Veterinary Medicine) (Chicago: U.S.FDA, August 20, 2007). Accessed at: es.epa.gov/ncer/publications/workshop/pdf/eirkson_chicago82007.pdf.

¹⁸² Food and Drug Administration website, "Office of Pharmaceutical Science: Environmental Impact Review at CDER." Accessed at: www.fda.gov/cder/OPS/environment.htm.

¹⁸³ GlaxoSmithKline website, "Global Public Policy Issues: Pharmaceuticals in the Environment." Accessed at: www.gsk.com/policies/GSK-on-pharmaceuticals-in-environment.pdf.

Further, while some programs have been established to address take back at end of life (which will not address excreted pharmaceuticals); reductions in use of some pharmaceuticals (particularly veterinary ones and some antibiotics); monitoring in the environment; and risk assessment, none to date examines redesign of pharmaceutical chemistries. The American Chemical Society's Pharmaceutical Green Chemistry Roundtable is addressing safer production of pharmaceuticals and the end of life chemistries of such substances. Preventing these substances from entering the environment by discouraging the misuse, overuse, and improper disposal of pharmaceuticals may be the most immediate as well as cost effective approach to resolving the presence of pharmaceuticals in the environment. However, a more long term strategy is also needed, particularly the design of pharmaceuticals that are not readily excreted, or that break down into benign substances in the environment.¹⁸⁴ Although these solutions may be difficult or even impossible to achieve, it is important to keep these solutions in mind and allow investigators to explore them.¹⁸⁵ Further, developing more advanced waste water filtration systems could serve as an important safety net to help to limit the introduction of pharmaceuticals (and other contaminants) to the environment.¹⁸⁶

3.4 Critical Lessons Learned – Findings Based on U.S. Analysis

Our research on policies and programs, analysis of these programs, and discussions with key stakeholders in the Great Lakes have identified several important gaps in federal and regional policy in the Great Lakes that have inhibited progress towards the toxics reduction goals of the *Great Lakes Water Quality Agreement* and the International Joint Commission. Some of the limits are a result of gaps in national policy structures; others in Great Lakes regional administrative and policy structures; and still others in a failure to comprehensively address chemicals management issues anywhere in the world to date. *Most importantly, we have found that until governments move upstream from identifying, assessing, managing, and removing chemicals once they are in the environment, wildlife, and human populations, to developing a holistic Great Lakes approach that ensures control of such chemicals before they reach the Great Lakes Basin, efforts to address chemicals of emerging concern will not reach their full potential.*

Clearly, there is a role for end of pipe systems, such as comprehensive wastewater treatment systems, to serve as a safety net to control such substances from entering the Basin. This is true in the short to medium term as characterizing, prioritizing, and taking preventive action on chemicals of concern will take some time given the size of the universe of chemicals considered in this report and resource limitations; and the fact that some substances have critical health value or uses in production and may not be readily substitutable at this point in time. Nonetheless, it is important that emissions control

¹⁸⁴ Sharon Batt, "Full Circle: Drugs, the Environment and Our Health," Women and Health Protection Website. Accessed at: www.whp-apsf.ca/en/documents/fullCircle.html.

¹⁸⁵ Sushil K. Khetan and Terrance J. Collins, "Human Pharmaceuticals in the Aquatic Environment: A Challenge to Green Chemistry," *Chemical Reviews*, 107 (2007) 2319-2364.

¹⁸⁶ Christian G. Daughton, "Environmental Stewardship and Drugs as Pollutants," *The Lancet*, 360 (October 5, 2002), 1035.

systems can only limit the introduction of contaminants into the Basin (as such systems can fail or be overwhelmed); do not reduce the inherent hazards associated with such substances through their lifecycles; and exclusive attention to end of pipe treatment may reduce attention to a broader, more comprehensive and upstream approach to prevention of chemicals of emerging concern.

Further, there is a need to continue efforts to restore ecosystems that have been damaged from previous impacts of chemical contamination. For example, several stakeholders have identified contaminated sediments as a critical chemical priority in the Basin, given the ability for chemicals to be reintroduced into ecosystems from sediment disturbances. While such efforts need to continue, these should not deter efforts to prevent new contaminants from entering the Basin that may ultimately contaminate sediments and be in need of similar clean-ups. Further, some of the techniques for redesigning chemicals and products to eliminate hazards, such as green chemistry, may prove useful in clean-up activities.

In this section, we identify several general lessons which relate to federal and regional policy reforms needed to more effectively ensure rapid identification, assessment/prioritization, and prevention of chemicals of emerging concern. We also identify some opportunities for improving the current approaches to chemicals management for chemicals of emerging concern in the Basin. Finally, we provide an overview of basic tenets of a comprehensive and preventive approach to chemicals of emerging concern.

The Nature of Chemicals of Emerging Concern: the Need for New Approaches

As noted in the introduction, concerns about chemicals are shifting from controlling releases emitted from industrial processes to controlling releases from products throughout their lifecycles. This shift has profound implications for chemical assessment, management, and monitoring. The current framework for assessment, managing, and monitoring has been slow to revise its approach in addressing releases from products.

In the past, many of the chemicals entering the Great Lakes were the result of uncontrolled industrial processes. Mercury from chloroalkali plants, dioxins/furans from pulp and paper mills and incinerators, and PAHs from steel mills are a few examples. Now many of the chemicals, and particularly many of the chemicals of emerging concern, are products. Synthetic musks are used as perfumes, NPEs are still used in some detergents (though this is changing), bisphenol A is found in certain plastics and can linings. In addition, prescription drugs and veterinary medicines are being excreted and disposed of in a way that takes them directly into water supplies. Rather than large volumes of hazardous chemicals generated by a few large industries, today we find small amounts of toxic chemicals released from a wide range of products ubiquitously distributed about our homes and workplaces. Current laws were not designed to address these kinds of exposures. Many of the current gaps in our understanding chemicals of emerging concern also relate to this process-product shift.

While the Great Lakes can always benefit from improved controls on industrial processes, media specific regulations to prevent emissions within a specific area, improved water treatment systems, and disposal restrictions on products containing chemicals of emerging concern, for most chemicals of emerging concern *most of the significant new strides in reducing their emissions into the Great Lakes Basin will be made through greater controls on products, the promotion of safer alternatives and a broader vision of pollution prevention and clean technologies (such as clean energy)*. Nonetheless, a comprehensive approach to prevention of chemicals of emerging concern will include processes for rapid characterization of hazards and exposure prevention and controls (for example, the workplace or wastewater treatments are important elements).

In this context, a strategy for chemicals of emerging concern based on monitoring and assessment before action will be inadequate to prevent their emission into the Great Lakes Basin. By the time these chemicals are in water or in people's bodies, it is too late. They may have already done damage to ecosystems or human health. Monitoring often takes place years after initial emission due to the costs and challenges of scientific methods for detecting certain contaminants. In addition, monitoring only addresses a small percentage of chemicals in the environment. Monitoring plays an important role in measuring progress in reductions, but should not be the starting point for determining whether a substance should be subject to regulatory attention. Further, chemical by chemical quantitative risk assessment processes can be slow and resource intensive and delay management actions while data are being collected or debated, which can lead to costly clean up efforts later in time.

Given that these chemicals of emerging concern tend to be dispersive (from multiple sources and generally uncontrolled and unregulated) and non-point in nature (except when coming out of a waste water treatment plant), *the most effective way to adequately control such sources is to redesign production systems, chemicals, and products in the first place so as to minimize environmental releases throughout a product's lifecycle while ensuring that chemicals are the safest available to meet a particular need and rapidly biodegrade in environmental media*. This approach to primary prevention has been advocated since the 1980s in addressing emissions from industrial facilities – toxics use reduction, pollution prevention, and cleaner production.^{187 188 189}

It is now an opportune time to adopt this same approach focused on finding solutions and safer substitutes rather than managing risks of individual substances to product based emissions. The field of green chemistry, "The design and use of chemical products and processes that reduce or eliminate substances hazardous to human health or the environment," through the application of twelve design principles offers a proactive approach to addressing the dispersive nature of chemicals of emerging concern.¹⁹⁰ Green

¹⁸⁷ Ken Geiser, *Materials Matter*, (Cambridge: MIT Press, 2001).

¹⁸⁸ Tim Jackson, *Clean Production Strategies*, (Florida: CRC Press, 1993).

¹⁸⁹ U.S. Office of Technology Assessment, *Serious Reduction of Hazardous Waste: For Pollution Prevention and Industrial Efficiency*, (1986).

¹⁹⁰ Paul Anastas and John Warner, *Green Chemistry Theory and Practice*, (New York: Oxford University Press, 1998).

chemistry focuses on eliminating the intrinsic hazards of substances rather than relying on costly, often ineffectual emissions control systems that reduce risks but do not eliminate them. Substitution is “the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organizational measures.”¹⁹¹ In this respect, substitutes for chemicals of emerging concern need not only be other chemicals but can be changes in processes or product design, for example replacing pesticides of concern with integrated pest management techniques where feasible. It is important to think holistically about substitutes so that broader, systems level alternatives, can be examined.

A second feature of chemicals of emerging concern (and most chemicals in general) is that they span jurisdictional boundaries, boundaries which more often than not impede control or preventive actions. For the general public and local level officials addressing the impacts of chemicals of emerging concern, for example, in surface waters, there is no difference between a pesticide, a pharmaceutical or an industrial chemical – all are chemicals. Scientifically there is little difference between these groups other than molecular structures.

Yet, we have created jurisdictional boundaries that prohibit broad regional or national approaches. Chemicals are assessed, regulated, and managed in completely different manners depending on their end use. Entirely separate legislation, regulations and departments govern pesticides, consumer products, drugs, cosmetics, and industrial chemicals.

This agency and law based focus has been fragmented and reactive in nature, often responding to well-established problems by managing or reducing exposure to individual harmful chemicals rather than stimulating the development of safer and cleaner chemicals, production systems, and products. During the 1970s, the U.S. Congress enacted a suite of broad regulatory statutes to control chemical releases to the air, water, and land through facility release permits. These media-focused waste and pollution control regulations, plus consumer product safety, pesticide, and occupational health laws, have had some successes in limiting exposures to toxic substances from manufacturing, use, and disposal processes, but they do not address in any integrated manner the entire lifecycle of chemicals from production through disposal.

Further, these laws often regulate chemicals in products based on their uses or exposure pathways (e.g. the workplace) and not their intrinsic hazards. For example, in the case of addressing lead in children’s lunchboxes, there was no clear jurisdictional authority; the Consumer Product Safety Commission was in charge of the outside of the lunchbox and the Food and Drug Administration in charge of the inside of the lunchbox as it touched

¹⁹¹ See Lothar Lissner and Joaquim Lohse, *Never Change a Running Process? Key Factors for Substitution Decisions in Complex Products and Production Processes*, (Presentation at UMASS Lowell Workshop on Methodologies for Substitution and Alternatives Assessment, December 2004). Accessed at: www.chemicalspolicy.org/downloads/Lissner_Lohse.ppt.

food. This uncoordinated and disjointed approach can also lead to important gaps in oversight of chemicals.

Despite attempts by some federal and state governments to address chemicals of emerging concern, discussions have occurred through current media-specific frameworks, for example, contaminants in surface waters, which can lead to end of the pipe approaches. Current media-specific frameworks focus primarily on reducing *industrial* emissions and wastes and not those that occur from disperse products.

As such, any Great Lakes policy for chemicals of emerging concern should eschew current disjointed approaches to chemicals of emerging concern for a legal framework that broadly addresses such chemicals in a holistic, preventive, and Basin-wide manner. It should address chemicals of emerging concern not as a water problem but a problem of chemical, product, and process design. A chemical of emerging concern is a chemical of emerging concern regardless of its source. The important challenge is to develop a systems approach that focuses as noted above on prevention and safer alternatives.

Challenges to a More Integrated Approach to Addressing Chemicals of Emerging Concern in the Great Lakes

Below we present a number of current challenges in policy with regards to chemicals of emerging concern that limit their effectiveness in practice. Most of these relate to national or regional policies but some relate to Great Lakes institutional structures that have limited actions on these chemicals to date.

1. Policies to date have mainly focused on single chemicals, reacting to individual problems rather than advancing a proactive framework.

As noted, there is no comprehensive Great Lakes, national, or state structure for addressing chemicals of emerging concern that spans chemical types at this time. When addressed, they are being addressed on only a chemical category by chemical category basis. Under current systems, they are also only addressed on a chemical by chemical basis and only after they are thoroughly identified in the environment or after significant, burdensome assessments have been undertaken. During the time such assessments occur, there is an implicit assumption that exposure with ecosystem and human health impacts are not occurring.

Industrial chemicals policies in both the U.S. and Canada were developed with the implicit assumption that there would be few existing chemicals of high concern that required regulatory intervention. The artificial distinction between “new” and “existing” chemicals has created a system whereby chemicals on the market prior to 1980 (representing the vast majority of industrial chemicals by volume) are assumed safe until demonstrated harmful. New chemicals undergo fairly extensive government review in both countries, though certain limits remain. Regulatory or voluntary preventive action on existing industrial chemicals under both the Canadian and U.S. regimes generally only occurs on a chemical by chemical basis and in response to extensive knowledge about

toxicity or presence in the environment. And this has only occurred for a small number of industrial chemicals. Further, the chemical by chemical focus, without adequate attention to the alternatives that might be used (and facilitation of their adoption) can lead to unintended consequences as in the case of substitution of PBDEs with other brominated flame retardants of concern. As such, a comprehensive approach is critical so that stakeholders know enough about the toxicity and use/exposure patterns of alternatives in order to not jump from one problem substance to another.

While pesticides undergo much more rigorous upfront testing than industrial chemicals, risk management actions are also undertaken on a substance by substance basis after significant risk assessment activities have been undertaken. An example of this challenge is the case of Atrazine where U.S. action has been slow despite European restrictions moving forward.

There is no comprehensive, new framework for addressing the health and environmental risks of engineered nanomaterials. Despite their very unique characteristics, current regulatory structures are being used and may not be adequate. There is currently no regulatory oversight whatsoever for environmental or health impacts of pharmaceuticals. Voluntary initiatives are only beginning to address the potential problems caused by such materials.

In contrast to federal government activities, regional and state/provincial policies have attempted to take a broader, multi-chemical approach (still mostly within the chemical type jurisdictional boundaries). For example the *Great Lakes Water Quality Agreement* calls for the virtual elimination of all persistent toxic substances in the Basin based on these inherent properties. The International Joint Commission called for a broad phase out of industrial organochlorine compounds based on the assumption that a large percentage of these or their byproducts exhibited persistence and toxicity. The Bi-national Toxics Strategy calls for the parties to “*adopt policies and regulatory and non-regulatory measures to identify, and minimize exposure to, toxic chemicals by replacing them with less toxic substitutes and ultimately phasing out the chemicals that pose unreasonable and otherwise unmanageable risk to human health and the environment and those that are toxic, persistent and bioaccumulative and whose use cannot be adequately controlled.*” Despite visionary statements, these initiatives have been slow, with limited resources, and focused primarily on management and clean up of individual substances.

