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*L'Association canadienne du droit de l'environnement*



Lowell Center for  
Sustainable Production  
UNIVERSITY OF MASSACHUSETTS

# **The Challenge of Emerging Substances of 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

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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 “emerging contaminants or chemicals of 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 “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 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 is necessary in efforts to ensure the quality of the Great Lakes ecosystem is protected. By moving upstream and considering toxicity and physical properties of chemicals at the chemical and product design stage and making changes in product and process design to employ less toxic and less bioavailable substances, the accumulation of these chemicals in the Great Lakes Basin may be preventable.

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 identification, assessment, and prevention of the range of emerging chemicals of 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.) relevant to being undertaken in both countries. These inventories along with the results of this analysis and database of scientific studies on emerging chemicals of concern will serve to inform recommendations made by the Work Group to the IJC Commissioners.

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

- 1) Chemicals identified in an emerging chemicals of 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 emerging chemicals of 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 binational efforts. Building on a vision that a prevention approach to address toxic substances is the most effective 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 adoption of safer alternatives for a broad range of chemical types before they become chemicals of concern?
2. What are the specific challenges of addressing emerging chemicals of concern in the region?
3. What policies and approaches are required to address emerging chemicals 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., states 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 Great Lakes vision of prevention;
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 emerging chemicals of concern from entering the Great Lakes Basin and recommendations 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 prevent the introduction of a broad range of emerging chemicals of concern into the Great Lakes Basin. The Great Lakes community is not alone in taking an approach to emerging chemicals of concern that focuses on artificial legal and jurisdictional approaches to 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.

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

1. The lack of an integrated system for the prevention of emerging chemicals of 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 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 emerging chemicals of 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 or non-chemical alternatives 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.

While the Great Lakes can always benefit from improved controls on industrial processes and improved water treatment systems, most of the significant new strides will 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 emerging chemicals of concern will include processes for rapid characterization of hazards and exposures prevention and controls (for example in the workplace or wastewater treatment).

The *Great Lakes Water Quality Agreement* and subsequent reports by the IJC set the stage for a visionary, prevention-oriented approach to the management of chemicals of concern in the Great Lakes Basin. The region's 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 Minnesota and New York and the province of Ontario, are engaged in discussions to develop comprehensive toxics reduction policies for industrial chemicals. The IJC Commissioners can demonstrate Great Lakes leadership in chemicals policy by advancing an integrated, prevention-based strategy for emerging chemicals of concern.

Based on the findings of our report, we propose the following recommendations to the Multi-Board Work Group on Chemicals of Emerging Concern in the Great Lakes (See Part 4 of the Report).

***Establish a Binational Strategy on Emerging Chemicals of Concern based on precaution and prevention.***

**Recommendation 1**

The IJC should urge the Parties to establish an intergovernmental taskforce on emerging chemicals of concern to develop a binational strategy for such chemicals that spans jurisdictional boundaries and focuses on approaches to ensure redesign of such chemicals toward safer alternatives. The taskforce would establish processes and authorities to implement the actions described below.

***Establish a Great Lakes rapid identification and screening process for chemicals of concern.***

**Recommendation 2**

Building on existing national programs of Canada and the U.S. as well as the GLWQA List and reviewing data from other jurisdictions for identification and screening substances of concern, the IJC should seek to establish a Great Lakes screening process for emerging chemicals of concern. The IJC process should use the criteria established under the GLWQA for persistence, bioaccumulation and/or toxicity, which would include carcinogenicity, reproductive and developmental toxicity, neurodevelopmentality, genotoxicity, respiratory toxicity, skin sensitization, 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 should be based on the most conservative criteria adopted internationally.

### **Recommendation 3**

Similarly, the IJC or other Great Lakes binational agency should apply an identification and screening process to chemicals used in drugs, other pharmaceutical products and nanomaterials that effectively characterizes their uses, possible exposures, and fate in the environment.

***Publish a Great Lakes List of Chemicals of Concern.***

### **Recommendation 4**

Building on the work of government scientists, Muir and Howard, and those of the national programs, substances should be identified and ranked as to their potential to become a chemical of concern in the Great Lakes Basin as high, medium, or low concern.<sup>1</sup> Substances with inadequate data needed for making such a categorization should be automatically considered as high concern. The results of this process should be widely publicized as a Great Lakes List of Chemicals of Concern. This list would be a tool to inform regulatory-, market-, research and innovation, and educational activities that support implementation of safer alternatives. A timeframe of two years to complete this process should be required.

***Action plans should be developed and implemented for chemicals identified under the Great Lakes List of Chemicals of Concern to achieve the goals outlined under the GLWQA, particularly prevention and application of safer alternatives.***

### **Recommendation 5**

The IJC should recommend that Parties commit to the development and implementation of mandatory action plans to substitute or prohibit chemicals of high concern listed in the Great Lakes List of Chemicals of Concern as well as develop action plans to reduce and ultimately substitute with substances of medium and low concern.

All action plans should include time-limited mandatory processes and programs that achieve pollution prevention through substitution with safer, technologically feasible alternatives, product redesign, and mandatory restrictions where necessary. Such action plans should prioritize high concern chemicals for preventive actions. Action plans should also consider end of life take-back considerations for products containing chemicals of concern. Given the variety and number of such chemicals, action plans should be developed in as expedient a manner as possible.

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<sup>1</sup> 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 Binational Toxics Strategy Meeting, Chicago, IL, 2008).

### **Recommendation 6**

To support these action plans, the IJC should urge the Parties to establish a binational 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.

#### ***Establish a Public Database and Clearinghouse of Information on Chemicals of Concern for the Great Lakes Basin.***

### **Recommendation 7**

The IJC should recommend to the Parties, the development 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. Such a database can provide government agencies and the public a vital source of information to track flows of emerging chemicals of concern in the Great Lakes Basin. This database would supplement existing pollutant inventories in Canada and in the United States, which apply to chemicals in medium to large scale manufacturing.

#### ***Ensure greater accountability by producers, users, vendors, importers, and disposers of chemicals, drugs, and nanomaterials in the Great Lakes Basin.***

### **Recommendation 9**

The IJC should urge the Parties to 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.

## 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.<sup>2</sup> 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 “emerging contaminants or chemicals of 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;
- contaminants entering the lakes through sewage treatment plants and overflows, such as ingredients in cosmetics, pharmaceuticals, and possibly nanomaterials;<sup>3</sup>
- contaminants, such as pesticides entering from run-off; and,
- end of life exposures, such as mercury from landfills.

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<sup>2</sup> 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](http://www.PollutionWatch.org)), and a joint project by CELA and Environmental Defence.

<sup>3</sup> 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.”

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 in part 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 source of contamination posing a threat to the health of the Great Lakes. The accumulation of these substances in the Great Lakes Basin may be preventable by taking the following steps: by looking upstream and considering toxicity and physical properties of chemicals at the chemical and product design stage and making changes in product and process design to employ less toxic and less bioavailable substances.

### ***Addressing Emerging Chemicals of Concern***

The term, “emerging chemicals (or contaminants) of 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.”

Emerging contaminants 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, an ability to detect at a lower concentration, or in new environmental compartments.

The second category makes up the vast majority of emerging contaminants. The types of chemicals defined as emerging contaminants 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 “emerging chemicals of concern” to include:

- 1) Chemicals identified in an emerging chemicals of concern report developed for the International Joint Commission (see Table 1);<sup>4</sup>
- 2) Chemicals which are persistent or bioaccumulative or toxic according to criteria outlined in the *Great Lakes Water Quality Agreement*;<sup>5</sup>

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<sup>4</sup> Keri Hornbuckle and Carolyn L. Persoon, *Bibliography of Emerging Chemical of Concern in the Great Lakes*, Prepared for the International Joint Commission, (2008).

3) Chemicals that may or may not have been detected in the Great Lakes Basin, but which are included in the categories of emerging chemicals of 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**

<b>Chemicals identified as Emerging Chemicals</b>
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 wildlife species.

As noted, due to the wide range of materials included in the definition of emerging chemicals of concern and their multiple sources, the 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 affect 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.

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<sup>5</sup> 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, emerging chemicals may be persistent, or bioaccumulative or toxic or any of the 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 prevention of the range of emerging chemicals of concern. The results of this analysis and the database of scientific studies on emerging chemicals of 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 was prepared as part of this project. CELA and 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 binational efforts. Building on a vision that a prevention approach to address toxic substances will be the most effective in the Great Lakes Basin, 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 adoption of safer alternatives for a broad range of chemical types before they become contaminants of concern?
2. What are the specific challenges of addressing emerging chemicals of concern in the region?
3. What policies and approaches are required to address emerging chemicals in the Great Lakes Basin?