Given the local impacts of most chemicals, several Canadian provinces and localities have issued ordinances banning cosmetic use of pesticides, given the lack of necessity for such uses and the availability of safer alternatives (including organic gardening). Several Great Lakes states and localities have issued environmentally preferable purchasing ordinances (one restricting PBT chemicals) and at least two states are examining chemicals policy overhauls to address prioritization of safer alternatives for a broad range of substances.

The limitations of chemical-by-chemical identification, assessment, and management for a broad range of chemicals of emerging concern necessitates a new solutions-based approach to chemicals of emerging concern focused on rapidly identifying the inherent hazards of substances, prioritizing those hazards of greatest concern for substitution, and advancing the design of inherently safer chemistries (as noted above). For example, under the European Union's *Registration, Evaluation and Authorization of Chemicals* (REACH) legislation, all chemicals that are very persistent and very bioaccumulative, persistent bioaccumulative and toxic, carcinogenic, mutagenic, and reproductive toxicants are assumed on the basis of their inherent properties to be Substances of Very High Concern. For these substances, there is an implicit assumption of their hazards to the health and environment and that they should only be used if there are no alternatives, if there is an economic or social necessity, or in some cases if there are data to demonstrate that they can be used safely, with the burden on the manufacturer.

Such a new approach needs to change the framework of thinking about chemicals of emerging concern from monitoring, end of pipe management, and studying effects to prioritization and alternatives assessment. Some prioritization can occur on the basis of chemical classes (such as brominated flame retardants) that allow action beyond single chemicals. Monitoring and risk management actions will always be necessary; however a first step when concerns are raised should be to examine whether alternatives exist that can achieve the chemical's functionality with significantly lower hazards to ecosystems and humans.

States and the EPA have significant successful experience with pollution prevention and design for environment partnership programs. These have tended to be under-funded and lacking a regulatory foundation to ensure their effectiveness. To be successful drivers of innovation, such initiatives need both "willingness" – the regulatory or market push – and "capacity" – knowledge, resources, and support – for the implementation of safer materials.¹⁹²

The Lowell Center for Sustainable Production has developed an Alternatives Assessment Framework that provides a systematic approach to alternatives assessment that focuses on goals, processes, and metrics.¹⁹³ Authorities in some states have also developed alternatives assessment methods and many public and private organizations have developed tools to support decision-making about safer alternatives.

2. Current policies have not adequately allowed the rapid identification, prioritization, and assessment or transition to safer alternatives for chemicals of emerging concern.

¹⁹² See Nicholas Ashford, "An Innovation-Based Strategy for a Sustainable Environment," In *Innovation-Oriented Environmental Regulation: Theoretical Approach and Empirical Analysis*, (Potsdam, Germany: European Commission Joint Research Centre, 1999).

¹⁹³ M. Rossi, J. Tickner, and K. Geiser, "Alternatives Assessment Framework, version 1.0," (Lowell Center for Sustainable Production, 2006). Accessed at: www.chemicalspolicy.org/downloads/FinalAltsAssess06_000.pdf.

Many of the early federal environmental protection statutes contained bold and far-reaching chemicals management goals and policies, such as the *Clean Water Act's* goal of clean water bodies by 1986. *The Great Lakes Water Quality Agreement* and subsequent IJC statements have issued bold goals of virtual elimination, zero discharge, sunsetting of industrial chlorine production, etc. However, in practice, many of these bold goals have never been attained. A recent report on chemicals policy in California has referred to three broad failures of chemicals regulations that this report has identified: the Data Gap, the Safety Gap, and the Technology Gap.¹⁹⁴ These gaps demonstrate that small changes in the current systems for assessing and managing chemicals of concern will be inadequate for this big and complex problem. Small improvements can serve important short term purposes but should not occur at the expense of developing new frameworks and approaches.

The Data Gap

During the last half century, thousands of chemical substances have been developed and put into commerce, often with little information about or consideration of their environmental or health implications. While we know a lot about some chemicals, for a large percentage of chemical substances, there is still little information on their health implications, and more importantly their exposures, and how they are used throughout supply chains (and the economy). For example, we have little information on what chemicals are used in what products, how the chemicals can lead to consumer exposures, and what potential alternatives might exist.

The limits of toxicological, use, and end of life data for potential chemicals of concern have been outlined in this report. For industrial chemicals the data gaps are still very large, particularly for lower production volume substances. Even when voluntary initiatives have been undertaken to gather toxicity data and make hazard or risk determinations, such as the HPV and ChAMP programs for high and mid-production volume industrial chemicals, there have been some limitations in the quality of the data and extent of compliance with such initiatives. Additionally, confidential business information concerns have limited sharing of important information on chemical toxicity and uses with downstream industrial users of chemicals, regulators (for example state agencies cannot obtain confidential information provided under TSCA), and the public. Many large retailers are now requiring full disclosure of product ingredients from suppliers to assess product hazards.

For pesticides, the toxicological database is significantly more complete; however, despite EPA efforts, data are lacking on health effects, uses, and environmental fate for many substances and inert ingredients. For pharmaceuticals, while extensive data on human toxicity and efficacy have been developed, very little about environmental fate is known. For engineered nanomaterials, there is little toxicological data being developed to date.

¹⁹⁴ M. Wilson, et al., *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation*, (California: California Policy Research Center, University of California, 2006). Accessed at: coeh.berkeley.edu/FINALgreenchemistryrpt.pdf.

New information gaps are becoming obvious for many of the chemicals of emerging concern reaching the Great Lakes through product based exposures. For many chemicals, and especially chemicals of emerging concern, we have limited knowledge about: (1) amount of chemicals used and contained in various products; (2) amount of chemical released from a product over its life cycle; and (3) how to regulate and monitor the ever changing formulations of products. At this point in time there is no way for chemical users or regulators to know the chemical constituents of most products, let alone their toxicological hazards. As a critical first step, databases of uses of chemicals of emerging concern in production of products should be created to ensure the proper management of such chemicals.

Voluntary initiatives to gather data on industrial chemicals such as ChAMP and HPV have important roles but also significant gaps as previously noted. In addition to being slow and incomplete, they have not been adequately linked to voluntary or regulatory preventive actions.

Without adequate health and environmental effects data, it is difficult to assess the risks of chemicals, set science-informed priorities, or feel confident that chemical substitutes are safer than chemicals of concern. Without data on exposures, uses, and supply chain flows, it is impossible to effectively manage chemicals or understand their environmental fates. Unfortunately, under the current system while data are collected, the lack of evidence of toxicity is often misinterpreted as evidence of safety—allowing exposure to continue—and the status quo is maintained. Collecting more data—on chemical toxicity, human body burdens, exposures, and uses—is critical to understanding how chemicals can affect human and ecosystem health as well as to promote effective chemicals management; however, study alone will not prevent harm.

The Safety Gap

Public opinion surveys show that most people believe that industrial chemicals are regulated like drugs where evidence of safety and efficacy is required before a substance can be used. While evidence of safety and testing are required for pharmaceuticals and pesticides, the vast majority of industrial chemicals were assumed safe under current laws. Additionally, pharmaceutical laws, and to some degree pesticide laws, do not guarantee end of life environmental protections.

Even when basic toxicity information is compiled, it is fed into regulatory systems in which the burden rests on government agencies to conclusively demonstrate the risks that each individual substance poses to health or ecosystems (in addition to cost-benefit balancing, which is challenging due to the immediate costs of restrictions versus the more distant benefits of action) before preventive action can be taken. Demonstrating unreasonable risks with current burdens requires significant toxicological and exposure data. Additionally, unreasonable risk debates focus attention and resources on whether exposures exceed some politically defined “safe” level. This frequently leads to time consuming debates over mechanisms of action of particular substances, delaying preventive actions. As previously noted, in addition to the lack of information being

misinterpreted under current policies as evidence of no problem, uncertainties in the risk assessment process lead to a default of no action until those data gaps are filled, thus continuing exposures.

While the safety gap is evident in the areas of industrial chemicals and pesticides, it is even more profound in the area of nanomaterials and pharmaceuticals, where a comprehensive regulatory framework to address the unique properties of the former one does not exist yet and the framework for the latter rarely addresses end of life exposures.

Our research has identified numerous voluntary and regulatory policy options that could be undertaken that would facilitate decision-making and protective action on chemicals of emerging concern without having to undertake resource intensive risk assessments, including:

- Green procurement programs
- Mandatory substitution planning for chemicals of concern
- Agency initiated alternatives assessment processes linked to action plans
- Voluntary supply chain dialogs and technical assistance interventions to firms for chemicals of concern
- Creation of product registries and databases of safer alternatives
- Chemical restrictions for groups/types of substances and/or particular uses
- Creation of rapid hazard screening databases prioritizing uses of highest concern.

The Technology Gap

There is little incentive under the current system to use safer chemicals if the more dangerous ones are not regulated. While the EPA has undertaken significant steps in working with industry to design safer chemicals and products through its Design for Environment and Green Chemistry efforts, these programs are woefully under-funded and marginalized. For example, the EPA has provided tools to industry to more effectively integrate health and environmental concerns at the design stage of chemicals, but few chemicals that have come through the agency's new chemicals review process have gone on to reach market prominence. Indeed, even less funding is available for the research and development of safer chemicals and products at the state or federal level. Similarly with pesticides, little research and technical support focuses on alternative pest control methods such as organic or integrated pest management. And only a small percentage of federal R&D funding on nanomaterials is focused on health and safety or how such materials can serve critical pollution prevention purposes. Only when governments provide the needed regulatory and market drivers can the development of safer chemicals become the norm rather than the exception. Some of these drivers include: tax incentives, technical support, supply chain dialogs, and information.

3. There is a lack of a clear bi-national strategy or any strategy at all for the Great Lakes Basin with regards to chemicals of emerging concern or achievement of the goals of the Great Lakes Water Quality Agreement.

Our interviews with key organizations and actors in the Great Lakes identified a lack of priority concern for chemicals and a lack of coordination between states, provinces, and federal governments that inhibits broad action. For example, for major Great Lakes coordinating bodies such as the Council of Great Lakes Governors and the Great Lakes Commission, there are no particular chemicals programs. While chemicals had higher priority in the 1970s-1990s, when significant advances were made in reducing chemicals of concern in the Basin, that priority attention has shifted to other, albeit important, areas such as watershed protection, etc. Some regional programs, such as the Lake Superior Bi-national Zero Discharge Demonstration Program, provide good examples of prevention-oriented regional collaboration that should be expanded.

Great Lakes Basin wide programs, including those under the EPA Great Lakes Program Office, are primarily voluntary in nature with inadequate resources and support to ensure implementation in practice. While there is some Basin-wide coordination on climate change, there are hardly any coordinated initiatives among Great Lakes states and provinces on chemicals of emerging concern. As previously noted, there is an important need for more coordinated governance structure in Great Lakes for chemicals of emerging concern.¹⁹⁵ One option may be for several states and provinces to indicate their interest in working on toxics reduction and green chemistry to the Great Lakes Commission, which could then initiate a Basin-wide initiative in this area.

3.5 Elements of an Ideal Approach to Chemicals of Emerging Concern

It is useful for the U.S. and Canada to move from the current approach to addressing chemicals of concern through a primarily reactive approach (control and clean up) for addressing such chemicals to an “aspirational” approach, one that seeks to limit emissions of chemicals of emerging concern into the Basin through a comprehensive approach. The Lowell Center for Sustainable Production has undertaken numerous research and stakeholder engagement processes to identify key elements of a comprehensive chemicals management approach including:

Establishing Visionary Goals: The *Great Lakes Water Quality Agreement* goal of virtual elimination of persistent toxic substances represents such a goal. Further, the *World Summit on Sustainable Development*, 2002 stated that countries. “Renew the commitment...aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment...which says that threats posed by toxic chemicals should be eliminated within one generation.”¹⁹⁶

¹⁹⁵ The lack of coordination for activities in the Great Lakes Basin has also been identified as a problem for Great Lakes environmental restoration efforts by the U.S. Government Accountability Office. *See* Great Lakes: Organizational Leadership and Restoration Goals Need to be Better Defined for Monitoring Restoration Progress, 2004, GAO-04-1024; Great Lakes: An Overall Strategy and Indicators for Measuring Progress are Needed to Better Achieve Restoration Goals, 2003, GAO-03-515.

¹⁹⁶ See: www.un.org/jsummit/html/documents/summit_docs.html

Taking an integrated, broad approach to chemicals management: Policies should take a comprehensive and integrated approach to all chemicals and chemical classes (not a chemical by chemical or product by product, media specific approach). They should focus data collection and risk management efforts on a wide range of substances. They should allow Great Lakes wide, coordinated actions on a broad spectrum of chemicals of emerging concern.

Focusing on adequate information to make informed decisions: Policies should ensure adequate data collection and dissemination on chemical properties, use, exposure, and movement through commerce and the environment of a wide range of substances that allow the rapid identification of chemicals of potential concern and rapid assessment and action, rather than relying on time consuming, resource intensive chemical by chemical assessments.

A focus on safer alternatives: Policies should establish processes for replacing chemicals of potential concern with safer alternatives (including non-chemical alternatives) and establish incentives, approaches, and mechanisms to facilitate the transition to safer, greener production systems and products. For example, the movement to an integrated pest management based system for pest control would require a shift to focusing on systems and the root cause of pest infestations (such as poor soil health and pest resistance, inadequate building conditions and poor sanitation control). The emphasis in a non-chemical pest management system is on eliminating the conditions that promote pest infestations and creating the conditions that naturally deter pests. This win-win strategy achieves both the elimination of pesticide use and the long-term sustainable suppression of pest pressures.

They should also ensure a safety net is in place to prevent or minimize chemical exposures and end of life management for all substances, particularly those that cannot be currently substituted.

In particular, the Lowell Center has identified six “modules” or components of broad chemicals reform that should be considered in developing national or regional policy frameworks. Within each of these modules, numerous options designed to fulfill that module are outlined:

1. Testing and Information Generation — options to ensure generation of adequate data on chemical toxicity, use, and exposure.
2. Information in the Production Supply Chain — options to ensure that data are shared throughout supply chains, including the public, to enhance the abilities of chemicals users to make informed decisions leading towards safer chemicals and products.
3. Screening, Assessment, Prioritization and Decision-Making — options to enhance the ability of agencies to more rapidly screen, prioritize, and make decisions on a broader range of substances.
4. Chemical Substitution and Use Reduction—options to enhance toxic chemicals use reduction and substitution of problems by safer alternatives.

5. Innovation and Green Chemistry — options to encourage research, development, and adoption of safer chemicals and products.
6. Program Administration and Implementation — options and considerations for effective implementation of chemicals policies. Such administration and implementation could occur at a national level (for example chemical testing); state level (chemical use and technical support to manufacturers); and a regional level (prioritization and action plans for reductions).

PART 4 – General Observations and A Proposed Roadmap to Address Chemicals of Emerging Concern in the Great Lakes Basin

Our analysis has outlined a series of gaps in current Regional, Canadian, and U.S. policies and programs. These gaps inhibit the ability of governments to rapidly identify, characterize, and proactively manage, for example by preventing the introduction of, chemicals of emerging concern to the Great Lakes Basin. Further, these gaps concern the limits in current policies as well as the lack of an overarching proactive, comprehensive framework for addressing such chemicals. Some of the key gaps we have identified include:

1. The lack of an integrated system for prevention of chemicals of emerging concern that spans chemical types, sources (whether industrial sources or product based), and jurisdictional boundaries. Despite the dispersive and product-based nature of such chemicals, current policies do not sufficiently address multiple chemicals or types and proactive management, including informed substitution through redesigning products or processes, to eliminate hazards in the first place.
2. A slow and cumbersome chemical by chemical testing and risk assessment approach to chemicals of emerging concern. Current approaches to chemical testing, assessment, and management have tended to focus on assessing the risks posed by single chemicals within chemical types and classes. Such processes are costly and inevitably decisions are not made until uncertainties are reduced, which can take years. The availability of proactive management options, particularly preventive options that include safer chemical or non-chemical alternatives, is rarely considered in decision-making processes. Finally, chemicals that span different classes and mechanisms of toxicity pose a large challenge for regulatory authorities to manage and a challenge to accurately and comprehensively characterize as to their risks.
3. Diminishing attention to toxics prevention efforts in the Basin and limited coordination between government authorities in this area.
4. Significant reliance on voluntary measures and use of chemical by chemical risk assessment and risk management processes to control releases of chemicals to the environment. This means that efforts to control or prevent releases have not kept up with the number of chemicals that are being identified or detected as chemicals of emerging concern in the Great Lakes Basin.

Based on the Bibliography conducted by Hornbuckle and Persoon, a number of chemicals—those used in industrial applications, consumer products, cosmetics, pharmaceuticals, and pesticides—have been detected in the Great Lakes. These probably represent the tip of the iceberg, since few substances have actually been subject to

monitoring in the Great Lakes Basin. For example, products containing engineered nanomaterials are rapidly being developed and their introduction into the Great Lakes Basin has likely already occurred.

The Chemicals Management Plan in Canada and the Chemicals Assessment and Management Plan in the U.S. are in their early phases of implementation. The scope and goals of each of these national programs focus primarily on industrial chemicals. This focus may mean that not all chemicals exhibiting persistence, or bioaccumulation, or toxicity traits will be assessed or managed in the proactive manner outlined in the *Great Lakes Water Quality Agreement*. Similarly, the current activities under the Great Lakes Bi-national Toxics Strategy (BTS) may not achieve the goals of the GLWQA. The scope and intent of the BTS was articulated by Carol Browner, representing the U.S., and Sergio Marchi, representing Canada, on April 7, 1997 at the signing of the strategy when they stated that they would:

...work in cooperation with their public and private partners toward the goal of virtual elimination of persistent toxic substances resulting from human activity, particularly those which bioaccumulate, from the Great Lakes Basin...An underlying tenet of this Strategy is that the governments cannot by their actions alone achieve the goal of virtual elimination...The goal of virtual elimination will be achieved through a variety of programs and actions, but the primary emphasis of this Strategy will be on pollution prevention.¹⁹⁷

The activities under BTS were undertaken through voluntary initiatives agreed upon between industry and government on the following key persistent toxic substances (primarily those that are considered legacy pollutants – industrial byproducts and chemicals subject to global restrictions) including mercury, PCBs, dioxins and furans, and hexachlorobenzene and benzo(a)pyrene.¹⁹⁸ The BTS concluded in 2006 with reductions in levels of persistent toxic substances being reported by U.S and Canada. Despite the inclusion of virtual elimination and pollution prevention in the BTS framework, the results demonstrated that the BTS has not fully achieved all its challenge goals. According to the 2007 Annual Report on the Bi-national Toxic Strategy: “Of the Strategy’s 17 challenge goals that were established in 1997, 12 have been achieved and one more is expected in the near future; significant progress has been made toward the remaining four challenge goals.”¹⁹⁹ On-going work to achieve the remaining goals of the BTS, including PCBs reduction, continues to this day, but at a much reduced focus.

With the completion of their initial scope of work, the U.S. and Canadian governments have used the BTS process as a forum to discuss a new scope and target of work on

¹⁹⁷ Canada and United States, “Great Lakes Bi-national Toxics Strategy,” (1997). Accessed at: bi-national.net/home_e.html.

¹⁹⁸ Environment Canada and U.S. Environmental Protection Agency Region V, “Great Lakes Bi-national Toxic Strategy Path Forward,” (2008).

¹⁹⁹ Environment Canada and United States Environmental Protection Agency, “2007 Annual Progress Report: Great Lakes Bi-national Toxics Strategy,” (2007). Accessed at: bi-national.net/bns/2007/2007GLBTS_en.pdf.

persistent toxic chemicals in the Great Lakes. This included the establishment of two work groups: substance and sector work groups, comprised of stakeholders that were interested in redefining a scope of work for the BTS. Since 2007, the work groups have met on a quarterly basis to outline the work-plan and scope of work under this BTS. Similar to the original BTS, the framework for future work of the BTS is based on a voluntary approach between industry and government to reduce a limited list of toxic chemicals that will be identified through each of the national chemicals programs (CMP in Canada and ChAMP in the U.S.) using a three step regime. This regime includes the following: substance identification, substance selection, and review of management status.²⁰⁰ The BTS framework aims to be dynamic in its approach in order to reflect the on-going changes in data availability on chemicals as well as progress made under the national programs. However, several stakeholders have expressed concerns regarding different aspects of the BTS framework. These include:

- the voluntary nature of the approach taken under the BTS framework in addressing toxic chemicals in the Great Lakes may not be fully protective of the health and quality of the Great Lakes ecosystem from input of toxic chemicals—especially without the inclusion of criteria for selecting toxic chemicals to consider all hazardous properties and a commitment to establishing proactive action plans for priority toxic chemicals;
- the lack of full accountability by governments to achieve the goals of the *Great Lakes Water Quality Agreement* as outlined in the Mission of the BTS: “...the Parties to the GLBTS agree to make an effort to eliminate or reduce to the maximum extent practicable the discharge of toxic pollutants into the Great Lakes Basin.” Whereas Article II of the *Great Lakes Water Quality Agreement* states “Consistent with the provisions of this Agreement, it is the policy of the Parties that: (a) The discharge of toxic substances in toxic amounts be prohibited and the discharge of any or all persistent toxic substances be virtually eliminated;”
- the definition of virtual elimination as presented in the BTS framework is inconsistent with the interpretation of virtual elimination outlined in the *Great Lakes Water Quality Agreement*.
- the governments’ almost exclusive reliance on the existing national programs to identify and evaluate the chemicals that require action, since this approach may be limiting and not comprehensive, particularly given some of the new approaches being under taken at the state and provincial levels.^{201 202}

²⁰⁰ Environment Canada and U.S. Environmental Protection Agency Region V, “Great Lakes Bi-national Toxic Strategy Path Forward,” (2008).

²⁰¹ See: “Chemical Selection Framework for the Bi-national Toxics Strategy NGO Proposal,” Prepared by the Canadian Environmental Law Association, Great Lakes United, Indiana Toxics Action and National Wildlife Federation, (August, 2008).

²⁰² See: “Comments on Bi-national Toxics Strategy Guide to the Substance and Sector Groups Memo,” dated September 15, 2008 from Canadian Environmental Law Association, Great Lakes United, Indiana Toxics Action and National Wildlife Federation to the Bi-national Toxics Strategy Sector Work Group and Bi-national Toxics Strategy Substances Work Group.

The absence of these elements in a BTS creates a gap in the Parties' approach to meet their obligations on toxic substances as outlined in the GLWQA.²⁰³ While progress to reduce levels of a few specific persistent toxic chemicals under the BTS framework is expected towards 2020, the framework is inadequate to promote the prevention of all chemicals of emerging concern in the Great Lakes Basin without significant efforts by the governments to ensure full accountability on the scope and approach of the BTS.

As a result of the limits within the national programs, as articulated in the analysis of this report, and the limitations of the BTS program, the role of the International Joint Commission in developing and providing advice to the governments of Canada and U.S. for achieving the goals of the GLWQA becomes increasingly more important. Under Article 4 (1)(c)(i) of the *Great Lakes Water Quality Agreement*, it states:

*The Parties adopt the Specific Objectives for the boundary waters of the Great Lakes System... subject to the following:...(c) Notwithstanding the adoption of Specific Objectives, all reasonable and practicable measures shall be take to maintain and improve the existing water quality in those areas of the boundary waters of the Great Lakes System where such water quality is better than that prescribed by the Specific Objectives, and in those areas having outstanding natural resource value.*²⁰⁴

The work of the IJC, particularly through the work of the Multi-Board Work Group, offers a unique opportunity not present in the BTS forum to develop a comprehensive framework that will identify, evaluate, and propose proactive measures for chemicals of emerging concern in the Great Lakes.

The GLWQA and subsequent reports by the IJC set the stage for a visionary, prevention-oriented approach to the management of chemicals of concern in the Basin. The region's approach paralleled similar efforts being undertaken in the Scandinavian countries. However, while progress stalled to a great degree in the Basin, it did not in other jurisdictions. Today, there is a renewed commitment to the prevention of chemicals of concern from entering the Great Lakes Basin. Numerous factors are changing the way governments and industry think about chemicals in everyday products. Regulations such as the European Union's Registration, Evaluation, and Authorization of Chemicals (REACH) legislation is affecting a cultural shift in industrial chemicals management, requiring data on chemical toxicity and uses, requiring preventive action for classes of chemicals, and shifting the burden of demonstrating safety for high concern chemicals to industry.

Stakeholders in several U.S. states and Canadian Provinces, including the Great Lakes states of Minnesota and New York and the Province of Ontario, are engaged in discussions to develop comprehensive toxics reduction policies for industrial chemicals.

²⁰³ See: "EPA and Environment Canada BTS framework," presented in September submissions by CELA, GLU, NWF and Indiana Toxics Action (September 2008).

²⁰⁴ IJC Government of United States and Canada, *Great Lakes Water Quality Agreement of 1978(Revised)*, Article IV(1)(c).

The state of Michigan has established a Green Chemistry research and education program to reorient efforts on chemicals to focus on design of greener alternatives. And, as a result of increasing consumer concern about toxic chemicals in products and a desire for safer alternatives, many major companies are initiating their own safer chemicals programs, prioritizing chemicals of higher concern for substitution. All of these factors, combined with new science on the health effects of chemicals and on the design of safer materials at the molecular level provide a strong impetus for the Great Lakes community to regain its leadership in toxics prevention. Most importantly, the Great Lakes community can be a leader in establishing comprehensive, solutions-oriented chemicals policies that span chemical categories. Such policies can go beyond the mandate of the GLQWA, which focuses on substances which are persistent, bioaccumulative and toxic to focus on all chemicals of emerging concern that pose a threat to the integrity of health and ecosystems in the Basin.

Based on the findings of our report, we outline below a new, comprehensive approach to addressing chemicals of emerging concern in the Great Lakes – a “roadmap” for chemicals of emerging concern. The roadmap would contribute to an enhanced accountability mechanism by decision makers as well producers, users, vendors, importers, and disposers of chemicals, drugs, and nanomaterials in the Great Lakes Basin.

This approach could potentially be established through revisions to the *Great Lakes Water Quality Agreement*. Given the changes in science and technology that have occurred since the passage of the GLWQA and new understandings of chemicals, their hazards, uses, and emissions, a more comprehensive approach to emerging chemicals of concern (which would be broadly applicable to all chemicals) would place the Great Lakes Basin in a new role of leadership in chemicals management activities.

Step I: Establishing an IJC Task Force on Chemicals of Emerging Concern

An IJC Task Force on Chemicals of Emerging Concern would be charged with developing a bi-national strategy for such chemicals that spans jurisdictional boundaries and focuses on rapid identification, screening and control and prevention actions for such chemicals. The Task Force would establish processes and collaborations to implement the actions described below.

Step II: Establishing a Great Lakes rapid identification and screening process for chemicals of emerging concern.

There is a need to undertake rapid assessments processes to identify chemicals of emerging concern given the thousands of chemicals that remain unassessed or monitored.

Building on existing national programs of Canada and the U.S., as well as the GLWQA List, discussions and efforts that have occurred through the BTS process, and data from other jurisdictions for identification and screening substances of concern, the proposed IJC Task Force should establish a Great Lakes screening process for chemicals of

emerging concern. The process would use the criteria established under the GLWQA for persistence, bioaccumulation and/or toxicity, which could include carcinogenicity, reproductive and developmental toxicity, neurodevelopmental toxicity, genotoxicity, respiratory toxicity, and endocrine disruption to capture substances of concern in the Great Lakes. Given the unique vulnerability of the Basin's ecosystems, determination of chemicals of concern could be based on the most conservative criteria adopted internationally. This identification, screening, and prioritization process should be applied to chemicals used in drugs, other pharmaceutical products, and nanomaterials in order to effectively characterize their uses, possible exposures, and fate in the environment.

Step III: Publishing a Great Lakes List of Chemicals of Concern.

Building on screening process above and the work of government scientists, Muir and Howard, and those of the national programs, substances should be prioritized as to their potential to become a chemical concern in the Great Lakes Basin as high, medium, or low concern.²⁰⁵ This categorization would be based on hazard screening as well as information on chemical uses and exposure potential that would need to be collected for the basin to identify uses and exposures of highest concern. Substances with exposure potential and inadequate hazard data needed for making such a categorization should be considered as high concern.²⁰⁶ The results of this process should be widely publicized as a Great Lakes List of Chemicals and Uses of Concern. This list would be a tool to inform regulatory-making processes, markets, research and innovation, and educational activities that support implementation of safer alternatives.

Step IV: Development of action plans for chemicals identified under the Great Lakes List of Chemicals of Concern to achieve the goals outlined under the GLWQA

The IJC Task Force should advocate that countries commit to the development and implementation of mandatory action plans to promote proactive activities, including substitution and prohibition (depending on particular use categories) of chemicals of high concern listed on the Great Lakes List of Chemicals of Concern.

The action plans should include mandatory processes and programs as well as voluntary initiatives that achieve pollution prevention through substitution with safer, technologically feasible alternatives and product redesign, combined with proactive management options implemented in a timely manner. Action plans should also consider end of life take-back considerations for products containing chemicals of concern. A

²⁰⁵ See Philip Howard, William Meylan and Derek Muir, "Screening Chemicals in Commerce to Identify Possible Persistent and Bioaccumulative Chemicals: New Results and Future Work," (Presented at Great Lakes Bi-national Toxics Strategy Meeting, Chicago, IL, 2008).