The analysis is substantially focused on the current approach taken to 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. Many of these also do not directly address the goal of source prevention – eliminating the hazard in the first place at the product design or production stage. These laws tend to limit exposures but will not prevent their emission into the Basin. It is important to note that some existing legislation does include provisions for pollution prevention measures.

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.<sup>6</sup> In the U.S., states have implemented significant programs to regulate

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<sup>6</sup> 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.

chemicals and pesticides. Clearly, both federal, provincial and state programs and policies reduce the entrance of emerging chemicals of 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 Great Lakes vision of prevention;
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 emerging chemicals of concern from ending up in the Basin and recommendations 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 emerging chemicals of concern in the Basin. The Great Lakes is not alone in this approach to emerging chemicals of concern that focuses on artificial legal and jurisdictional approaches to 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-based strategy for emerging chemicals of concern.

### ***The Preventive Vision for Persistent Chemicals 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 effective chemicals policy grounded in 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.<sup>7</sup>

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.<sup>8</sup>

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.”<sup>9</sup>

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 binational 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.*”<sup>10</sup> As a result, both governments made significant progress to reduce these chemicals through bans on specific uses of chemicals and implementation of control measures.

Today the challenges posed by the on-going emission releases, exposure and 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 scientists are finding a new generation

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<sup>7</sup> *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.

<sup>8</sup> *Ibid.* Article 2.

<sup>9</sup> 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).

<sup>10</sup> *Ibid.* Annex 12.

of chemicals building up in the Great Lakes 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.<sup>11</sup> 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 contaminants, they can pass unidentified through treatment and into the environment.<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup>

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.<sup>15</sup> Discharge limits have been established for what EPA refers to as conventional pollutants (fecal bacteria, etc.), non conventional pollutants (phosphorus, for example), and toxic

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<sup>11</sup> 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](http://www.ecojustice.ca/publications/reports/the-green-infrastructure-report/attachment).

<sup>12</sup> The Groundwater Foundation, "Pharmaceuticals and Personal Care Products: An Emerging Issue." Accessed at: [www.groundwater.org/gi/docs\\_pack/fa13.pdf](http://www.groundwater.org/gi/docs_pack/fa13.pdf).

<sup>13</sup> Niklas Rickland, Amelie Kierkegaard, Michael S. McLacklan and Cajsa Wahlberg, "Mass Balance of Decabromodiphenyl Ethane and Decabromodiphenyl Ether in WWTP," *Chemosphere*, (2008).

<sup>14</sup> 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](http://pubs.acs.org/cgi-bin/article.cgi/esthag/2002/36/i06/html/es011055j.html).

<sup>15</sup> U.S. Environmental Protection Agency, *National Pollution Discharge Elimination System (NPDES)*. Accessed at: [cfpub.epa.gov/npdes/](http://cfpub.epa.gov/npdes/).

pollutants (some 60 substances) as defined by the *Clean Water Act*, which includes pesticides, volatile organic compounds, PCBs, and some metals,<sup>16</sup> 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.<sup>17</sup> 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 treatment as they were prior) so it is possible for these biosolids to accrue high levels of dangerous materials.<sup>18</sup>

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. Emerging contaminants, such as pharmaceuticals, flame retardants or even nanoparticles are therefore not within the scope of this biosolids rule.<sup>19</sup>

While EPA maintains that use of appropriate biosolids as fertilizer is safe, 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.<sup>20</sup>

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<sup>16</sup> Wastewater Engineering Virtual Library, *Overview of Federal Wastewater Discharge Limits*. Accessed at: [www.cleanh2o.com/ww/limits.html](http://www.cleanh2o.com/ww/limits.html).

<sup>17</sup> Great Lakes Sustainability Fund. Accessed at: [sustainabilityfund.gc.ca/default.asp?lang=En&n=68D63344-1#stp](http://sustainabilityfund.gc.ca/default.asp?lang=En&n=68D63344-1#stp).

<sup>18</sup> Mary Lee Dunn, "Sewage Sludge Draws New Attention," *New Solutions*, 13 no. 4 (2003), 341-348.

<sup>19</sup> 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](http://www.epa.gov/OW-OWM.html/mtb/biosolids/503pe/503pe_1.pdf).

<sup>20</sup> Mary Lee Dunn, "Sewage Sludge Draws New Attention." *New Solutions*, 13 no. 4 (2003), 341-348.

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.<sup>21</sup> 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.<sup>22</sup> 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 metals.<sup>23</sup> 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.)<sup>24</sup> to the Sewer Use By-law and the requirements for pollution prevention plans.

Creative wastewater treatment techniques may be more successful in removing emerging contaminants than traditional systems and could act as a short term solution for preventing these substances from entering the environment. 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.<sup>25</sup> 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.<sup>26</sup> 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.<sup>27</sup> While these techniques produce cleaner effluent, they do not solve the problem of contaminated biosolids.

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<sup>21</sup> Canadian Council of Ministers for the Environment, *Municipal Wastewater Effluent*. Accessed at: [www.ccme.ca/ourwork/water.html?category\\_id=81](http://www.ccme.ca/ourwork/water.html?category_id=81).

<sup>22</sup> 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](http://www.ecojustice.ca/publications/reports/the-green-infrastructure-report/attachment).

<sup>23</sup> City of Toronto, Sewer Use By-law, *Municipal Code*, Chapter 681. Accessed at: [www.toronto.ca/legdocs/municode/1184\\_681.pdf](http://www.toronto.ca/legdocs/municode/1184_681.pdf).

<sup>24</sup> David McKeown, "Human Health and Ecological Assessment of Toronto Biosolids Pellet: Technical Summary," (Toronto: Medical Office of Health, Toronto Public Health, November 2004).

<sup>25</sup> 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.

<sup>26</sup> 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).

<sup>27</sup> 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).

In addition to the inability of wastewater treatment plants to fully prevent direct or indirect (e.g. biosolids) introduction of emerging chemicals of 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 emerging chemicals of concern into the Basin.

## **PART 2 – Canadian Analysis and Findings**

This section reviews the most relevant Canadian legislation with respect to the entry of emerging chemicals of concern into the Great Lakes. In separate sections, we examine the *Canadian Environmental Protection Act* and the Chemicals Management Plan; procedures for new chemicals under the *New Substances Notification Regulations*, the *Food and Drugs Act* and the *Pest Control Products Act*. In Canada, the primary responsibility for chemicals policy resides with the federal government, where the primary decisions are made on 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 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.<sup>28</sup>

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<sup>28</sup> 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

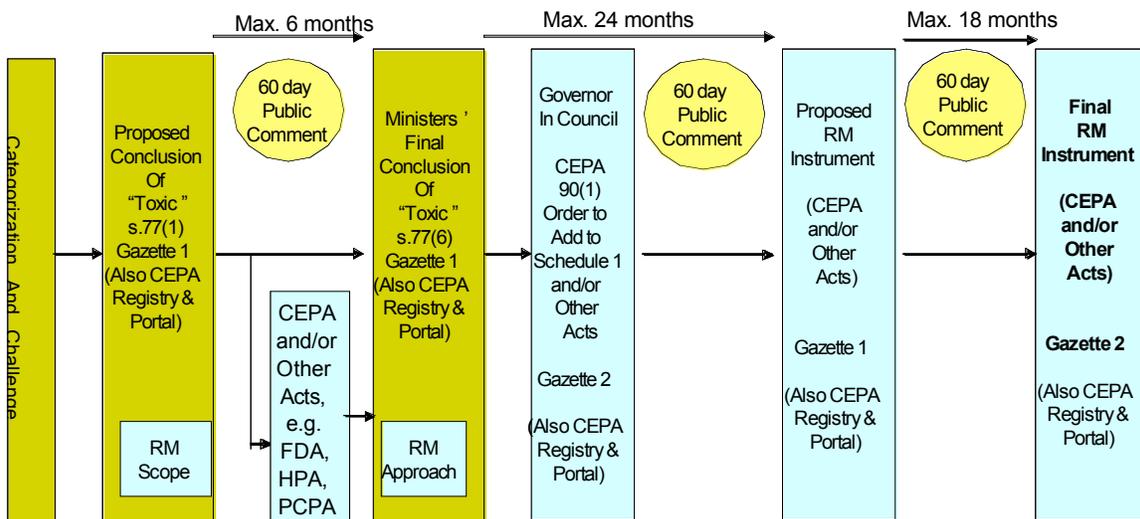
(c) constitute or may constitute a danger in Canada to human life or health."

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.

### 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.<sup>29</sup>

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.

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<sup>29</sup> 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.<sup>30</sup>

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<sup>30</sup> 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](http://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.<sup>31</sup>

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.<sup>32</sup> 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.<sup>33</sup>

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

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<sup>31</sup> 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](http://www.oag-bvg.gc.ca/internet/English/parl_cesd_200803_01_e_30127.html#ch1hd5d).

<sup>32</sup> 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](http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/psl1-lsp1/paraffins-paraffines/paraffins-paraffines-eng.pdf).