²⁰⁶ The Dutch Quick Scan Approach, which was used to prioritize chemicals for risk management actions prior to the passage of the REACH regulation, is a model for this method of prioritization. See *Implementation Strategy on Management of Substances*, Dutch Ministry of Housing, Spatial Planning and the Environment, progress report December 2001 and second progress report October 2002.

model to explore may be U.S. EPA's PBT action plans.²⁰⁷ The action plans and approach taken by the Task Force should strengthen accountability mechanisms for those industries producing, using, selling, importing, or disposing of chemicals, pharmaceuticals, pesticides, and nanomaterials, which are introduced into the Great Lakes Basin market. This may include improvements to monitoring regimes to ensure the effectiveness of action plans developed on chemicals identified under the Great Lakes List of Chemicals of Concern as well as end of life take back programs.

Step V: Establishing a Bi-National Safer Alternatives Program

To support these action plans, the Task Force should urge the Parties to establish a bi-national safer alternatives initiative to be coordinated by a Great Lakes agency. This initiative would aim to provide tools, technical support, and incentives for research, development and application of alternatives, such as green chemistry, and establish a process to assess safety of alternatives to ensure benefits to the Great Lakes environment, health, and economy. Its mandate should include a scope to explore efficient treatment of chemicals and prevent emissions from energy production and other sources, such as farming operations.

Step VI: Establishing a Public Database and Clearinghouse of Information on Chemicals of Concern for the Great Lakes Basin.

The Task Force should develop a plan for the establishment of a publicly accessible database that records the uses of high and medium concern substances in the Great Lakes Basin modeled after the Interstate Mercury Education and Reduction Clearinghouse. This database would be housed at a relevant Great Lakes Agency. Such a database can provide government agencies and the public with a vital source of information to track flows of chemicals of emerging concern in the Great Lakes Basin. It could also include information on environmental fate of chemicals, impacts, their uses and benefits, and safer alternatives for different use types. This database would supplement existing pollutant inventories in Canada and in the United States, which apply to chemicals in medium to large scale manufacturing.

This roadmap would build on existing legal and administrative structures in the U.S. and Canada and would require new collaborations and infrastructure at the Basin level.

²⁰⁷ <http://www.epa.gov/pbt/pubs/epaaaction.htm>

Appendix A: Comparison of criteria used to determine persistence, bioaccumulation and toxicity under *Great Lakes Water Quality Agreement* (GLWQA), European Union (EU) *Registration, Evaluation and Authorisation of Chemicals* (REACH) program, Canada's CEPA Chemicals Management Plan (CMP), U.S. EPA Chemicals Assessment and Management Program (ChAMP), and *Stockholm Convention on Persistent Organic Pollutants*

Criteria	GLWQA, 1989	EU REACH	Canada's CEPA CMP	U.S. EPA PBT and ChAMP	Stockholm Convention on Persistent Organic Pollutants*	Conclusion
1.PERSISTENCE (P) Half -life in fresh water	> 56 days (8 weeks)	> 40 days (5.7 weeks)	>=182 days (26 weeks)	>= 60 days (8.5 weeks) considered persistent, moderate hazard Not persistent if half life <60 days, low hazard	>60 days (two months /8.5 weeks)	GLWQA, REACH, EPA at least three times more stringent than CMP
Half life in marine water		>60 days				CMP does not set more protective criteria for freshwater
Half life in soil		>120 days	>=182 days		>six months (approx. 180 days/26 weeks) (soil)	
Half life in sediment		>120 days in freshwater sediment or	>=365 days	>=60 days considered persistent, moderate hazard Not persistent if half life <60 days, considered low hazard	> six months (approx. 180 days/26 weeks)	REACH two times more stringent than CMP
		Half life of >180 days in marine sediment				
Half life in air			>=2 days or is subject to		>2 days	Only CMP and Stockholm Convention

Criteria	GLWQA, 1989	EU REACH	Canada's CEPA CMP	U.S. EPA PBT and ChAMP	Stockholm Convention on Persistent Organic Pollutants*	Conclusion
			atmospheric transport from its source to remote place			evaluate persistence using air half life
VERY Persistent (vP) Half life in water		>60 days in marine or freshwater or	No ``very persistent`` category	>190 days in water, soil and sediment, considered high hazard		CMP does not have vP category
Half life in sediment		>180 days in marine or freshwater sediment or		>190 days in water, soil and sediment, considered high hazard		Like vP threshold, Canada does not establish a criteria for vP in sediment
Half life in soil		>180 days				
2. BIOCONCENTRATION (B)		BCF> 2,000	BCF>=5,000 or BAF>=5,000 or Log K _{ow} >=5	BCF>=1,000 or BAF>=1,000 considered bioaccumulative and moderate hazard or BCF<1,000 or BAF<1,000 considered not bioaccumulative and low hazard Log K _{ow} >4	BCF >5,000 or Log K _{ow} > 5	REACH established BCFs that are two and half times more stringent than CMP U.S. EPA PBT five times more stringent than CMP
VERY Bio accumulative (vB)		BCF>5,000	Same as bioaccumulative category in CMP	BAF or BCF>=5,000 considered bioaccumulative and high hazard.		
3. TOXIC (iT_e)		Chronic NOEC < 0.01 mg/l	Chronic NOEC <= 0.1 mg/l	Chronic (ChV or LOEC) <0.1	Not restricted to aquatic	REACH ten times more stringent than CMP

Criteria	GLWQA, 1989	EU REACH	Canada's CEPA CMP	U.S. EPA PBT and ChAMP	Stockholm Convention on Persistent Organic Pollutants*	Conclusion
Chronic				mg/l considered high hazard Chronic (ChV or LOEC) <0.1 to 10 mg/l considered moderate hazard Chronic (ChV or LOEC) >10 mg/l considered low hazard	environment. Evidence of adverse effects to human health or to the environment Or toxicity or ecotoxicity data that indicated the potential for damage to human health or to the environment	CMP classifies chemicals as toxic, which would be classified as high hazard under EPA CMP no moderate or low hazard category
Acute	Acute LC50 < 0.5 mg/l are considered hazardous substances are also other measures	Short term LC50 or EC50 <0.01 mg/l (Definitely fulfilled) Short term LC50 or EC50<0.1 mg/l	Acute LC50 (EC50)<=1 mg/l	Acute LC50 (EC50)<=1 mg/l		GLWQA twice as stringent as CMP U.S. EPA same as CMP

* Note: Under the Stockholm Convention on POPs, persistence under Stockholm convention also includes “evidence that the chemical is otherwise sufficiently persistent...”. For bioaccumulation, “evidence that a chemical presents other reasons for concern, such as high bio-accumulation in other species, high toxicity or ecotoxicity; or monitoring data in biota...”

Sources:

- *Great Lakes Water Quality Agreement*, 1987, Annexes 10 & 12.
- Technical Guidance Document REACH. Guidance on information requirements and chemical safety assessment. Part C. PBT Assessment. (European Chemical Agency, May 2008). Government of Canada, *Persistence and Bioaccumulation Regulations*, S.O.R./2000-107, C. Gaz.II 134 no. 7 (March 29, 2000). See: canadagazette.gc.ca/partII/2000/20000329/html/sor107-e.html.
- Toxicity from Environment Canada's Ecological Categorization Criteria and Process.
- U.S. EPA Category for persistent, bioaccumulative and toxic new chemical substances Federal Register November 4, 1999 volume 64, number 213 pages 0194-60204 Used for moderate production volume chemicals in ChAMP program.
- United Nation Environment Program. *Stockholm Convention on Persistent Organic Pollutant Text and Annexes*, Annex D.

Appendix B: Overview and Analysis of the *Toxic Substances Control Act*, Its Implementation, and Voluntary Programs under EPA's Office of Pollution Prevention and Toxics

TSCA was passed in 1976 after years of debate over the scope of influence government (in this case EPA) should have over production decisions. Toward the end of the 1960s several notable incidents involving synthetic chemicals and heavy metals attracted the attention of the media and the American public. Government agencies were dealing with the “toxic of the month” problem and lacked a comprehensive way to address toxic chemical hazards other than limited regulations controlling emissions to air and water. During the spring of 1970, the newly established Council on Environmental Quality (CEQ), an Executive Branch office dedicated to coordinating national environmental policy, embarked on research into the problems of synthetic chemicals and metals and options for their control. The result of this research was a pioneering 1971 report, entitled *Toxic Substances*.²⁰⁸

The report noted particular concern about the large growth in production amount and sheer number and uses of synthetic substances in society. This concern was coupled with inadequate information on chronic chemical hazards, exposures, how chemicals reacted in the environment, and the levels of exposure at which effects might occur. CEQ noted that existing controls for industrial chemicals were inadequate and often ineffective, addressing only large-scale emissions to air and water but not consumer and disposal hazards. Existing controls only dealt with problems after the fact and did not deal with the “multiplicity of ways by which man can be exposed to these substances.” Thus, the CEQ concluded that the evidence indicated the “high priority need for a program of testing and control of toxic substances,” and that “we need no longer remain in a purely reactive posture with respect to toxic substances.”²⁰⁹ While legislation existed to place responsibility for testing and safety on manufacturers of drugs and pesticides, no such legislation existed for the large number of industrial chemicals on the market.

Earlier regulation on clean water and air had addressed primarily wastes coming from production processes (an end of the pipe focus). These acts generally placed the burden on the Environmental Protection Agency (EPA) to establish standards and demonstrate risks before acting. However, TSCA exerted control over production and use decisions, affecting the types of chemicals that could be produced and limitations on their use, placing an upfront burden on manufacturers.

The most relevant sections of TSCA in the context of chemicals of emerging concern include:

- Section 4: Testing of Chemical Substances and Mixtures
- Section 5: New Chemicals/Manufacturing and Processing Notices

²⁰⁸ Council on Environmental Quality, *Toxic Substances*. (Washington, DC: U.S. Council on Environmental Quality, April 1971).

²⁰⁹ *Ibid.*

- Section 6: Regulation of Hazardous Chemical Substances
- Section 8: Reporting and Retention of Information
- Section 9: Relationship to other laws
- Section 26: Action with Respect to Categories

These sections are discussed below:

Section 4

Section 4 of TSCA Compels EPA administrator to require testing of a chemical substance or mixture, new or existing if: (1) The subject chemical or mixture “may present an unreasonable risk (hazard/risk or “A” finding), **or** The chemical will be produced in substantial quantities and either may enter the environment in substantial quantities or lead to significant human exposure (exposure or “B” finding) **and (2)** Inadequate data exist for use in risk assessment **and (3)** Testing is necessary to develop the needed data. EPA has developed criteria for when substances meet the A or B hazard/risk or exposure finding.

Testing rules are generally written for individual chemicals though can be written for small groupings of similar substances. All testing rules must undergo detailed notice and comment procedures, including economic analysis. Chemical producers, importers and processors (including those who intend to produce, import or process) can be required to conduct health effects, environmental effects, environmental fate, and other types of needed studies (e.g., monitoring) under these rules. All studies conducted under a test rule must adhere to EPA approved test methods, including Good Laboratory Practice Standards (GLPS). Specific producers, importers and processors are required to immediately comply with test rules while others (processors and those that produce the substance as a by-product or non-isolated intermediate) would only be required to comply if specifically noted in the final test rule. The cost of performing the required testing is shared among manufacturers and/or processors of each test rule chemical.

Chemicals are referred for test rule development in the following types of instances:

Designation by the TSCA Interagency Testing Committee (ITC). A role of the ITC (made up of representatives from several federal agencies²¹⁰ is to identify chemicals subject to TSCA for which there are toxicity concerns and limited data on human or ecological effects, fate, etc. These chemicals can be formally added to a Priority Testing List (for testing to meet the needs of EPA or other agencies) and EPA must within one year issue a proposed test rule (or advanced notice of rulemaking) or notice stating the agency’s rationale for not doing so.

Requests for testing action from other EPA offices. The OPPT receives requests for testing action development directly from other EPA Offices and other federal agencies but there is no statutory deadline or requirement to issue test rules for these requests.

²¹⁰ These include the Occupational Safety and Health Administration, EPA, National Institute for Occupational Safety and Health, the Department of Transportation, the Consumer Product Safety Commission and Department of Commerce.

Concerns raised by OPPT for existing or new substances. Through its implementation of TSCA's new and existing chemicals programs OPPT may identify chemicals for test rules but as above there is no statutory deadline for developing such rules.

These sources are integrated into a Master Testing List which consists of more than 500 substances and categories of substances (such as endocrine disruptors) for which there are federal government or international testing needs that could be filled by international, federal or voluntary or mandatory corporate actions.²¹¹

In addition to formal test rules EPA may also enter into Enforceable Consent Agreements (ECAs), which generally emanate from an invitation in a formal test rule notice where a consensus exists among the Agency and interested parties (including chemical manufacturers and representatives of the public) about the adequacy of the proposed testing program and other relevant features of the agreement. These agreements include the same types of testing as formal rules but allow more flexibility in the testing protocol (for example tiered testing) and interaction in developing the most relevant testing approach and are much more efficient legally and administratively.

Section 5

Section 5 of TSCA prohibits the manufacture, processing, or import of a "new chemical substance" or "significant new use" of an existing substance unless a pre-manufacture notification (PMN) is submitted to EPA at least 90 days before the commencement of manufacture or processing. The pre-manufacture stage is before actual marketing has occurred to ensure lifecycle attention to the chemical and its potential impacts. The PMN must contain mandatory and reasonably ascertainable information on the chemical identity, physical characteristics, processing, by products and use, and available toxicity data but there is generally no required testing for such substances. During this 90-day period, EPA reviews the chemical's human and environmental risks and exposures, examining the data submitted in addition to other information. As there are no particular testing requirements under Section 5, EPA relies heavily on predictive models, including structure activity relationships and expert judgment in reviewing new chemicals. EPA can then request more data, prohibit or limit manufacture, or halt the review process. Certain types of chemicals and chemical uses are exempted from the review process and EPA is authorized to make future exemptions.²¹² EPA's new chemical review process is multilayered and extensive and has been reviewed in detail elsewhere.

After 90 days if the EPA has not initiated any action, the manufacturer or importer can issue a Notice of Commencement at which time manufacture or import can commence (this applies to all future manufacturers or importers unless EPA issues a Significant New Use Rule. The possible outcomes of a new chemicals review include:

²¹¹ See www.epa.gov/oppt/chemtest/pubs/index1.pdf.

²¹² These exemptions include: substances manufactured, processed, or distributed only for export; substances manufactured or processed only in small quantities for research and development, including product development; test marketing, if the substance "will not present any unreasonable risk of injury to health or the environment" as a result of the test marketing activity; non-isolated intermediates (temporary intermediates with no exposure); polymers meeting specific requirements; and Low Volume and Low Release and Exposure, subject to restrictions on use.

- no action by EPA;
- voluntary withdrawal by the manufacturer, often in response to concerns raised by EPA;
- Section 5e orders to prohibit or limit activities associated with the chemical if: there are insufficient data to evaluate effects and (1) it may present an unreasonable risk; or (2) it is or will be produced in substantial quantities or result in substantial exposure. Such orders can include: exposure mitigation, testing, labelling and hazard communication and record keeping. EPA frequently relies on Section 5e Consent orders as they are more efficient legally and administratively and allow more flexibility for the Agency and manufacturer/importer.
- Section 5f order limiting the substance if substance presents or will present an unreasonable risk.