<sup>33</sup> 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](http://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.

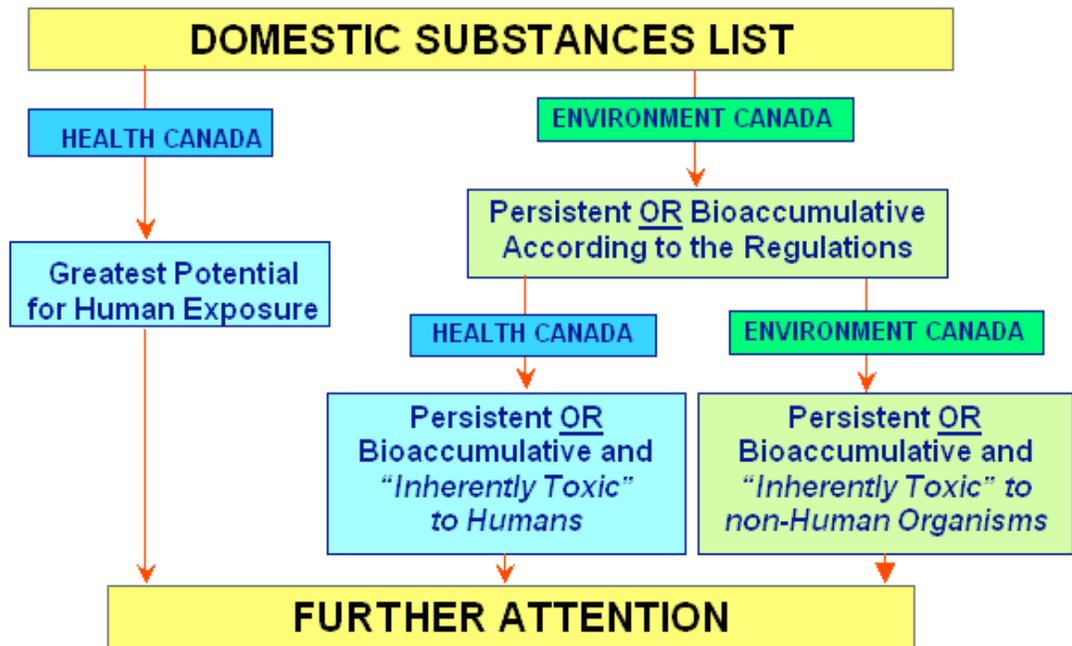
To meet the GLWQA's goals, only a complete prohibition on CPs and the substitution of safer alternatives or process changes would eliminate discharges and non-point source releases into the Great Lakes.

### *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.



Source: Government of Canada, Categorization. Chemicals Management Plan, 2008

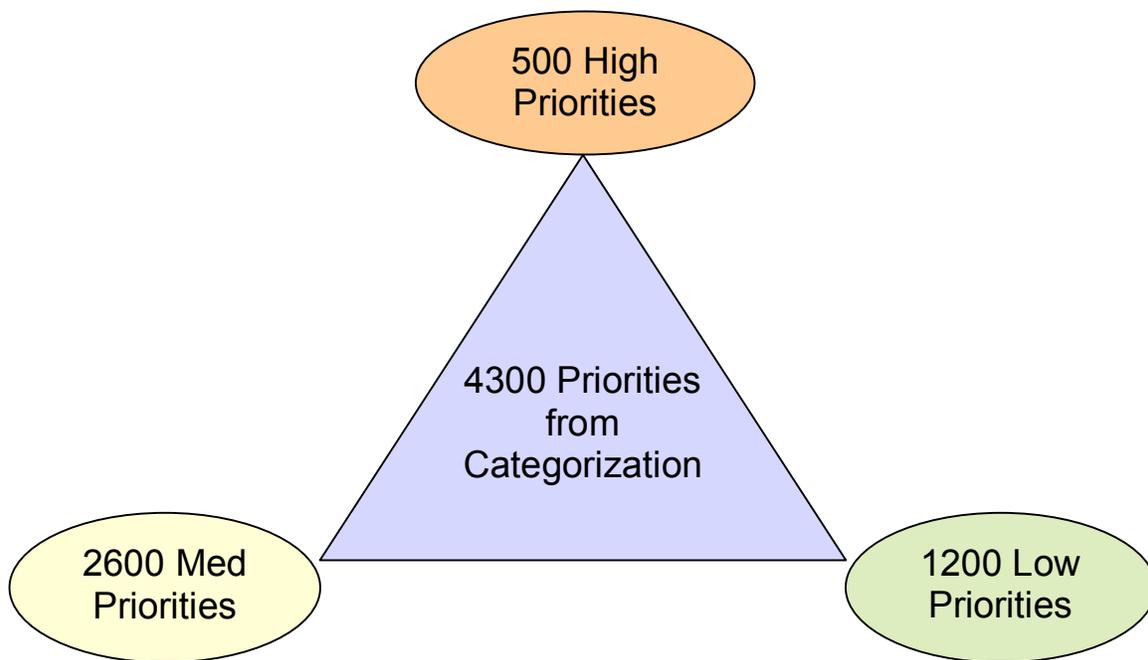
*What were the implications of categorization for emerging chemicals?*

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 the two 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 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 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). Then 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 emerging chemicals of concern in the Great Lakes.<sup>34</sup>

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.<sup>35</sup>

The highest concentrations accumulated in fish from the lower Great Lakes were from three major synthetic musks, Galaxolide® (HHCB), Tonalide® (AHTN), Traseolide®(ATII), respectively.<sup>36</sup> 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.<sup>37</sup>

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

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

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

<sup>36</sup> 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.

<sup>37</sup> 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.<sup>38</sup> 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 and therefore 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.<sup>39</sup>

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, 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

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

<sup>39</sup> 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 environment 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, then 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 emerging chemicals of concern in the Great Lakes.<sup>40</sup>

**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 emerging chemicals of 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)<sup>41</sup> and the *Stockholm Convention on Persistent Organic Pollutants* (POPs) (see box at the end of this section).

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<sup>40</sup> 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/CEPARegistry/subs\\_list/dsl/DSLsearch.cfm?critSearch=PB](http://www.ec.gc.ca/CEPARegistry/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.

<sup>41</sup> Accessed at: [www.epa.gov/champ/pubs/basic.htm](http://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.<sup>42</sup> Exposure was the more important parameter for consideration. The end result of the health assessment is a chemical

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<sup>42</sup> 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).

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 in 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, 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.<sup>43</sup>
- 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 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 approach focused on data rich substances and using models to fill in data on substances that had limited or no data.

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

- 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, 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.<sup>44</sup> 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.
- 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

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<sup>44</sup> 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).

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 Binational 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.”<sup>45</sup> 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 to the public, it is very difficult to assess the effectiveness of such plans in reductions or prevention.

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

**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.”<sup>46</sup> 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 to achieve this purpose. 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 of 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 tetrachloroethylene) took over 10 years from being a proposed CEPA toxic substance to the development and finalization of a pollution prevention plan. In

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<sup>46</sup> 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](http://www.ec.gc.ca/substances/ese/eng/challenge/batch1/batch1_54079-53-7_rm.cfm#9).*

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).<sup>47</sup> 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 considers a chemical bioaccumulative with a bioconcentration factor of greater than or equal to 5,000, whereas this is more than double the REACH criteria (BCF>2,000). The criteria for

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

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  $\log K_{ow}$  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*

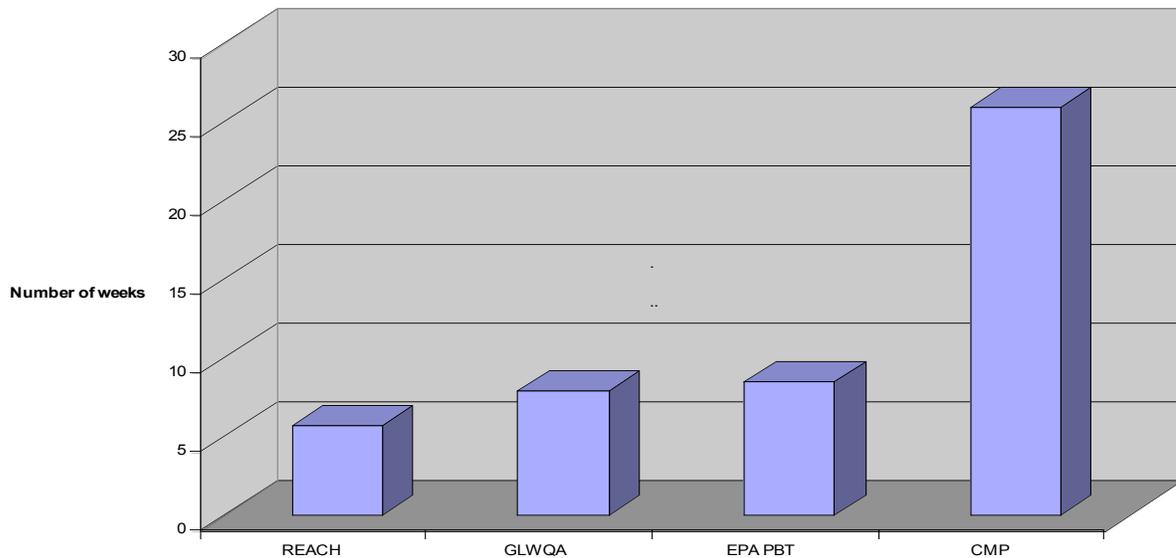
The P, B, iTe criteria used in CMP are much higher than those used in the *Great Lakes Water Quality Agreement*, the European REACH, and the U.S. PBT and CHAMP and Organisation for Economic Cooperation and Development (OECD) programs. This difference in criteria results in an uneven playing field, such 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.

### One Word, Persistence and four different meanings

Number of weeks required to consider a chemical persistent in water



## 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.<sup>48</sup> 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 emerging chemicals of concern.<sup>49</sup> 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.<sup>50</sup>

### *How do the New Substances Notification Regulations Work?*

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

<sup>49</sup> 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](http://www.chemicalsubstanceschimiques.gc.ca/organotins-organostanniques_e.html).

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

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.<sup>51</sup> 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.

#### *Quantities between 100 to 1,000 kilograms*

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

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.<sup>52</sup>

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.<sup>53</sup> 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.

#### *Quantities over 10,000 kilograms*

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<sup>52</sup> *New Substances Notification Regulations*, Schedule 4.

<sup>53</sup> NSNR, Schedule 5.

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.<sup>54</sup> 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 only required to provide this information 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:<sup>55</sup>

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

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<sup>54</sup> NSNR, Schedule 6.

<sup>55</sup> CEPA, Section 84 and 85.

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.<sup>56</sup>

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.<sup>57</sup> 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 Notice.

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.

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

<sup>57</sup> 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](http://canadagazette.gc.ca/partI/2006/20060617/html/regle1-e.html).

When a substance is suspected to be 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.<sup>58</sup>

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 developing mesothelioma.<sup>59</sup> Another study demonstrated that silver nanomaterials – used

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

<sup>59</sup> 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](http://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](http://hesa.etui-rehs.org/uk/dossiers/files/The%20Lancet%20Nano.pdf).

extensively for a variety of antimicrobial applications – pose potential hazards in aquatic animals.<sup>60</sup>

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.<sup>61</sup>

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.<sup>62</sup> In Canada, approximately 80 companies are marketing products with nanomaterials.<sup>63</sup>

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

Only new substances, such as carbon nanotubes, are governed by the NSNR 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 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.

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<sup>60</sup>Michael Berger, "Problematic new findings regarding toxicity of silver nanoparticles," (June 6, 2008). Accessed at: [www.nanowerk.com/spotlight/spotid=5966.php](http://www.nanowerk.com/spotlight/spotid=5966.php).

<sup>61</sup>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.

<sup>62</sup>The Project for Emerging Nanotechnologies, (2009). Accessed at: [www.nanotechproject.org/inventories/consumer/](http://www.nanotechproject.org/inventories/consumer/)

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

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).<sup>64</sup> 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.

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.<sup>65</sup>

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<sup>64</sup> 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.

<sup>65</sup> 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.

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.<sup>66</sup>

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

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<sup>66</sup> Ibid.

## **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 emerging problem chemicals 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 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.<sup>67</sup>

**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.

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<sup>67</sup>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](http://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.<sup>68</sup> 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.<sup>69</sup> 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.<sup>70</sup>

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.<sup>71</sup> As a result, pharmaceuticals and personal care products are now being recognized as a widespread source of water pollution. They are considered to be emerging chemicals of 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 by people, hospitals or long-term care facilities down the sink or into the toilet. 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 is managed as

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<sup>68</sup> Ibid, p.8.

<sup>69</sup> 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.

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

<sup>71</sup> 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.<sup>72</sup>

Some pharmaceuticals and some ingredients in personal care products, such as musk fragrances, are persistent.<sup>73</sup> 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.<sup>74</sup>

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<sup>72</sup> 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*.

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

<sup>74</sup> 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, 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.”<sup>75</sup> 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.<sup>76</sup> 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 substances in products regulated under the F&DA, such as pharmaceuticals or genetically

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<sup>75</sup> *Food and Drugs Act*, Section 2.

<sup>76</sup> 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).

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.<sup>77</sup>

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.<sup>78</sup> 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

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<sup>77</sup> Ibid.

<sup>78</sup> 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.<sup>79</sup> 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:

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<sup>79</sup> 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.<sup>80</sup> 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

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<sup>80</sup> 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 FDA-regulated products.<sup>81</sup> 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.

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<sup>81</sup> 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](http://www.ec.gc.ca/substances/ese/eng/challenge/batch1/batch1_123-31-9_rm.cfm).

## Triclosan: Case Study

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.<sup>82</sup>

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.<sup>83</sup>

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.”<sup>84</sup>

Triclosan has been identified as a high production volume substance with 1 million pounds used or manufactured in the U.S.<sup>85</sup> 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

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

<sup>83</sup> 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](http://www.cdc.gov/exposurereport/pdf/factsheet_triclosan.pdf).

<sup>84</sup> Ibid.

<sup>85</sup> Green Media Toolshed, *Pollution in Your Community*, (2005). Accessed at: [www.scorecard.org](http://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 emerging chemicals of 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.<sup>86</sup> 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.

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

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<sup>86</sup> Health Canada, "Issue identification Paper: Environmental Assessment Regulations," p. 13.

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.<sup>87</sup>

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.<sup>88</sup>

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.<sup>89</sup> The Ontario Pesticides Advisory Committee is also reviewing pesticide products and recommending

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

<sup>88</sup> CEPA, ss. 81(6)(a).

<sup>89</sup> 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,<sup>90</sup> formulants,<sup>91</sup> and contaminants.<sup>92</sup> 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.<sup>93</sup> 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

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<sup>90</sup> Registration Requirements for Adjuvant Products, Regulatory Directive 93-15. Accessed at: [www.pmra-arla.gc.ca/english/pdf/dir/dir9315-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/dir/dir9315-e.pdf).

<sup>91</sup> Formulants Program, Regulatory Directive 2004-01. Accessed at: [www.pmra-arla.gc.ca/english/pdf/dir/dir2004-01-e.pdf](http://www.pmra-arla.gc.ca/english/pdf/dir/dir2004-01-e.pdf).

<sup>92</sup> 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](http://www.pmra-arla.gc.ca/english/pdf/dir/dir9804-e.pdf).

<sup>93</sup> 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.<sup>94</sup>

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.

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<sup>94</sup> Science Policy Notice SPN2001-0. Accessed at: [www.pmra-arla.gc.ca/english/pdf/spn/spn2001-01-e.pdf](http://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,<sup>95</sup> 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.<sup>96</sup>

## **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

<sup>95</sup> 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](http://www.ec.gc.ca/toxics/TSMP/en/criteria.cfm).

<sup>96</sup> 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  $\geq 3$ . Like the persistence analysis described above, this requirement is based on intended use.<sup>97</sup>

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.<sup>98</sup> In such a case, the active ingredient would be assessed against the TSMP "Track 1" criteria.<sup>99</sup>

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

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

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

<sup>99</sup> TSMP Track 1 substances targeted for virtual elimination. Accessed at: [www.ec.gc.ca/toxics/TSMP/en/track1.cfm](http://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.<sup>100</sup>

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.<sup>101</sup> 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.<sup>102</sup>

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.”<sup>103</sup> In the meantime, however, a number of pest control products containing endosulfan are still registered for use in Canada.<sup>104</sup>

### *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.

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<sup>100</sup> TSMP Track 2 substances are managed through a life cycle management approach. Accessed at: [www.ec.gc.ca/toxics/TSMP/en/track2.cfm](http://www.ec.gc.ca/toxics/TSMP/en/track2.cfm).

<sup>101</sup> The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy, Regulatory Directive 99-03. Accessed at: [www.pmr-arla.gc.ca/english/pdf/dir/dir9903-e.pdf](http://www.pmr-arla.gc.ca/english/pdf/dir/dir9903-e.pdf).

<sup>102</sup>, Regulatory Directive DIR99-03, *ibid*.

<sup>103</sup> PMRA Preliminary Risk and Value Assessments of Endosulfan, (2007). Accessed at: [www.pmr-arla.gc.ca/english/pdf/rev/rev2007-13-e.pdf](http://www.pmr-arla.gc.ca/english/pdf/rev/rev2007-13-e.pdf).