EPA can also propose a Significant New Use Rule (SNUR) where there is an indication that production volumes will increase significantly or uses will change. To make a significant new use determination the Agency must consider the following factors (though a risk finding is not required): the projected manufacturing and processing volume, the anticipated extent to which the use changes the type or form of exposure, the magnitude and duration of exposure, and the manner and methods of manufacture, processing, distribution in commerce, and disposal

As a Section 5e order is only binding on original PMN submitter, a SNUR mimics the consent order and extends it to other companies that want to manufacture or import. SNURs can also be applied when there is concern for increased production (and need for additional testing/information as production volumes increase) or new uses of chemicals once they reach the market that may present an unreasonable risk (new uses of existing chemicals accounts for a significant portion of chemical use today). SNURs can also be applied for existing chemicals when production is discontinued (for example the Penta Brominated Diphenyl Ether or PFOS²¹³) or particular uses are discontinued. Any company that wants to manufacture or import a chemical subject to a SNUR must submit a Significant New Use Notification to EPA 90 days prior to manufacture, with a review process similar to new chemicals.

**Regulatory (And Voluntary Testing) Actions on PMNs through September 30, 2002 – Total PMNs – 36,000
With about ½ going on to TSCA Inventory**

Regulatory Action	Number
§5(e) Consent Orders without SNURs	743
§5(e) Consent Orders with SNURs	500
Non-§5(e) SNURs	437
§5(f) Actions	4

²¹³ Following 3M's removal of PFOS from the market, in March 2002, EPA issued a SNUR on 13 known or discontinued PFOS chemicals, extending this to 75 additional chemicals and excluding from the definition of "significant new use" specifically defined controlled exposure uses in semiconductor manufacture, aviation hydraulics, and photography.

PMNs withdrawn often in face of action	1,552
Approximate Voluntary Testing Actions	300
TOTAL ACTIONS	3,536

Section 6

Section 6: Authorizes the EPA to issue regulations to address the risks of existing substances if “there is a reasonable basis to conclude that . . . a chemical substance or mixture . . . *presents or will present an unreasonable risk of injury to health or the environment* [emphasis added]. . . using the least burdensome requirements” that are necessary to address that risk. Such regulations can be issued immediately under Section 7 when a threat of harm is imminent. EPA actions under Section 6 can include the following (with burdens higher for stricter actions):

- (a)(1) To prohibit (or limit) the manufacture, processing, or distribution in commerce of a substance/mixture;
- (a)(2) To prohibit (or limit) the manufacture, processing, or distribution in commerce of substance/mixture for a particular use or for a particular use at a particular concentration;
- (a)(3) To require a substance/mixture, or any article containing the substance/mixture, to be labelled or accompanied by warnings and instructions for use, distribution, or disposal;
- (a)(4) To require manufacturers and processors of a substance/mixture to keep records of manufacturing/processing methods and conduct reasonable monitoring or testing necessary to assure regulatory compliance;
- (a)(5) To prohibit or otherwise regulate commercial use of a substance/mixture;
- (a)(6) To prohibit or otherwise regulate disposal of a substance/mixture, or any article containing the substance/mixture, by manufacturers, processors, or anyone who uses it, or disposes of it, for commercial purposes; or
- (a)(7) To require manufacturers or processors to notify distributors, other persons in possession of the substance/mixture, and the general public of the risk of injury and replace or repurchase the substance/mixture.

EPA is required to evaluate a number of factors in making a Section 6 unreasonable risk finding, including health and environmental effects, exposure, the benefits of the substance/mixture, the availability of substitutes, and the economic effects of a rule. EPA can also undertake voluntary consent orders to achieve Section 6 actions, as was the case with Penta and Octa Brominated Diphenyl Ethers.

A listing of Section 6 actions taken by EPA is below²¹⁴:

Action	Proposal Date	Final Date	Prompting Action	Present Status
Ban on manufacture, processing, distribution in commerce of fully halogenated chlorofluoralkanes for aerosol propellents	5/13/77	3/17/78	Component of federal actions regarding ozone-depleting CFCs	Superseded by later air regulations
Ban on manufacturing, processing, distribution in commerce and use of PCBs	6/7/78	5/31/79	Implemented statutory ban on PCBs	Ban in place -- numerous other actions taken to regulate certain PCBs uses
Ban on storage and disposal of dioxin-contaminated waste at one facility in Arkansas	3/11/80	5/19/80	Imminent Hazard (withdrawn in light of RCRA authority)	Superseded by 1984 RCRA rule
Limited certain uses of metalworking fluids (3 separate actions)		1/23/84 6/14/84 9/20/84	Unreasonable risk of injury to human health	Bans presently in place
Ban on manufacture, importation, processing, and distribution of asbestos	1/29/86 ¹	7/12/89	Unreasonable risk of injury to human health	Ban on existing uses overturned ("Corrosion Proof Fittings" case) in court in 1991 Ban on new uses remains in effect
Ban on hexavalent chromium chemicals in comfort cooling towers	3/29/88	1/30/90	Final EPA health assessment for chromium and subsequent listing as a hazardous air pollutant	Ban presently in place
Regulation of "Land Application of Sludge from Pulp and Paper Mills Using Chlorine and Chlorine Derivative Bleaching Processes"	5/10/91		Unreasonable risks to wildlife and humans presented by dioxins and furans in certain paper mill sludges	MOUs ² entered into with pulp and paper industry; Water rule promulgated
Ban on acrylamide/-methylacrylamide grouts	10/2/91		Worker exposure issue -- known human neurotoxicant, probable human carcinogen	Proposal withdrawn (12/2/2002) based on development of PPE ³
Ban on lead fishing sinkers	3/9/94		Response to Citizen's Petition	Final action under development

¹ Advanced notice of proposed rulemaking (ANPR) issued on 10/17/79.

² MOUs = Memoranda of Understanding.

³ PPE = personal protective equipment. It was determined that the newly developed PPE provided adequate protection from exposure to acrylamide.

²¹⁴ U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics, "Overview: Office of Pollution Prevention and Toxics Programs," (December 24, 2003).

Section 8

Section 8 of TSCA involves recordkeeping and data generation. Section 8a gives broad authority for EPA to require, through rulemaking, that manufacturers and processors of chemicals (excluding small manufacturers) maintain records and report data to EPA including: chemical identity, use categories, health and environmental information, by products and people exposed. Such information is often used to inform ITC decisions or decisions to issue test or restriction rules under TSCA.

Such rules are also used to update the TSCA Inventory. In particular the Inventory Update Rule requires manufacturers or importers of non-polymeric chemicals over 25,000 lbs on the TSCA inventory at a single site every five years to report site specific current data on production, use (only domestic use and processing), certain data about manufacture, exposure, etc.²¹⁵ Additional information on domestic processing and use is required for chemicals manufactured in amounts of 300,000 pounds or more at a single site.²¹⁶ These data are used in EPA risk assessment and prioritization activities. The reporting requirements will be expanded to reporting of inorganic chemical substances with a site-specific production volume of 300,000 pounds or greater.

Section 8(e) of TSCA requires that firms notify EPA of new unpublished or published information that supports a conclusion of significant risk. It states that “any person who manufactures, processes or distributes in commerce a chemical substance or mixture in the U.S. and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall inform the EPA Administrator of such information, unless that person has actual knowledge that the Administrator has been adequately informed of such information.”

Significant risk can include both exposure or hazard information on a particular chemical. Information that must be submitted include epidemiological or clinical studies, studies of occupational exposure, health effects studies, ecological effects studies, environmental fate studies, and both emergency and non-emergency reports of environmental contamination. Finally, under TSCA Section 8(d), EPA can issue rules to require that manufacturers or importers or processors submit lists of and unpublished or completed health studies. Finally, under Section 8(c) EPA can require companies to record, retain, and report allegations of

²¹⁵ The types of chemicals, the amounts manufactured or imported, certain details about their manufacture, and other data number of workers reasonably likely to be exposed to the chemical substance at the site of manufacture or import; the physical form(s) of the substance as it leaves the submitter's possession; the percentage of the total production volume associated with each physical form; and the maximum concentration of the chemical substance at the time it is reacted onsite to produce a different chemical substance or as it leaves the site where it is manufactured or imported.

²¹⁶ The type of processing or use operation; The NAICS codes that best describe the industrial activities associated with the processing or use; The industrial functions of the chemical substance during the processing or use operation; The percent production volume, number of sites, and number of workers associated with each processing or use/NAICS/industrial function combination; The commercial and consumer uses; The indication of the presence of the substance in consumer products intended for use by children; The percent of production volume associated with each commercial or consumer use; and The maximum concentration associated with each commercial or consumer use.

significant adverse reactions (for example by workers or consumers) without formal proof or causal evidence.

Section 9

Section 9 requires the EPA to formally refer regulation of an unreasonable risk to other agencies if that risk “may be prevented or reduced to a sufficient extent under a federal law not administered by the Administrator.” These “referral agencies” include the Occupational Safety and Health Administration and the Consumer Product Safety Commission. If that agency determines that activity does not present a risk or initiates regulatory actions on their own within 90 days then EPA is prohibited from regulating that substance. This generally means that EPA actions on chemicals in consumer products are often referred to the Consumer Product Safety Commission and the laws it implements. EPA actions on chemicals that pose workplace risks are often referred to the Occupational Safety and Health Administration.

Section 26

Section 26 of TSCA allows EPA to extend any action taken with respect to a chemical substance or mixture to an entire category without undertaking rule-making. Categories are under TSCA defined as “a group of chemical substances the members of which are similar in molecular structure, in physical, chemical or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act.” For new chemicals, more than 45 categories currently exist, with EPA providing guidance on the type of risk concerns and testing desired for each categories in its new chemicals review process.

Voluntary Programs under the auspices of TSCA and the EPA Office of Pollution Prevention and Toxics

Given the burdens associated with many of the TSCA requirements (discussed in the next section), the U.S. EPA Office of Pollution Prevention and Toxics has undertaken numerous voluntary chemical assessment and management initiatives. These fall into two broad categories – (1) programs on enhanced chemical testing, assessment, and characterization; and (2) programs on safer product design:

1. Programs on enhanced chemical testing, assessment, and characterization

In 1998, following studies on the lack of data on high production volume (HPV) chemicals, those used over one million pounds per year, EPA initiated its Chemical Right to Know Initiative. This program started with the High Production Volume Chemicals Challenge Program and the Voluntary Children’s Chemical Evaluation Program. However, more recently as a result of obligations resulting from the U.S.-Canada-Mexico Security and Prosperity Partnership, the EPA has initiated the Chemicals Assessment and Management Program (CHAMP) to obtain data on mid-production volume chemicals.

Voluntary Children’s Chemical Evaluation Program (VCCEP): In 1998, the EPA asked producers of some 23 chemicals that have been documented in human tissues to voluntarily evaluate their products with regards to their risks to children’s health. In 1999, 35 companies and consortia agreed to test 20 of these chemicals. EPA later redrafted the project as a pilot program in response to stakeholder concerns of excessive animal testing. As part of the voluntary testing, manufacturers are asked to write a “Data Needs Assessment” to communicate to EPA what, if any, information should be collected during the next phase of the program (there are three tiers of testing in the project corresponding to increasingly detailed tests). Information is then evaluated by a Peer Consultation Group of experts in toxicology and in evaluating exposure. EPA then determines whether an additional round (a higher tier) of voluntary testing is necessary. EPA issued Data Needs Decisions for seven chemicals — n-dodecane, undecane, decane, benzene, m-xylene, o-xylene, and toluene — identifying whether additional hazard and/or exposure information were needed to adequately assess the potential risks to children and prospective parents. Sponsors of five chemicals have agreed to provide additional information to address uncertainties and one chemical (deca-BDE) was dropped as Tier 2 data were not provided. EPA is considering modifications to the program to enhance its effectiveness.

High Production Volume Challenge (HPV): In 1998, the EPA entered into a voluntary “challenge” with the American Chemistry Council and the environmental advocacy group Environmental Defense for industry to provide basic screening level data on some 2800 chemicals manufactured or imported in quantities over 1 million lbs per year. The HPV program allows companies the flexibility to test chemical categories based on the characteristics of a given substance as opposed to individual tests. To date, industry consortia have “adopted” about 2200 chemicals (which amounts to approximately 99% by tonnage of the HPV chemicals) and produced summaries of toxicity data. However, there are about 500 “orphan” chemicals (though it is unclear how many are still in manufacture) which have not been adopted by industry consortia and the program does not address chemicals that have achieved HPV status since 1998. EPA has only begun to issue rules for data on the remaining HPV chemicals. The EPA review process for HPV chemical submissions includes 3 steps: (1) Tier I – EPA used a computerized sorting process to prioritize the HPV chemicals into first, second, and third priority groups for further review; (2) EPA evaluates the quality and completeness of the data set contained in each HPV Challenge Program submission, identifies any data gaps, and characterizes the potential hazards of HPV chemicals. The key output of Tier II is a screening-level hazard characterization for each chemical or chemical category, and about 100 of these have been completed; (3) In March of 2008 EPA published a first collection of documents on chemical risk-based prioritization for HPV chemicals and approximately 150 have been completed so far. The documents are based on the Tier II hazard reports and use information gathered through the HPV program and the Inventory Update Rule and will inform future prioritization decisions. Where appropriate, EPA can then initiate further voluntary or regulatory options for chemicals indicating a need for elevated concern. Findings from these reviews can be found on the EPA HPV website - www.epa.gov/hpv.

Chemicals Assessment and Management Program (ChAMP): ChAMP encompasses a commitment made by President Bush, Canadian Prime Minister Stephen Harper and Mexican President Felipe Calderon at the August 2007 Security Prosperity Partnership Summit that committed the three countries to work together to accelerate and strengthen the management of

chemicals in North America. Each country is sharing scientific information and approaches to chemical testing and risk management.

This commitment includes enhanced regulatory cooperation between the U.S. and Canada on high and moderate production volume chemicals, the establishment of a Mexican chemical inventory, coordinated Research & Development on new approaches to testing and assessment, and the development of mechanisms to share scientific information and best practices.

Under ChAMP (www.epa.gov/champ), by 2012, the U.S. will complete screening-level hazard and risk characterizations and initiate action, as needed, on 6,750 high and moderate production volume chemicals manufactured or imported in the U.S. each year. The EPA will build on and apply the results of EPA's work on the High-Production Volume (HPV) chemicals (produced or imported in the U.S. in quantities of 1 million pounds or more per year), the information gathered in the 2006 Inventory Update Reporting Rule, or IUR, as well as Canada's categorization work. These efforts will be extended to Moderate Production Volume (MPV) chemicals (produced or imported in the U.S. in quantities above 25,000 and less than 1 million pounds per year).