<sup>104</sup> See [pr-rp.pmr-arla.gc.ca/PR\\_SOL/PUBLIC\\_REGISTRY.LBL\\_RESULTS](http://pr-rp.pmr-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.<sup>105</sup>

*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.<sup>106</sup> 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.<sup>107</sup>

*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

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

<sup>106</sup> PCPA, ss. 35(1)-(3).

<sup>107</sup> The registry is available at: [www.pmra-arla.gc.ca/english/pubreg/pubreg-e.html](http://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.<sup>108</sup>

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.<sup>109</sup> 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

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<sup>108</sup> PCPA, s. 16(1).

<sup>109</sup> 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.<sup>110</sup> The PMRA has decided not to launch special reviews of these substances because many of them are subject to re-evaluation requirements.<sup>111</sup>

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<sup>110</sup> David Suzuki Foundation Request for Review, (June 28, 2006). Accessed at: [www.davidsuzuki.org/files/WOL/June\\_28\\_06\\_Pesticides.pdf](http://www.davidsuzuki.org/files/WOL/June_28_06_Pesticides.pdf).

<sup>111</sup> 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](http://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.<sup>112</sup> 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.<sup>113</sup>

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.<sup>114</sup>

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-

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<sup>112</sup>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](http://www.cec.org/files/PDF/POLLUTANTS/LindaneNARAP-Nov06_en.pdf).

<sup>113</sup>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](http://chm.pops.int/Convention/POPsReviewCommittee/RecommendationsofthePOPRC/tabid/440/language/en-US/Default.aspx).

<sup>114</sup>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](http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_corp-plan/report-lindane-rapport/index-eng.php).

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.<sup>115</sup>**

- 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.<sup>116</sup> 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 emerging chemicals of 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.

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<sup>115</sup> 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.

<sup>116</sup> 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."<sup>117</sup>

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**

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<sup>117</sup> *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 emerging chemicals of 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, state and regional policies regarding emerging chemicals of 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, state, and local levels; (3) a detailed review of important federal statutes, policies and programs relevant to emerging chemicals of concern in the Great Lakes Basin; and (4) an analysis of their strengths and weaknesses with regards to identification, characterization and prevention of emerging chemicals of concern. 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 emerging chemicals of concern in the Great Lakes Basin.

As noted in the introduction, the emerging chemicals of 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 primary prevention of emerging chemicals of concern and ways to advance a more comprehensive approach to prevention of emerging chemicals of concern in Section 3.5. *It is important to reiterate that our focus is on policies and programs that address rapid identification, characterization and primary prevention of emerging chemicals of concern and not on policies that would manage emissions or waste of such materials.* Such policies are not preventive in nature and given the myriad of different types of chemicals of concern are likely to be inefficient in achieving prevention.

### **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.<sup>118</sup>

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,

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<sup>118</sup>Robert Glicksman, “From Cooperative to Inoperative Federalism: The Perverse Mutation of Environmental Law and Policy,” *Wake Forest Law Review*, 41 (2006), 719-803.

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 emerging chemicals of 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

### ***3.2 Review of Inventory of Policies and Programs Pertaining to Emerging Chemicals of 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 emerging chemicals of 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 and programs that would affect inputs of emerging chemicals of concern in the Great Lakes region.

Our research efforts identified 222 currently enacted statutes, policies and programs that address emerging chemicals of concern in the Great Lakes Region. These include international (9), federal (28), regional (4), state (95) and municipal (86) 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 an analysis of the efficacy of the myriad of local, state and federal policies which would be beyond the scope of this project. However, some of the most relevant policies and programs are reviewed in detail in the following sections.

#### ***International***

Our database highlights nine international efforts that may address emerging chemicals of 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 binational 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 twenty-eight federal efforts – legislation, policy, and programs - that may address emerging chemicals of 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 emerging chemicals of 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 emerging chemicals of concern in the future.

### ***State and Municipal***

Our database highlights ninety-five state and eighty-six municipal efforts that may address emerging chemicals of 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. Six Great Lakes states (IL, IN, MI, MN, NY 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 (NY) has restricted the use of chromated copper arsenate.

One Great Lakes state (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 Wisconsin regulates “hazardous substances” while 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 labelling/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 states (IL and MI) and one municipality (MN) have enacted legislation that regulates children's products or toys. Two Great Lakes States (IL and NY) 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 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 (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); lead (MI, MN, and NY); mercury (MI, NY, OH, and PA); 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 and WI); toxic substances (MI); and xenoestrogens (PA). New York and Minnesota 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: children's products (IL, IN, MI, MN, NY and WI) and cosmetics (IL and NY). The legislation proposed to regulate children's products includes restrictions on phthalates (IL, MN, and NY) and bisphenol A (MN and NY), lead (IN) and toxic substances (MI). Additionally, children's product legislation proposed in Illinois and Wisconsin seeks to designate priority chemicals of concern and regulate these chemicals in children's products. The proposed legislation in Illinois and Wisconsin 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: pollution prevention (NY which recently established a pollution prevention institute and PA); biomonitoring (IN); environmental health tracking (NY); product stewardship (electronics-IL, IN, MI, WI, NY, PA; 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 preemption laws that prohibit local governments from restricting the use, sales and distribution of pesticides. However, these preemption 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.

## **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.<sup>119</sup>

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

LEVEL OF POLICY/PROGRAM	DETAILED OVERVIEW OF CURRENTLY ENACTED POLICIES/PROGRAMS
International	<ul style="list-style-type: none"> <li>• 9 Policies/Programs</li> <li>• Most are voluntary commitments.</li> <li>• Includes binational efforts to address chemicals in the Great Lakes specifically as well as broader international efforts that may ultimately impact the Great Lakes Region.</li> <li>• Focus on chemical properties rather than chemical class (i.e. industrial chemicals, pesticides, pharmaceuticals, etc.).</li> <li>• Employ a number of different policy strategies, including pollution prevention, chemical restrictions, prioritization, data collection, alternatives assessment, right-to-know, and product stewardship.</li> </ul>
Federal	<ul style="list-style-type: none"> <li>• 28 Policies/Programs</li> <li>• Focus on single classes of chemicals (i.e. industrial chemicals, pesticides, consumer products, pharmaceuticals, etc.).</li> <li>• 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.</li> <li>• Some attempts to establish and promote regional efforts in the Great Lakes.</li> </ul>
Regional	<ul style="list-style-type: none"> <li>• 4 Policies/Programs</li> <li>• Focus on frameworks for coordinated action in the Great Lakes Region.</li> </ul>
State/Municipal	<ul style="list-style-type: none"> <li>• 95 State Policies/Programs; 86 Municipal Policies/Programs</li> <li>• <u>INDUSTRIAL CHEMICALS</u> <ul style="list-style-type: none"> <li>• <i>Pollution Prevention</i>—Seven Great Lakes states (IL, IN, MI, MN, NY, OH, WI) have implemented multi-pollutant, multi-media</li> </ul> </li> </ul>

<sup>119</sup> 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/](http://www.springerlink.com/content/j453163328217214/).

	strategies that shift the focus from end-of-pipe regulation to reduction of pollution at the source.
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LEVEL OF POLICY/PROGRAM	DETAILED OVERVIEW OF CURRENTLY ENACTED POLICIES/PROGRAMS
State/Municipal (cont.)	<ul style="list-style-type: none"> <li>• <u>INDUSTRIAL CHEMICALS</u> (cont.) <ul style="list-style-type: none"> <li>• <i>Single Chemical Restrictions</i>—Four Great Lakes states (IL, MI, MN and NY) have banned pentabrominated diphenyl ether and octabrominated diphenyl ether. Six Great Lakes states (IL, IN, MI, MN, NY 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.</li> <li>• <i>Multiple Chemical Policies</i>—One Great Lakes state (WI) has enacted legislation that regulates "hazardous substances" and two municipalities (NY(2)) have enacted policies that encourage the reduction of pollution from PBTs.</li> <li>• <i>Regulation of Product Categories</i>—Five Great Lakes states (IL, MN, NY, PA, WI) have enacted toxics in packaging laws. Two Great Lakes states (IL, MI) and one municipality (MN) have enacted legislation that regulates children's products or toys. Two Great Lakes states (IL, NY) 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.</li> <li>• <i>Biomonitoring</i>—Two Great Lakes states (IL, MN) have enacted biomonitoring legislation.</li> <li>• <i>Green Chemistry</i>—One Great Lakes state (MI) has issued an executive directive on green chemistry.</li> <li>• <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.</li> <li>• <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 that Great Lakes.</li> </ul> </li> <li>• <u>PESTICIDES</u> <ul style="list-style-type: none"> <li>• <i>Notification Requirements</i>—Two Great Lakes states (IL, NY) and 18 municipalities have enacted legislation that requires notification of certain pesticide applications.</li> <li>• <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</li> </ul> </li> </ul>

	requires notification when pesticides are used in these facilities.
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LEVEL OF POLICY/PROGRAM	DETAILED OVERVIEW OF CURRENTLY ENACTED POLICIES/PROGRAMS
State/Municipal (cont.)	<ul style="list-style-type: none"> <li>• <u>PESTICIDES</u> (cont.) <ul style="list-style-type: none"> <li>• <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.</li> <li>• <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.</li> </ul> </li> <li>• <u>PHARMACEUTICALS</u> <ul style="list-style-type: none"> <li>• <i>Pharmaceutical Disposal Procedures</i>—One Great Lakes state (IN) has established pharmaceutical disposal procedures.</li> <li>• <i>Take-Back</i>—Eight municipalities in the Great Lakes Region have begun to implement pharmaceutical take-back programs.</li> </ul> </li> <li>• <u>NANOMATERIALS</u> <ul style="list-style-type: none"> <li>• 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).</li> </ul> </li> </ul>