For the more than 2,200 HPV chemicals that were part of the HPV Challenge Program, the Agency began, in 2007, to develop and post interim screening-level hazard characterizations. In 2008, EPA updated these and combined them with use and exposure data under the 2006 IUR Rule to develop and post Risk-Based Prioritizations (RBPs) (www.epa.gov/hpv). The RBPs summarize basic hazard and exposure information, detail the preliminary evaluation of potential risks and identify additional data or testing that may be needed to better characterize the chemical. This process enables the EPA to make judgments as to whether control measures should be pursued to address potential exposure risks or whether the chemical is a low priority for further action.

Through this process, EPA is making judgments on whether a chemical presents either a high, medium or low priority and what further action it requires. If it is concluded that a chemical is a priority for action, and that additional information is needed to clarify EPA's assessment, or if regulatory control action may be needed, there are several steps the agency can initiate under TSCA. They can informally request additional information from manufacturers or importers. They can also issue reporting rules under Section 8 of TSCA, Significant New Use Rules and/or test rules. They can also pursue product stewardship approaches or Challenge programs, as well as initiate efforts to identify and consider safer substitutes under the Design for the Environment program.

Action on high and medium priority cases will be taken, especially on cases where particularly serious issues are identified: high priority special concern cases. Additional exposure and use information will be sought for these cases to clarify or resolve the risk issues identified in the RBP. Once this has been received, further action will be determined. For cases identified as high priority but not "special concern," follow-up action will be initiated by 2012. Most medium priority cases will be dealt with after 2012.

For the almost 4,000 moderate volume chemicals, or MPVs, hazard based prioritizations, or HBPs will be developed. There is no HPV Challenge data or IUR use and exposure information for most of the MPV chemicals, so the approach relies on existing available test data, structure activity relationship (SAR) analyses, and the results of the Canadian categorization work, when available, to prepare the HBPs, which also will identify next steps, where needed. Next steps will focus on gaining additional exposure information to provide a risk context. In most cases, follow-up action will be deferred until after 2012 unless prompt action is needed.

In Sept 2008, it was announced that as part of ChAMP, the TSCA Inventory of industrial chemicals will be reset. At present there are more than 83,000 chemicals on the inventory, and a great many of these are no longer being produced or imported so an update will reflect only those chemical substances currently manufactured or imported in the U.S., as called for under TSCA section 8(b). Chemicals would be removed that are no longer being manufactured or imported. Companies will be invited to certify they have manufactured or imported specific chemicals. Chemicals that remain on the reset TSCA inventory would maintain their current status. A new chemical notice would only be needed if a company decided, at a later date, to produce a chemical no longer on the reset inventory. Periodic resets in the future would continue to keep the Inventory current.

It was also announced in September 2008, that as part of ChAMP, a phased Inorganic HPV Challenge approach will proceed, allowing EPA to obtain, review and evaluate hazard and use information on the HPV inorganic chemicals. An initial “development” phase will allow EPA to take full advantage of the work completed or underway by the OECD, Canada’s categorization efforts, and future REACH work. The implementation phase will likely include sponsorship opportunities but a vigorous use of test rules will be pursued in the absence of this to ensure submission of quality data sets.

Following a 2-3 year data development period, after 2012, a ChAMP-type prioritization assessment of the inorganic HPV chemicals will begin. This assessment would apply the IUR exposure / use reporting on inorganics which will be received in 2011. Preparation of prioritization assessments on Moderate Production Volume inorganic chemicals would follow, informing decisions on any needed next steps for these chemicals.

2. Programs on Safer Product Design

EPA has initiated several programs designed to ensure that safer chemicals come to market and that safer alternatives are available to chemicals identified as higher concern. These programs include:

Sustainable Futures Initiative: The Sustainable Futures Initiative is a voluntary pilot project initiated in 2002, the goal of which is to make new chemicals safer, available faster, and at lower cost. It works by giving chemical developers the same risk-screening and safer chemical design models that EPA uses to evaluate new chemicals before they enter the market. Sustainable Futures promotes pollution prevention in chemical design and processing. Employees of participating firms must undergo training sessions to ensure their comprehension of the project, and the firm must show that principles of pollution prevention influence decision-making, in

addition to providing examples of PMN notices that successfully used screening tools to assess chemical hazards and worker exposure. Participating businesses are rewarded for these efforts with expedited reviews of future PMNs, or some flexibility in the form which the PMN can be submitted.

Pollution Prevention Partnerships: The *Pollution Prevention Act* of 1990 elevated pollution prevention as the fundamental goal of the environmental protection efforts in the U.S. While the Act did not prescribe any particular agency actions, it has led to the establishment of a number of EPA voluntary research and outreach efforts. Pollution prevention represents an important and indirect route to chemicals management — production process redesign and product design change can result in a substantial reduction or substitution of problem materials. EPA's efforts on pollution prevention have ranged from voluntary sector or use based initiatives to examine alternatives to problem substances or process changes to reduce waste or emissions, to procurement guidelines, to product labelling initiatives, to design challenges.

Design for Environment: The Design for Environment (DfE) program is a series of partnerships with industry to prevent chemical exposures through educated business decisions. As an overall program, DfE identifies a range of technologies, products, and processes that can be used to prevent pollution; evaluate and compare hazards, performance, and cost tradeoffs of the alternatives; encourage and enable use of subsequent information by providing mechanisms and incentives to institutionalize continuous environmental improvement; and distribute this information to the industrial community. Three initiatives of particular note are the Furniture Flame Retardant Partnership, designed to identify safer alternatives to Penta-BDE; the Printed Circuit Board Partnership, designed to identify safer alternatives to Tetrabromobisphenol-A; and the Formulators Project, designed to support formulators to reformulate products to be environmentally safer, cost-competitive, and effective (focused to date on surfactants, solvents and in the future fragrances). The Safer Detergents Stewardship Initiative is a voluntary program to recognize companies that voluntarily switch to safer surfactants (those that break down quickly to non-polluting compounds and help protect aquatic life in both fresh and salt water), in particular nonylphenol ethoxylates.

Green Chemistry: Green Chemistry is the design of chemical products and processes that reduce or eliminate the use or generation of hazardous substances. Green Chemistry applies across the life cycle, including the design, manufacture, and use of a chemical product. The EPA has undertaken a range of Green Chemistry initiatives: (1) The Presidential Green Chemistry Challenge. The Challenge offers individuals, groups or organizations rewards for innovations that help benefit human or environmental health. Grants and awards are given jointly through an EPA/National Science Foundation partnership. (2) Educational materials. EPA and American Chemical Society have partnered in efforts to ensure that green chemistry innovations are being incorporated into students' education of chemistry. (3) The Synthetic Methodology Assessment for Reduction Techniques program (SMART). The Program is used by the Office of Pollution Prevention and Toxic Substances (OPPTS) to review manufacturing methods in new chemical submissions and is designed to complement the New Chemicals Program. Based on the review, EPA may suggest methods for pollution prevention that invoke the principles of Green Chemistry. (4) The Green Chemistry Institute. A partnership between the American Chemical Society (ACS) and EPA precipitated the Institute, a non-profit entity that promotes

environmentally friendly chemistry by means of research, education, and communication and conveyance of information to government, advocacy, educational and corporate institutions.

Critiques of TSCA and Other Voluntary Programs

Below we provide additional details on specific critiques of TSCA and its Implementation through various programs.

1) Unequal Treatment of “New” and “Existing” Chemicals: For Existing Chemicals, those on the TSCA inventory, there are no automatic testing or review requirements. These substances are subject to significant risk notification requirements under TSCA Section 8(e) and various data provision requirements under Section 8(a), such as the Inventory Update Rule. They can also be subjected to Significant New Use Rules which would require pre-manufacture notification if a particular substance or use ceases.

However, to restrict an existing chemical in commerce, EPA must demonstrate an unreasonable risk – which includes strong toxicological evidence as well as showing that the benefits of regulation outweigh the risks of not regulating and that the least burdensome means to reduce risk was chosen. While this burden is reduced for restrictions that do not involve bans, it is a high administrative hurdle. Given this burden, as well as an appeals court decision from 1990, EPA has not committed the resources to apply these regulatory authorities under TSCA. Instead, the Agency has engaged in voluntary commitments with industries, when possible and has used other tools such as test rules and Significant New Use Rules.

Example: Asbestos and the limits of TSCA.

The EPA’s experience in attempting to regulate asbestos in 1990, demonstrates the near impossibility for EPA to restrict chemicals in commerce through regulatory means. Following ten years of research, public meetings, and regulatory impact analyses in 1989, the EPA issued a final rule under Section 6 of TSCA to prohibit the future manufacture, importation, processing and distribution of asbestos in almost all products. The asbestos industry challenged the EPA’s ban and took its appeal to the Fifth Circuit Court of Appeals. In a landmark case (*Corrosion Proof Fittings v. EPA*), the court held that the EPA had presented insufficient evidence (including risk information) to justify its asbestos ban. The court found that: (1) the agency had not used the least burdensome regulation to achieve its goal of minimizing risk, (2) had not demonstrated a reasonable basis for the regulatory action, and (3) had not adequately balanced the benefits of the restriction against the costs to industry. In its conclusions the court held that “the EPA’s regulation cannot stand if there is any other regulation that would achieve an acceptable level of risk as mandated by TSCA” and that “EPA, in its zeal to ban any and all asbestos products, basically ignored the cost side of the TSCA equation.” Such a sharp reprimand from the court has placed a chill on efforts by the EPA to use its Section 6 authority to restrict chemical production or use.

For new chemicals, EPA has significant influence and ability to control chemicals before they come to market through the New Chemicals Program. The new chemicals provisions of TSCA apply at the pre-manufacture stage (before any marketing has occurred) and place a low initial

threshold for agency action: “may present an unreasonable risk to human health or the environment or substantial exposure throughout their production, use, and disposal.” In conducting the pre-manufacture reviews, the EPA uses a multidisciplinary lifecycle review approach involving long-standing agency scientists to rapidly assess the risks associated with new chemicals. Through deterrence from potentially harmful chemicals and guidance toward safer chemicals and production methods, the EPA is able to provide strong signals to manufacturers as to types of chemicals that might present an unreasonable risk and types of chemicals and synthesis pathways that will reduce risks. These mechanisms include:

- *Categories of chemicals.* The EPA has used its “Chemical Categories” list to indicate the types of chemicals and risks that are of concern to the agency and the types of data the agency needs to evaluate those risks. As a result, companies are more likely to present data to avoid the possibility of regulatory orders or to avoid certain chemicals of concern (i.e., the EPA has issued guidance providing strong signals to avoid bringing persistent, bioaccumulative, and toxic substances to market).
- *Informal communication and negotiation with submitters.* The EPA regularly discusses concerns with pre-manufacture notification submitters. If EPA staff express concern, submitters are not likely to question those concerns because they generally do not have the data to refute them. They either withdraw the chemical or come up with the data (a large percentage of pre-manufacture notifications are withdrawn and many chemicals never go to market or come to market with changes in design and use). Further, EPA informally advises submitters to modify production process or substances to minimize risks, placing the burden on industry to make such changes.
- *Pollution prevention initiatives.* EPA has initiated voluntary programs to encourage the development of safer chemical products and production systems, including providing software to firms to understand chemical risks and safer syntheses. These help to internalize considerations of safety at the earliest points of the research and design phase of chemicals.

Despite these successes, there are some particular limits of the program, including the short time period for EPA review (90 days, extendable to 180) which places EPA on a treadmill with thousands of pre-manufacture notifications to review each year and allows manufacturers to commence manufacture if EPA has not responded in the 90 day timeframe; the fact that there is no minimum set of pre-manufacture data requirements; and that there are rarely tiered data/follow-up requirements once chemicals actually become marketed (when they are subject to the higher burdens under TSCA section 6), which could lead to repeating the current problems of existing chemicals.

Once a new chemical is on the market (on the TSCA inventory), unless there is some restriction on use, the chemical may be used by any company for any use, since production and use information is not binding on the PMN submitter or future manufacturers. The burden to act (“will present an unreasonable risk” for limitations or “may present an unreasonable risk” for a testing rule) is completely on EPA. EPA can continue vigilance over new chemicals once they enter the market with the lower threshold for action through a Significant New Use Rule. While the term Significant New Use is broadly defined, the burden is on EPA to imagine, at the pre-manufacturing stage, any significant new uses or exposures and whether they have the potential

to pose an unreasonable risk. This can be extremely difficult in the face of missing information about production processes or market potential of the substance. The difficulty of issuing a SNUR is perhaps one of the greatest weaknesses in the New Chemicals Program, in that a chemical may end up being used in a way that results in much higher exposures than originally envisioned. SNURs have been developed for less than 5% of PMNs^{217 218}. As of 2002, about 900 SNURs had been issued. For existing chemicals, which make up the vast majority by volume of new uses of chemicals, SNURs are rarely used, meaning that there is little ability of EPA to track how chemical uses change over time or their subsequent risks.

Congress noted that, “as chemical substances frequently are not manufactured in large volumes for a large number of uses initially, the authority to require notification for these substances as uses mount or as volumes increase is extremely important.²¹⁹” SNURs are a means to require toxicity testing at a more logical stage in the lifecycle of a chemical, when that substance has achieved economic viability.²²⁰ They provide a “safety net by which we would be able to return to and reconsider the appropriateness of levels of use and types of exposure for a chemical about which we had reason to be concerned” but did not give rise to sufficient concerns for action.²²¹ The Government Accounting Office found that because of the uncertainties in EPA’s toxicity and exposure assessments (due to limited data), as well as unforeseen changes in chemical use, unless EPA monitors new chemicals after they complete the pre-manufacture review process it will not achieve the Act’s “objective of identifying and controlling unreasonable risks from new chemicals before they occur or become widespread.”²²²

2) *Limited Information on Chemicals in Commerce*: TSCA requires industry to submit only limited data on chemical hazards and use. As such, studies from the 1990s found only limited amounts of basic toxicological data on the most widely used chemicals in commerce.²²³ The HPV Challenge program found that a significant amount of unpublished data existed in industry

²¹⁷ GAO - United States General Accounting Office, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, (Washington, DC: U.S. General Accounting Office, September 1994). GAO/RCED-94-103.

²¹⁸ Elizabeth Brown, Julia Hatcher, Carlyne Hathaway, William Rawson, and Robert Sussman, “A Practitioner’s Guide to the *Toxic Substances Control Act*,” in *TSCA Deskbook*, ed. Environmental Law Institute and Latham & Watkins, (Washington, DC: Environmental Law Institute, 1999), 7-81.

²¹⁹ United States Congress - Staff House Committee on Interstate and Foreign Commerce, 94th Congress 2nd Session. 1976, *Legislative History of the Toxic Substances Control Act*, (Washington, DC: Government Printing Office, December 1976).

²²⁰ Conservation Foundation, *Significant New Use Rules (SNURs) for Existing Chemicals*, (Washington, DC: Conservation Foundation, 1983).

²²¹ Ellen Silbergeld, Testimony before the United States Senate Committee on Environment and Public Works - Subcommittee on Toxic Substances, Research, and Development, *Reauthorization of the Toxic Substances Control Act*, (May 17 and July 13, 1994a).

²²² GAO – U.S. General Accounting Office, *Assessment of New Chemical Regulation Under the Toxic Substances Control Act*, (Washington, DC: U.S. General Accounting Office, June 15, 1984). GAO/RCED-84-84.