### 3.3 Review of Federal Policies Regulating Emerging Chemicals of Concern

In this section, we provide a detailed overview of the key pieces of federal legislation and policy/programmatic efforts for identifying, characterizing and decision-making on emerging chemicals of 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 Emerging Chemicals of Concern are included in Appendices A-C. In the next section, we explore the broader implications of these policies and general themes with regards to limits, challenges, and opportunities to more preventive approaches to emerging chemicals of concern in the Basin.

The laws regulating emerging chemicals of 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 emerging chemicals of concern. As noted in the introduction, we have focused in this report on 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. Clearly, there is an important need for such laws as a “safety net” when and if chemicals of concern enter the environment, but our approach 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 emerging chemicals of concern. Some programs, such as the Center for Disease Control’s biomonitoring effort, examine some of the industrial and pesticide emerging chemicals of concern. Also, the US Geological Survey has undertaken numerous national and state level surface water monitoring studies to understand the levels of various emerging chemicals of concern

(pharmaceuticals, pesticides, personal care products, etc.) in surface waters. Nonetheless, it is unclear if and how the results of these programs 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 framework 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.<sup>120</sup>

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 Binational Toxics Strategy signed in 1997 between the US and Canada.<sup>121</sup>

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

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<sup>120</sup> Great Lakes Commission website, "Data and Monitoring." Accessed at: [www.glc.org/monitoring/](http://www.glc.org/monitoring/).

<sup>121</sup> U.S. Environmental Protection Agency website, "Great Lakes Monitoring." Accessed at: [epa.gov/grtlakes/monitoring/air2/index.html](http://epa.gov/grtlakes/monitoring/air2/index.html).

information about the health of the Great Lakes and improve decision making and environmental management between the two countries.<sup>122</sup> 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.<sup>123</sup>

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.<sup>124</sup>

**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.<sup>125</sup> CDC sees the goal of the program as providing the data necessary to evaluate and ultimately prevent diseases related to environmental factors.<sup>126</sup> 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 in 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.<sup>127</sup>

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<sup>122</sup> U.S. Environmental Protection Agency website, "State of the Lakes Ecosystem Conference." Accessed at: [www.epa.gov/solec/](http://www.epa.gov/solec/).

<sup>123</sup> U.S. Environmental Protection Agency website, "Lake Superior Lakewide Management Plan (LaMP 2004)." Accessed at: [www.epa.gov/glnpo/lakesuperior/2004/](http://www.epa.gov/glnpo/lakesuperior/2004/).

<sup>124</sup> U.S. Environmental Protection Agency website, "About the Great Lakes National Program Office." Accessed at: [epa.gov/greatlakes/about.html](http://epa.gov/greatlakes/about.html).

<sup>125</sup> Centers for Disease Control website, "National Environmental Public Health Tracking Program." Accessed at: [www.cdc.gov/nceh/tracking/biomonitoring.htm](http://www.cdc.gov/nceh/tracking/biomonitoring.htm).

<sup>126</sup> 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](http://www.cdc.gov/nceh/tracking/biomontrack.htm).

<sup>127</sup> 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](http://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.<sup>128</sup>

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.<sup>129</sup> 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, manufacturing 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).<sup>130</sup> 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

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<sup>128</sup> 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/](http://pubs.usgs.gov/sir/2007/5213/).

<sup>129</sup> Centers for Disease Control website, "National Environmental Public Health Tracking Program: Policy and Legislation." Accessed at: [www.cdc.gov/nceh/tracking/policy.htm](http://www.cdc.gov/nceh/tracking/policy.htm).

<sup>130</sup> U.S. Environmental Protection Agency, "PBT Final Rule Summary." Accessed at: [epa.gov/tri/lawsandregs/pbt/pbtrule-sum.pdf](http://epa.gov/tri/lawsandregs/pbt/pbtrule-sum.pdf).

(IMERC),<sup>131</sup> 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 labelling requirements.<sup>132</sup> 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.<sup>133</sup> 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 today<sup>134</sup> (See Appendix A for an in-depth overview of TSCA and EPA’s voluntary programs under its Office of Pollution Prevention and Toxics).

<b>Approximate Number of Existing Chemicals in TSCA Inventory (October, 2003)</b>	
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

<sup>131</sup> 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](http://www.newmoa.org/prevention/mercury/imerc/about.cfm).

<sup>132</sup> Nicholas Ashford and Charles Caldart, *Technology Law and the Working Environment*, (Washington, DC: Island Press, 1997).

<sup>133</sup> 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.

<sup>134</sup> 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.”<sup>135</sup>

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.”

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<sup>135</sup> 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).<sup>136</sup> 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.<sup>137</sup> 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)

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<sup>136</sup> 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).

<sup>137</sup> 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](http://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.<sup>138</sup> These can be categorized in the following ways (these limitations are further outlined in Appendix A):

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 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)

None of the industrial chemicals outlined in the Persoon and Hornbuckle database as emerging chemicals of concern in the Great Lakes have been subject to regulatory

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<sup>138</sup> Richard Denison, *Not That Innocent: A Comparative Analysis of Canadian, European, and U.S. Policies on Industrial Chemicals*, (Washington, DC: Environmental Defense; Government Accountability Office, 2007); *Chemicals Regulation: Comparison of U.S. and Recently Enacted European Approaches to Protect Against the Risk of Toxic Chemicals*, (Washington, DC GAO-07-825).

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 much 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 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. 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.<sup>139</sup>

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

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<sup>139</sup> 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](http://pubs.acs.org/cen/government/85/8502regulation.html).

*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.

### **3.4 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.

#### ***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.”<sup>140</sup>

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 labelled, 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.”<sup>141</sup> 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. And 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 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.<sup>142</sup> 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.

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<sup>140</sup> U.S. Food and Drug Administration website, “FDA Authority Over Cosmetics.” Accessed at: [www.cfsan.fda.gov/~dms/cos-206.html](http://www.cfsan.fda.gov/~dms/cos-206.html).

<sup>141</sup> Cosmetic Ingredient Review, (2008). Accessed at: [www.cir-safety.org/](http://www.cir-safety.org/).

<sup>142</sup> U.S.FDA, “Inventory of Effective Food Contact Substance (FCS) Notifications,” (December 2008). Accessed at: [www.cfsan.fda.gov/~dms/opa-fcn.html](http://www.cfsan.fda.gov/~dms/opa-fcn.html); U.S.FDA, “The List of ‘Indirect’ Additives Used in Food Contact Substances.” Accessed at: [www.cfsan.fda.gov/~dms/opa-indt.html](http://www.cfsan.fda.gov/~dms/opa-indt.html).

## ***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 labelling 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 labelling 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 labelling 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 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 Acts* contain several limitations that challenge the ability of the Consumer Product Safety Commission to act quickly on emerging chemicals of 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 few very materials of concern, require few restrictions and as they are negotiated there is no expedited process for emerging chemicals of 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 labelled, defining a substance as hazardous is difficult due to the high scientific burdens imposed to list a substance as hazardous and subject to labelling 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 labelling, 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.<sup>143</sup> 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 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

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<sup>143</sup> See U.S. Code of Federal Regulations, *Protection of the Environment*, 40 CFR §158.300.

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.<sup>144</sup> 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).<sup>145</sup> 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.
- 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.

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<sup>144</sup> 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.

<sup>145</sup> See USGS website. Accessed at: [water.usgs.gov/nawqa/](http://water.usgs.gov/nawqa/).

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.<sup>146</sup>

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 application violations. Minnesota has also noted violations in how Terminix follows the label.<sup>147</sup>

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

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<sup>146</sup> 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,

<sup>147</sup> See [www.consumeraffairs.com/news03/terminix\\_ny.html](http://www.consumeraffairs.com/news03/terminix_ny.html); and [www.syix.com/emu/html/mn.html](http://www.syix.com/emu/html/mn.html).

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.<sup>148</sup>

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.<sup>149</sup> 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  $\geq 2$  pesticide compounds  $>90\%$  of the time, and  $\geq 10$  compounds  $\sim 20\%$  of the time. While the science of studying complex mixtures is growing (particularly with the development of high throughput testing and genomics), these are rarely thoroughly considered in risk assessment activities in part due to the lack of defensible methodologies.<sup>150</sup>

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

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<sup>148</sup> See [www.epa.gov/pesticides/regulating/data\\_requirements.htm#performance](http://www.epa.gov/pesticides/regulating/data_requirements.htm#performance).

<sup>149</sup> See [www.epa.gov/pesticides/reregistration/REDs/factsheets/chlorpyrifos\\_fs.htm](http://www.epa.gov/pesticides/reregistration/REDs/factsheets/chlorpyrifos_fs.htm) and [www.epa.gov/pesticides/reregistration/REDs/factsheets/diazinon\\_ired\\_fs.htm](http://www.epa.gov/pesticides/reregistration/REDs/factsheets/diazinon_ired_fs.htm).

<sup>150</sup> See Caroline Cox and Michael Sorgan, "Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health," *Environmental Health Perspectives*, 114 no. 12 (December 2006), 1803-1806.

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.<sup>151</sup>

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 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

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<sup>151</sup> 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](http://www.jhsph.edu/publichealthnews/press_releases/2006/halden_sludge.html).

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.<sup>152</sup> 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.<sup>153</sup> 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.<sup>154</sup>

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.

EPA has established procedures for firms to determine whether an engineered nanomaterial is subject to PMN requirements. 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.<sup>155</sup> 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-

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<sup>152</sup> See [www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf](http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf).

<sup>153</sup> U.S. Environmental Protection Agency website, "Nanoscale Materials Stewardship Program." Accessed at: [www.epa.gov/oppt/nano/stewardship.htm](http://www.epa.gov/oppt/nano/stewardship.htm).

<sup>154</sup> 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/](http://blogs.edf.org/nanotechnology/2008/08/20/tired-of-waiting-with-apologies-to-ray-davies/).

<sup>155</sup> See [www.nanolawreport.com/EPA%20Pre-manufacture%20Notice%20Number%20P-08-0177.pdf](http://www.nanolawreport.com/EPA%20Pre-manufacture%20Notice%20Number%20P-08-0177.pdf).

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.<sup>156</sup> 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.<sup>157</sup> 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.<sup>158</sup>

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.<sup>159</sup>

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 germs.<sup>160</sup> 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

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<sup>156</sup> 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/](http://blogs.edf.org/nanotechnology/2008/10/09/epas-nano-consent-order-sanitized-transparency-is-still-very-revealing/).

<sup>157</sup> 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/](http://www.nanolawreport.com/2008/10/articles/epa-consent-order-for-multiwalled-carbon-nanotubes/).

<sup>158</sup> See [www.epa.gov/fedrgstr/EPA-TOX/2008/October/Day-31/t26026.htm](http://www.epa.gov/fedrgstr/EPA-TOX/2008/October/Day-31/t26026.htm).

<sup>159</sup> See [www.epa.gov/fedrgstr/EPA-TOX/2008/November/Day-05/t26409.htm](http://www.epa.gov/fedrgstr/EPA-TOX/2008/November/Day-05/t26409.htm).

<sup>160</sup> U.S. Environmental Protection Agency website, "Pesticide Registration: Clarification for Ion Generating Equipment." Accessed at: [www.epa.gov/oppad001/ion\\_gen equip.htm](http://www.epa.gov/oppad001/ion_gen equip.htm).

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 2 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.<sup>161</sup> 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 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.<sup>162</sup> 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.<sup>163</sup>

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<sup>161</sup> 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](http://www.edf.org/pressrelease.cfm?contentID=7564).

<sup>162</sup> See [www.commondreams.org/news2008/0728-10.htm](http://www.commondreams.org/news2008/0728-10.htm).

<sup>163</sup> See U.S. EPA, "Nanoscale Materials Stewardship Program: Interim Report," (2009). Available at: [www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf](http://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](http://www.edf.org/pressrelease.cfm?contentID=9094).

## Pharmaceuticals

Pharmaceuticals are exclusively regulated under the FFDCA, 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).<sup>164</sup> 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.<sup>165</sup> 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 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.<sup>166</sup>

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

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<sup>164</sup> U.S. Department of Health and Human Services, "Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications," (July 1998).

<sup>165</sup> 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](http://query.nytimes.com/gst/fullpage.html?res=9B01E4D81339F937A25750C0A9649C8B63&sec=&spon=&pagewanted=1).

<sup>166</sup> See The Code of Federal Regulations, *Food and Drugs*, tit. 21. Accessed at: [www.cfsan.fda.gov/~lrd/cfr25-33.html](http://www.cfsan.fda.gov/~lrd/cfr25-33.html).

(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.<sup>167</sup>

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.

### **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.<sup>168</sup> 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

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<sup>167</sup> 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](http://www.whitehousedrugpolicy.gov/news/press07/022007.html).

<sup>168</sup> 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](http://www.whtp-apsf.ca/en/documents/fullCircle.html).

rivers across 30 states.<sup>169</sup> 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.<sup>170</sup> Moreover, because there are no standard setting limits on the amounts of pharmaceutical and personal care product ingredients in drinking water,<sup>171</sup> 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.<sup>172,173</sup>

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.<sup>174</sup> 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.<sup>175</sup> 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.<sup>176</sup> 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

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<sup>169</sup> 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.

<sup>170</sup> Sabine Vollmer, "Looking at Drugs in Water." *The News and Observer Online*, November 12, 2008. Accessed at: [www.newsobserver.com/business/story/1291129.html](http://www.newsobserver.com/business/story/1291129.html).

<sup>171</sup> The Groundwater Foundation website, "Pharmaceuticals and Personal Care Products: An Emerging Issue." Accessed at: [www.groundwater.org/gi/docs\\_pack/fa13.pdf](http://www.groundwater.org/gi/docs_pack/fa13.pdf).

<sup>172</sup> O.V. Enick, and M.M. Moore, "Assessing the Assessments: Pharmaceuticals in the Environment," *Environmental Impact Assessment Review*, 27 (2007), 707-729.

<sup>173</sup> 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](http://www.whtp-apsf.ca/en/documents/fullCircle.html).

<sup>174</sup> Christian G. Daughton, "Environmental Stewardship and Drugs as Pollutants," *The Lancet*, 360 (October 5, 2002), 1035.

<sup>175</sup> 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).

<sup>176</sup> O.V. Enick, and M.M. Moore, "Assessing the Assessments: Pharmaceuticals in the Environment," *Environmental Impact Assessment Review*, 27 (2007), 707-729.

compounds which officials fear may have substantial consequences for the long-term health of reproductive systems in people and wildlife.<sup>177</sup>

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've been introduced into ecosystems.<sup>178</sup> 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 animals<sup>179</sup> because they are seen to have an insignificant effect on "the quality of the human environment."<sup>180</sup> 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.<sup>181</sup>

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.<sup>182</sup> Further, developing more advanced waste water filtration systems could serve as an

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<sup>177</sup> 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).

<sup>178</sup> 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).

<sup>179</sup> 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](http://es.epa.gov/ncer/publications/workshop/pdf/eirkson_chicago82007.pdf).

<sup>180</sup> Food and Drug Administration website, "Office of Pharmaceutical Science: Environmental Impact Review at CDER." Accessed at: [www.fda.gov/cder/OPS/environment.htm](http://www.fda.gov/cder/OPS/environment.htm).

<sup>181</sup> GlaxoSmithKline website, "Global Public Policy Issues: Pharmaceuticals in the Environment." Accessed at: [www.gsk.com/policies/GSK-on-pharmaceuticals-in-environment.pdf](http://www.gsk.com/policies/GSK-on-pharmaceuticals-in-environment.pdf).

<sup>182</sup> 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](http://www.whtp-apsf.ca/en/documents/fullCircle.html).

important safety net to help to limit the introduction of pharmaceuticals (and other contaminants) to the environment.<sup>183</sup>

### **3.5 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 and managing chemicals once they are in the environment, in wildlife and human populations, to ensuring that chemicals are inherently less hazardous and break down benignly in the environment, efforts to address emerging chemicals of 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 manage 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 universe of chemicals considered in this report and resource limitations; and some substances have critical health value or uses in production and may not be readily substitutable at this point in time. Nonetheless, such 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 extensive attention to end of pipe treatment may reduce attention to a broader, more comprehensive and upstream approach to prevention of emerging chemicals of 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 emerging chemicals of concern. We also identify some opportunities for improving the current approaches to chemicals management for

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<sup>183</sup> Christian G. Daughton, “Environmental Stewardship and Drugs as Pollutants,” *The Lancet*, 360 (October 5, 2002), 1035.

emerging chemicals of concern in the Basin. Finally, we provide an overview of basic tenets of a comprehensive and preventive approach to emerging chemicals of concern.