²²³ Environmental Defense Fund, *Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States*, (Washington, DC: Environmental Defense Fund, 1997); U.S.EPA - United States Environmental Protection Agency, *What Do We Really Know about the Safety of High Production Volume (HPV) Chemicals*, (Washington, DC: United States Environmental Protection Agency, Office of Pollution Prevention and Toxics, 1998).

files. Similarly, data on chemical uses and exposures along supply chains have been limited at best. While risk data have been developed as a result of Significant Risk Notifications under Section 8e of TSCA, these may not include the actual substance name or manufacturer identify. Further, under TSCA manufacturers are required to share only limited information on chemical toxicity and potential exposures along supply chains to product manufacturers, retailers, or the public. Only the Occupational Safety and Health Administration implemented Hazard Communication Standard, requires that MSDS sheets be prepared for chemical products and shared with workers. However, MSDSs are often incomplete and inadequate for proper decision-making about safer substances.

This lack of information extends to new chemicals. Since there are no test data requirements for the most part for new chemicals, historically only very small percentage (less than 50% and less than 10% for some end points) of pre-manufacture notifications contain actual test data. Toxicity data increase with chemicals in “chemical categories” where EPA provides indications of requested data. To build a dataset to analyze chemical risks in the face of missing data, EPA scientists have developed elaborate models and methods, which some critics believe have limitations. The main area of criticism is in the Agency’s systematic reliance on Structure Activity Relationships to assess potential risk for new chemicals, unless further data are requested from manufacturers through Section 5e actions. Several validation exercises have demonstrated that for many ecotoxicity endpoints and many physical characteristics of chemicals, QSAR analysis is a reasonably accurate method for predicting chemical properties.²²⁴ However, estimates for some physical characteristics and human health endpoints have not proven as successful²²⁵. Some evidence exists to indicate that SAR analysis may under-predict risks some of the time.²²⁷ In some cases, however, QSARs overestimate risks. It is clear that TSCA cannot serve its protective purposes if SAR does not accurately predict hazard.²²⁸ Nonetheless, the SAR process is combined with the professional judgment of a multi-disciplinary group of agency scientists who have combined hundreds of years of experience in the agency. A concern is whether this “institutional memory” will be lost when these scientists retire in the coming 5-10 years.

EPA has attempted to fill toxicological data gaps for existing chemicals with large voluntary initiatives such as the High Production Volume (HPV) Challenge. The HPV challenge has resulted in a significant amount of data compiled from manufacturer files and some new data

²²⁴ U.S.EPA – U.S. Environmental Protection Agency, *U.S. EPA/EC Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships*, (Washington DC: Office of Pollution Prevention and Toxics, United States Environmental Protection Agency, March 1994). 743-R-94-001.

²²⁵ Maurice Zeeman, “Ecotoxicity Testing and Estimation Methods Developed Under Section 5 of the *Toxic Substances Control Act (TSCA)*,” in *Fundamentals of Aquatic Toxicology*, ed. Gary Rand, (London: Taylor and Francis, 1995) 703-715.

²²⁶ U.S.EPA – U.S. Environmental Protection Agency, *U.S. EPA/EC Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships*, (Washington DC: Office of Pollution Prevention and Toxics, United States Environmental Protection Agency, March 1994). 743-R-94-001.

²²⁷ GAO - United States General Accounting Office, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, (Washington, DC: U.S. General Accounting Office, September 1994). GAO/RCED-94-103.

²²⁸ David Durenburger, Opening statement before the Subcommittee on Toxic Substances and Environmental Oversight of the Committee on Environment and Public Works, United States Senate, *Toxic Substances Control Act Oversight*, July 27, 29, and August 1, 1983.

generated on chemicals and chemical categories. While significant additional data have been developed as a result of this program, numerous limitations have been identified, including: (1) slow speed of completing program elements. The EPA has taken years to complete hazard characterizations under the program and is only now beginning to complete risk characterizations and has delayed testing rules for “orphan” chemicals (of 270 orphan chemicals only 16 have been subjected to test rules after 5 years, though some may not be currently in use); (2) at least 30% of the hazard characterizations EPA has posted as of May 2008 had identified gaps in the datasets provided by sponsors, even though these are claimed to be final; (3) there are nearly 600 chemicals that have reached HPV status since the Challenge was launched but are not included in it. Despite industry assurances that these would be covered in an additional Extended HPV Program, only about 1/3 of them have been sponsored. As such there are hundreds of high production volume chemicals which still lack basic testing information.²²⁹ Despite these gaps, EPA has moved forward with the Chemical Assessment and Management Program (CHAMP) to fill in data gaps for mid-production volume chemicals using structure activity relationship data and loose clustering of chemicals, reaching broad hazard conclusions without clearly identifying data gaps. A new Inorganic HPV program proposed under ChAMP may not make sense given the delays in the current HPV program.

EPA has attempted to fill in data on chemical use and exposure through its Inventory Update Rule requirements. However, there are significant gaps in this data, including extensive claims of confidential business information (see below) which inhibits any public use of the data as well the fact that reportable information elements are only required if they are “readily obtainable” by the manufacturers. Yet despite these limits EPA is using this data (to the exception of other contradictory exposure and use data) to develop risk characterizations for HPV chemicals, which has the potential to underestimate chemical risks.²³⁰ While EPA may use conservative exposure scenarios in absence of exposure data, such scenarios may not fully capture possible exposures if data on use types is weak or non-existent. For example, where data are deemed not readily obtainable, those exposures may be ignored in the analysis; in other words, lack of data can possibly be equated with evidence of safety.²³¹

EPA’s ability to provide public information on chemical production and risk has also been hindered by strict confidential business information provisions of TSCA. Disclosure of CBI is generally prohibited except where necessary to protect human health. And such information cannot be shared outside the federal government (other than contractors). During the early history of TSCA, industry had to substantiate confidentiality claims; claiming confidential information now requires little more than a routine check-off procedure. A 1998 EPA analysis found that 65 percent of the information in industry filings to the agency under TSCA was claimed as confidential.²³² About 40 percent of substantial risk notifications claim chemical

²²⁹ See Richard Denison, *Environmental Defense Fund’s Comments on ChAMP: EPA’s Recent Commitments and Possible New Initiatives for Existing Chemicals: Docket EPA-HQ-OPPT-2008-0319*, (May 2, 2008). Accessed at: www.edf.org/documents/7871_Comments_ChAMP_May08.pdf.

²³⁰ Richard Denison, *Environmental Defense Fund’s Comments on ChAMP: EPA’s Recent Commitments and Possible New Initiatives for Existing Chemicals: Docket EPA-HQ-OPPT-2008-0319*, (May 2, 2008). Accessed at: www.edf.org/documents/7871_Comments_ChAMP_May08.pdf.

²³¹ *Ibid.*

²³² L. Goldman, “Preventing Pollution? U.S. Toxic Chemicals and Pesticides Policies and Sustainable Development,” *Environmental Law Reporter*, 32 (2002), 11018-11041.

identity as confidential. Further, EPA is not required to review CBI requests and must challenge each one individually. Such claims do not have expiration dates and while health and safety studies cannot be claimed as CBI, chemical and submitter identity generally can be.²³³ EPA has the burden of demonstrating that such confidentiality claims are unfounded, a lengthy and expensive process.^{234 235 236}

3) Slow and Cumbersome Chemical-by-Chemical Risk Assessment and Management Processes: EPA's ability to issue regulations for testing of chemicals is limited by the scientific and legal evidence the agency must amass before it can act. As a result of this burden, EPA has required testing on less than 250 existing chemicals and 1000 new chemicals. Despite a legislative history and TSCA Section 2b stating that a lack of data on chemical risks should trigger a requirement that industry provide that information, EPA and the courts have interpreted TSCA to require some evidence through actual test data or modeling that the substance (or surrogates) may present an unreasonable risk or substantial exposure before the agency can initiate testing orders under Section 4 or 5(e). In *Chemical Manufacturers Association v. EPA* (1988), the DC Circuit concluded that in establishing a test rule, the Agency must "find a more-than-theoretical basis for concluding that the substance is sufficiently toxic, and human exposure to it is sufficient in amount, to generate an unreasonable risk of injury to health." As of 2008, EPA had issued test rules for only a small percentage of the "orphan" HPV chemicals, likely due to the administrative challenges and costs of issuing them. Even though most PMNs have no actual test data, EPA does have an upper hand in informally requesting test data for new chemicals as the agency has the ability to "stop" the 90 day PMN clock. Nonetheless, the percentage of Section 5(e) rules and Significant New Use Rules is relatively small.

While data are increasing, particularly for existing chemicals, as a result of the HPV and CHAMP processes, the process of moving from test data to risk assessment to risk management action is still cumbersome, costly, and time consuming and only done on a chemical by chemical basis for the most part.

²³³ Richard Denison, *Not That Innocent: A Comparative Analysis of Canadian, European, and U.S. Policies on Industrial Chemicals*, (Washington, DC: Environmental Defense, 2007).

²³⁴ Warren Muir, Testimony before the United States Senate Committee on Environment and Public Works - Subcommittee on Toxic Substances, Research, and Development. Reauthorization of the *Toxic Substances Control Act*, May 17 and July 13, 1994.

²³⁵ GAO - United States General Accounting Office, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, (Washington, DC: U.S. General Accounting Office, September 1994). GAO/RCED-94-103.

²³⁶ Lynn Goldman, Testimony before the United States Senate Committee on Environment and Public Works - Subcommittee on Toxic Substances, Research, and Development. Reauthorization of the *Toxic Substances Control Act*, (July 13, 1994).

Appendix C: Consumer Product Safety Legislation and Its Implementation

The two main laws regulating consumer product safety are the *Consumer Product Safety Act* (CPSA) and the *Federal Hazardous Substances Act* (FHSA). Under the *Federal Hazardous Substances Act*, a hazardous substance is: "Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." This definition of a hazardous substance has been interpreted to include both acute and chronic toxicity.

Thus, for a toxic substance to be considered hazardous under the FHSA, it must not only be toxic but people must also be exposed to the substance, it must be bioavailable (can enter the body) and there must be a significant risk of an adverse health effect associated with the customary handling and use of the substance.

In general, companies make the determination as to whether their product contains a hazardous substance, though in some rare cases, the CPSC may issue a regulation defining a particular chemical or substance as hazardous. The CPSC has developed regulatory definitions of acute toxicity as well as voluntary, though interpretable, guidelines to assist companies in determining the hazards of substances in their products (so as to comply with FHSA) including carcinogenicity, neurotoxicity, reproductive/developmental toxicity, exposure, bioavailability, risk assessment, and acceptable risk. For example, in its guidance on lead in consumer products, the CPSC states: "In evaluating the potential hazard associated with products that contain lead, the Commission staff considers these major factors on a case-by-case basis: that the total amount of lead contained in a product, the bioavailability of the lead, the accessibility of the lead to children, the age and foreseeable behavior of the children exposed to the product, the foreseeable duration of the exposure, and the marketing, patterns of use, and life cycle of the product."

As such, the law requires that evidence that a substance may cause substantial illness be demonstrated before it is labelled as hazardous, although there is little guidance as to what is meant by "substantial" (i.e. of medical or toxicological significance). This strict risk-based definition means that many toxic chemicals that are components of consumer products, but may leach out during normal use, would be unlikely to meet the standard of a hazardous substance due to a lack of information demonstrating a substantial risk. Thus, the mere presence of a hazardous chemical in a product and the potential for leaching would not be sufficient to meet this standard. Indeed for many substances, as noted previously, very little direct toxicological data exists, though it is unclear whether data based on SAR/QSAR would be sufficient to meet this standard. If data do not exist to document a risk, then under the law the substance is not considered hazardous.

These two laws authorize CPSC activities in the following areas:

Testing: There are no mandatory pre-market testing required for consumer products, rather the law requires manufacturers to ensure that their products are not hazardous or are properly labelled. CPSC may selectively test certain product types for restricted or prohibited substances such as lead on a periodic basis. Or it may request that EPA initiate testing on a particular chemical or undertake its own risk assessment activities (for example on phthalates).

Product Safety Standards: The CPSC has authority to promulgate mandatory federal safety standards for specific consumer products deemed to be unreasonably dangerous to the public. Most of the consumer product safety standards are set to avoid injury or acute hazards such as choking, burns, etc. There are less than 20 mandatory federal standards for toxic chemicals in toys and consumer products, the most notable being lead in paint.²³⁷ Safety standards and regulations can range from outright bans to restrictions to voluntary actions, and from written guidance to consumer information and outreach. The 1981 amendments to the *Consumer Product Safety Act* require CPSC to defer to a voluntary standard—rather than issue a mandatory regulation—if CPSC determines that the voluntary standard adequately addresses the hazard in question and where there is likely to be considerable compliance with the voluntary standard.

Labeling: Whether or not a product must be labeled depends on its contents (if it contains a hazardous substance as defined above) and the likelihood that consumers will be exposed to any hazards it presents. To require labeling, a product must meet the definition of a hazardous substance: toxicity, exposure, and potential for harm. Manufacturers, distributors, and /or importers make determinations on if and how to label their products in accordance with FHSA requirements (which requires that hazardous substances in products be labeled). It is the company's responsibility to comply with these requirements. Companies are only required to list the hazardous ingredients in their products.

Recalls: The CPSC has authority to recall products either because they contain a defect, which makes them unsafe, or because they violate an existing consumer product safety rule. Voluntary recalls are the CPSC's preferred method of enforcement given the legal burdens of issuing mandatory recall regulations.

²³⁷ See www.cpsc.gov/businfo/reg1.html or www.access.gpo.gov/nara/cfr/waisidx_04/16cfrv2_04.html for a list of products for which safety standards have been developed.

Appendix D: U.S. Case Studies on Policies and Programs Relevant to Great Lakes Chemicals of Concern

Case Study: Polybrominated diphenyl ethers

Polybrominated diphenyl ethers or PBDE started to be used commercially as flame retardants in 1960. They are organic compounds that are members of a broader class of brominated chemicals used as flame retardants; these are called brominated flame retardants, or BFRs. These chemicals are major components of commercial formulations often used as flame retardants in furniture foam (pentaBDE), plastics for TV cabinets, consumer electronics, wire insulation, back coatings for draperies and upholstery (decaBDE), and plastics for personal computers and small appliances (octaBDE).

The chemical structure of PBDE is simple. It is composed of two rings (phenyl rings) linked by an oxygen bridge (ether linkage). “Poly” means many. “Bromine” is a type of mineral (a halogen). There are up to ten locations where a bromine atom can attach to a carbon on the rings. If a PBDE has ten bromines, it’s called a deca-BDE; five bromines is a penta-BDE.²³⁸ The three major types of PBDE mixes are named for the predominant BDE: Penta; Octa; and Deca. When products containing PBDEs are exposed to a certain level of heat, the bromine atoms come off the rings and quench the fire.

The general public is exposed to PBDEs through the use of consumer products in homes, offices, cars and schools. Exposures to PBDEs in some occupational settings, e.g., in computer recycling facilities, can be much higher than those of the general public. As consumer products are used and after they are discarded, PBDEs are released into the environment where they can bioaccumulate in wildlife and food animals. PBDEs have been measured in house and office dust, indoor air, plant and animal-based foods, terrestrial and marine animals, and in human breast milk, blood and fat. The levels of PBDEs measured in humans in the United States and Canada are typically at least 10 times higher than those in Europe, and appear to be doubling every few years.²³⁹ Specific to the Great Lakes region, a study released in 2005 dated sediment cores to see trends in PBDEs and PBBs (Polybrominated Biphenyls). The study showed higher concentrations in Lake Michigan than Lake Erie, and Lake Superior. The study also showed rapid increase in both PBDEs and PBBs in sediments, concurrent with market increase in demand for these flame retardants. The total burdens of these compounds in the sediment of Lakes Michigan and Erie were 110 and 10 metric tons, respectively. The estimated total burden of these compounds in all of the Great Lakes was approximately 200 tons.²⁴⁰

²³⁸ Suzanne Snedeker, “PBDEs – Polybrominated Diphenyl Ethers,” (Cornell University Sprecher Institute for Comparative Cancer Research, February 2007). See envirocancer.cornell.edu/pbde/brief.pdf.

²³⁹ California Dept of Toxic Substances Control website, “Emerging Chemicals of Concern.” See www.dtsc.ca.gov/AssessingRisk/EmergingContaminants.cfm.

²⁴⁰ L. Y. Zhu and R.A. Hites, “Brominated Flame Retardants in Sediment Cores from Lakes Michigan and Erie,” *Environmental Science & Technology*, 39 (2005), 3488-3494; erratum 39 (2005), 5904.

PBDEs have structural similarities to some of the polybrominated and polychlorinated biphenyls (PBBs and PCBs) and in the limited toxicity testing to date, they have produced some of the toxic effects and physiologic changes typical of the PBBs and PCBs. These effects include developmental and nervous system toxicity, as well as mimicry of estrogen and interference with the activity of thyroid hormone. Specific studies include: a single dose of PBDEs given to mice in early development causing effects on learning and memory, spontaneous motor behavior and habituation capability that worsened with age;²⁴¹ a low dose of PBDEs given to mice in early development leading to changes in behaviour;²⁴² a single dose of PBDEs given to mice in early development significantly impairing spontaneous motor behaviour;²⁴³ PBDEs as an endocrine disruptor during development;²⁴⁴ and a single very low dose of PBDEs given to rats in early development causing decreased sperm count in adult offspring.²⁴⁵

In June 2006, the U.S. EPA promulgated a Significant New Use Rule (SNUR) in the Federal Register to require notification to EPA ninety days prior to U.S. manufacture or import, for any use, of the commercial products pentaBDE and octaBDE after January 1, 2005.²⁴⁶ Thus before the chemical can be manufactured or imported for the significant new use, the company would be required to provide advance notification to EPA under Section 5 of TSCA. This action builds on the November 3, 2003, announcement by the Great Lakes Chemical Corporation, the only U.S. manufacturer of these chemicals, who agreed to voluntarily phase-out PentaBDE and OctaBDE production by December 31, 2004. In Europe, the European Union enacted a ban on PentaBDE and OctaBDE in all products which took effect on August 15, 2004. Scientists working under the Persistent Organic Pollutants (POPs) Review Committee of the Stockholm Convention on POPs reviewed commercial mixture pentaBDE and commercial mixture octaBDE for inclusion on the original “dirty dozen” list of banned toxic chemicals.²⁴⁷ Based on decisions made from the Fourth Conference of the Parties under the Stockholm Convention, these two commercial mixtures were added to Annex A for elimination.²⁴⁸ In Canada, a PBDE regulation was finalized on July 9th, 2008. As originally proposed, the final regulation bans the manufacture of all PBDEs and the import and use of tetra- through hexaBDE (ingredients in the discontinued Penta and Octa commercial mixtures) but fails to ban heptaBDE through to

²⁴¹ P. Eriksson, E. Jakobsson, A. Fredriksson, “Brominated Flame Retardants: A Novel Class of Developmental Neurotoxicants in our Environment?” *Environmental Health Perspectives*, 109 no. 9 (September 2001), 903-8.

²⁴² I. Branchi, E. Alleva, L.G. Costa, “Effects of Perinatal Exposure to a Polybrominated Diphenyl Ether (PBDE 99) on Mouse Neurobehavioural Development,” *Neurotoxicology*, 23 no. 3 (September 2002), 375-384.

²⁴³ P. Eriksson, H. Viberg, E. Jakobsson, U. Orn, A.A. Fredriksson, “Brominated Flame Retardant, 2,2',4,4',5-Pentabromodiphenyl Ether: Uptake, Retention, and Induction of Neurobehavioral Alterations in Mice During a Critical Phase of Neonatal Brain Development,” *Toxicological Sciences*, 67 no. 1 (May 2002), 98-103.

²⁴⁴ T. Zhou, M.M. Taylor, M.J. DeVito, K.M. Crofton, “Developmental Exposure to Brominated Diphenyl Ethers Results in Thyroid Hormone Disruption,” *Toxicological Sciences*, 66 no. 1 (March 2002), 105-16.

²⁴⁵ S. Kuriyama, and I. Chahoud, “Maternal Exposure to Low Dose 2,2',4,4',5 Pentabromo Diphenyl Ether (PBDE 99) Impairs Male Reproductive Performance in Adult Male Offspring,” *Organohalogen Compounds*, 61 (2003), 92-95.

²⁴⁶ U.S. Environmental Protection Agency website, “Polybrominated diphenylethers (PBDEs)” See www.epa.gov/oppt/pbde/.

²⁴⁷ The Daily Green website, “Adding the 'Nasty Nine' to the 'Dirty Dozen. The United Nations Considers Expanding Toxic Chemical Ban by 75%,” (October 14, 2008). See www.thedailygreen.com/environmental-news/latest/toxic-chemicals-47101403.

²⁴⁸ Accessed at: www.iisd.ca/download/pdf/enb15174e.pdf

Note: The listing of the commercial penta-BDE and commercial octa-BDE includes specific exemption for articles containing these POPs. This exemption will permit the recycling of articles that contain these POPs.

decaBDE and thus the DecaBDE commercial mixture.²⁴⁹ Additional management measures are under consideration based on the release of a State of Science Report in March 2009.^{250 251}

The U.S. EPA's Design for Environment Program hosts a Furniture Flame Retardancy Partnership helping industry factor environmental and human health considerations into their decision-making as they choose chemical flame retardants for fire safe furniture foam. This broad, multi-stakeholder partnership was formed as the result of concerns about the worldwide occurrence of pentaBDE in the environment and human tissues and works to develop and disseminate information on alternative technologies for achieving furniture fire safety standards.

At the state level, eleven states (California, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, New York, Oregon, Rhode Island, and Washington) have enacted and fourteen states (Alaska, California, Connecticut, Hawaii, Illinois, Maryland, Michigan, Minnesota, Missouri, Montana, New York, North Carolina, Oregon, and Vermont) have proposed legislation prohibiting the use of PBDEs. Of the states that have enacted legislation, two (Maine and Washington) restrict pentaBDE, octaBDE, and decaBDE, four (Illinois, Maryland, Minnesota, and Rhode Island) restrict pentaBDE and octaBDE and require further study of decaBDE, and five (California, Hawaii, Michigan, New York, and Oregon) restrict pentaBDE and octaBDE. Of the states that have proposed legislation, six states (Alaska, Connecticut, Missouri, Montana, North Carolina and Vermont) have proposed bills restricting pentaBDE, octaBDE, and decaBDE, eight states (California, Hawaii, Illinois, Maryland, Michigan, Minnesota, New York, and Oregon) have proposed bills to restrict decaBDE, and one state (Connecticut) has proposed a bill restricting certain PBDEs.

Many issues and challenges remain: landfill disposal and release of PBDEs into the air and wastewater are major, unresolved issues; electronic equipment recycling plants are sources of PBDE release; and levels of PBDEs in people and wildlife need to be monitored to characterize trends over time. The potential of these substances to do harm, even if based on limited evidence, combined with documentation of their presence in breast milk and cord blood should be sufficient to trigger a search for alternative ways to obtain the flame retarding properties of these chemicals. And, if safer alternative ways of providing the same flame retarding function can be found, then the substitution should not have to wait for quantitative evidence showing that the estimated risk of potential health outcome exceeds an "acceptable" risk threshold.²⁵²

A critical lesson from the case of PBDEs is to think beyond chemical by chemical substitution and examine the functionality that one is trying to achieve, its need, and how that functionality can be achieved through safer chemistries or material designs. Further, given the transition from PBDEs to other brominated flame retardants that are being identified as chemicals of concern by

²⁴⁹ Canadian Environmental Law Association website, "Groups Call for Ban on All PBDEs." See www.cela.ca/newsevents/detail.shtml?x=3950.

²⁵⁰ Accessed at: www.chemicalsubstanceschimiques.gc.ca/decabde_e.html.

²⁵¹ *Canada Gazette*, Notices, Vol. 143, No. 13 — March 28, 2009. Accessed at: gazette.gc.ca/rp-pr/p1/2009/2009-03-28/html/notice-avis-eng.html#d103.

²⁵² J. Tickner, and D. Kriebel, "The Role of Science and Precaution in Environmental and Public Health Policy," in *The Precautionary Principle and Public Policy Decision-making: A Prospective Analysis of the Role of the Precautionary Principle for Emerging Scientific and Technological Fields in Different Regions of the World*, ed. Fisher, Jones and von Schomberg, (London: Edward Elgar, 2006).

some government bodies and in the scientific literature (tetrabromobisphenol-a – TPPBA and hexachlorobromo dodecane – HCBDD) and that exhibit persistence, it is critical to take a broad approach to substitution to ensure that one problem is not substituted with another. Further, despite their benefits in flame retardancy, one approach may be a class based approach to avoid all chlorinated and brominated flame retardants given their propensity to be persistent, bioaccumulative and toxic (an approach to reduction of persistent and bioaccumulative chemicals recommended by the IJC in the past) when safer, functional alternatives have been identified. This is the approach being taken by some major corporations such as Dell and Apple.

Case Study: Triclosan

Triclosan is an antimicrobial pesticide traditionally only used in hospital settings. Today its more than 40 formulations have been approved for use in 140 kinds of consumer products, mainly in hand soaps and dish detergents. Triclosan falls under the regulatory direction of the *Federal Insecticide, Fungicide, and Rodenticide Act* which requires evidence of its antimicrobial properties, and the *Food Drug and Cosmetics Act* which oversees its antimicrobial use in over-the-counter applications such as toothpaste.²⁵³ Further, FDA regulates antimicrobial products, such as triclosan, differently depending on its use in a consumer product. If it kills germs for health purposes (gingivitis, for example) it is regulated as a pharmaceutical, if it is intended for cosmetic purposes, (deodorant, for example) it is regulated as a cosmetic, while if it is not intended for the human body, rather for use in a household cleaner, it is regulated as a pesticide by EPA.²⁵⁴ However the prevalence of triclosan in the environment and in the human body provides evidence that question the efficacy of current regulatory protections: 97 percent of women tested found triclosan in their breast milk; 75 percent of Americans over age 6 tested found triclosan in their urine; and 58 percent of rivers and streams tested have shown the presence of triclosan.²⁵⁵

Triclosan is increasingly being added to consumer products, often without consumer knowledge. One such consumer product is toothpaste, to which the American Dental Association has stated: “The use of antimicrobial agents such as triclosan in consumer products has not been studied extensively. No data exist to support their efficacy when used in such products or any need for them...it may be prudent to avoid use of antimicrobial products in consumer products.”²⁵⁶ The widespread-presence of triclosan has led some to worry that its constant use could lead to microbial resistance, and worse still, that antimicrobials may not protect us from bacteria and viruses any better than plain soap and water.²⁵⁷

²⁵³ Ann Blake, “Antimicrobials in Wastewater: Triclosan and Quats,” (Presented to National NAHMMA, October 15, 2008).

²⁵⁴ Aviva Galaser, “The Ubiquitous Triclosan: A Common Antibacterial Agent Exposed,” *Pesticides and You*, 24 no. 3 (2004), 12-17. Accessed at: www.beyondpesticides.org/pesticides/factsheets/Triclosan%20cited.pdf.

²⁵⁵ Environmental Working Group website, “Pesticide in Soap, Toothpaste and Breastmilk - Is it Kid-Safe?” (2007-2009). See www.ewg.org/reports/triclosan.

²⁵⁶ Aviva Galaser, “The Ubiquitous Triclosan: A Common Antibacterial Agent Exposed,” *Pesticides and You*, 24 no. 3 (2004), 12-17. Accessed at: www.beyondpesticides.org/pesticides/factsheets/Triclosan%20cited.pdf.

²⁵⁷ Ann Blake, “Antimicrobials in Wastewater: Triclosan and Quats,” (Presented to National NAHMMA, October 15, 2008).

In 2002 it was estimated that 95% of triclosan was used in consumer products which were used or disposed of through household drains and into wastewater treatment plants.²⁵⁸ This increase in use has resulted in an increase in the amount of triclosan that is sequestered in the sludge of wastewater treatment plants, quantities that have increased by 5 orders of magnitude since it was first used in consumer products. When these biosolids are used as fertilizer or otherwise applied to land surfaces, triclosan can degrade into chloroform or the carcinogen dioxin when exposed to sunlight. Triclosan in the human body has been shown to disrupt the body's hormones, particularly testosterone and estrogen.²⁵⁹

As early as 2000, similar findings in Europe led policy makers to publicly state that antimicrobial products were not only unnecessary for household use but were detrimental to aquatic environments and could lead to the creation of "super bugs" such as those seen after the overuse of penicillin.²⁶⁰ In the case of triclosan, its widespread use in an array of often-used products can contribute to the creation of antibacterial/antimicrobial resistant bacteria. Moreover, because triclosan persists in the environment, even diluted concentrations in the environment can lead to resistance over time.²⁶¹

²⁵⁸ Aviva Galaser, "The Ubiquitous Triclosan: A Common Antibacterial Agent Exposed," *Pesticides and You*, 24 no. 3 (2004), 12-17. Accessed at: www.beyondpesticides.org/pesticides/factsheets/Triclosan%20cited.pdf.

²⁵⁹ Ann Blake, "Antimicrobials in Wastewater: Triclosan and Quats," (Presented to National NAHMMA, October 15, 2008).

²⁶⁰ Aviva Galaser, "The Ubiquitous Triclosan: A Common Antibacterial Agent Exposed," *Pesticides and You*, 24 no. 3 (2004), 12-17. Accessed at: www.beyondpesticides.org/pesticides/factsheets/Triclosan%20cited.pdf.

²⁶¹ Teresa M. Barbosa, and Stuart B. Levy, "The Impact of Antibiotic Use on Resistance Development and Persistence," *Drug Resistances Updates*, 3 (2000), 303-311.