## **The Nature of Emerging Chemicals of 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 emerging chemicals, are products. Synthetic musks are used as perfumes, NPEs are still used in some detergents (though this is changing), bisphenol 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 emerging chemicals also relate to this process-product shift.

While the Great Lakes can always benefit from improved controls on industrial processes and improved water treatment systems, *most of the significant new strides will 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 emerging chemicals of concern will include processes for rapid characterization of hazards and exposures prevention and controls (for example, the workplace or wastewater treatments are important elements).

In this context, a strategy for emerging contaminants 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. And 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.

Given that these emerging chemicals of concern tend to be dispersive (from multiple sources and generally uncontrolled and unregulated) and non-point in nature, *the only way to adequately address 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.<sup>184 185 186</sup>

It is now critical 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 emerging chemicals of concern.<sup>187</sup> Green 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.”<sup>188</sup> In this respect, substitutes for chemicals of 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 emerging chemicals of concern is the types of chemicals that span jurisdictional boundaries, boundaries which more often than not impede preventive actions. For the general public and local level officials addressing the impacts of emerging contaminants, 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 differently depending on their end use. Entirely separate legislation, regulations

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<sup>184</sup> Ken Geiser, *Materials Matter*, (Cambridge: MIT Press, 2001).

<sup>185</sup> Tim Jackson, *Clean Production Strategies*, (Florida: CRC Press, 1993).

<sup>186</sup> U.S. Office of Technology Assessment, *Serious Reduction of Hazardous Waste: For Pollution Prevention and Industrial Efficiency*, (1986).

<sup>187</sup> Paul Anastas and John Warner, *Green Chemistry Theory and Practice*, (New York: Oxford University Press, 1998).

<sup>188</sup> 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](http://www.chemicalspolicy.org/downloads/Lissner_Lohse.ppt).

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.

Despite attempts by some federal and state governments to address emerging chemicals of 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 but not eliminating industrial emissions and wastes and not those that occur from disperse products.

No one agency or piece of legislation addresses the inherent hazards of chemicals, focusing on reducing those hazards. This often leads to jurisdictional conflicts (between regional and federal governments and between federal government agencies) between agencies that are often resource limited. 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 food. This uncoordinated and disjointed approach can also lead to important gaps in oversight of chemicals.

*As such, any Great Lakes policy for emerging chemicals of concern should eschew current disjointed approaches to emerging chemicals of concern for one that broadly addresses such chemicals, by their inherent hazards rather than their legal frameworks. It should address emerging chemicals of concern not as a water problem but a problem of chemical, product, and process design. An emerging chemical of concern is an emerging chemical of concern regardless of its source. The important challenge is to develop a systems approach that focuses as noted above on prevention and safer alternatives.*

One approach to addressing chemicals of concern in a broader manner could consist of the establishment of an intergovernmental council on emerging chemicals of concern, consisting of representatives of different agencies from the state, federal, and regional levels, along with other stakeholders. The council would be tasked with prioritizing emerging chemicals of concern and recommending voluntary/regulatory actions to be taken on them. The council could establish a process with the following elements:

1. Identifying hazard/chemical properties that lead to a substance being considered a chemical of concern. Given the historic emphasis on precautionary approaches to chemical hazards, criteria for identifying substances of concern should use the most conservative international definitions. For engineered nanomaterials additional criteria to define higher concern are likely necessary.
2. Undertaking a rapid screening based on chemical structure and toxicological data to categorize chemicals as higher, medium and lower concern. Such processes have been discussed since the 1990s, at the national level in both the US and Canada, and at the Great Lakes level. It is important for them to be implemented now in a comprehensive manner. Such a screening could occur for all industrial chemicals, pesticides, pharmaceuticals, and nanomaterials and should consider the implications of interactive and cumulative exposures. A further prioritization could be based on existing knowledge of emissions, exposure and use type. This step is critical as analytical chemists cannot monitor or analyze when they do not know what they are looking for. While having some toxicological data for each chemical (through in-vivo testing or high throughput screening) is preferable in many cases, it is more cost and time effective to have tools to rapidly characterize chemical hazards on the basis of SARs and other information and then monitoring can be more targeted. Additionally, efforts to establish processes for characterizing the implications of exposure to multiple chemicals may provide additional input in the prioritization process.
3. Based on this categorization, which could be widely published and used by authorities, industry, and the public to focus attention on areas for prevention, a list of proposed actions could be established, ranging from green chemistry challenges for chemicals or chemical categories, to regional regulatory restrictions. Such regulatory process may need to be implemented within jurisdictional legal frameworks, though states may have more flexibility to take a broader approach.
4. Additionally, identification of chemicals as emerging chemicals of concern could be linked to detailed alternatives assessments that would outline safer production process and product options.

Such a council could be coordinated through the IJC or under the auspices of the Binational Toxics Strategy

## **Challenges to a More Integrated Approach to Addressing Emerging Chemicals of Concern in the Great Lakes**

Below we present a number of current challenges in policy with regards to emerging chemicals of 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 prevention-based framework.**

In addition to emerging chemicals of concern being addressed on a chemical type by chemical type 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 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.

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 Binational 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 emerging contaminants of concern necessitates a new solutions-based approach to emerging chemicals of 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 emerging chemicals of 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.<sup>189</sup>

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<sup>189</sup> 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).

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.<sup>190</sup> 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 emerging chemicals of concern.**

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.<sup>191</sup> 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 limitations in the quality of the data and

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<sup>190</sup> 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](http://www.chemicalspolicy.org/downloads/FinalAltsAssess06_000.pdf).

<sup>191</sup> 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](http://coeh.berkeley.edu/FINALgreenchemistryrpt.pdf).

extent of compliance with such initiatives. For pesticides, the toxicological database is significantly more complete; however, despite EPA efforts, data are lacking on health effects, uses environmental fate, for many substances and for many 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.

For many of the emerging chemicals of concern, reaching the Great Lakes through product based exposures, new information gaps are becoming obvious. For many chemicals, and especially emerging chemicals, 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 emerging chemicals of 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.

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. And 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 preventive action on emerging chemicals of 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

### *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 binational strategy or any strategy at all for the Great Lakes Basin with regards to emerging chemicals of 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 Binational 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. Unlike efforts on climate, there is little coordinated Great Lakes states and provinces initiative on chemicals of concern. As previously noted, there is an important need for more coordinated governance structure in Great Lakes for emerging contaminants. 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.

### ***3.6 Elements of an Ideal Approach to Emerging Chemicals of Concern***

It is useful for the U.S. and Canada to move from the current approach to addressing chemicals of concern through a reactive approach addressing such chemicals with an “aspirational” approach, one that ensures that emerging chemicals of concern rarely occur. 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.”<sup>192</sup>

**Taking an integrated, broad approach to chemicals management:** Policies should take a comprehensive and integrated approach to all chemicals and chemical classes (not

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<sup>192</sup> See: [www.un.org/jsummit/html/documents/summit\\_docs.html](http://www.un.org/jsummit/html/documents/summit_docs.html)

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 emerging contaminants.

**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.

## PART 4 – General Observations and Recommendations

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 prevent the introduction of emerging chemicals of concern to the Great Lakes Basin. Further, these gaps concern the limits in current policies as well as the lack of an overarching prevention-oriented framework for addressing such chemicals. Some of the key gaps we have identified include:

1. The lack of an integrated system for prevention of emerging chemicals of 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 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 emerging chemicals of 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 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 desired preventative and precautionary manner as outlined in the *Great Lakes Water Quality Agreement*. Similarly, the current activities under the Great Lakes Binational 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.<sup>193</sup>

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.<sup>194</sup> 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 2007 Annual Report on the Binational 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.”<sup>195</sup> 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 forum to discuss a new scope and target of work on 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. Over the past year, 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

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<sup>193</sup>Canada and United States, “Great Lakes Binational Toxics Strategy,” (1997). Accessed at: [binational.net/home\\_e.html](http://binational.net/home_e.html).

<sup>194</sup>Environment Canada and U.S. Environmental Protection Agency Region V, “Great Lakes Binational Toxic Strategy Path Forward,” (2008).

<sup>195</sup>Environment Canada and United States Environmental Protection Agency, “2007 Annual Progress Report: Great Lakes Binational Toxics Strategy,” (2007). Accessed at: [binational.net/bns/2007/2007GLBTS\\_en.pdf](http://binational.net/bns/2007/2007GLBTS_en.pdf).

following: substance identification, substance selection and review of management status.<sup>196</sup> 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. They are concerned about:

- the voluntary nature of the approach taken under the BTS framework in addressing toxic chemicals in the Great Lakes, which 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 commit to action plans based on sunseting, substitution and implementation of safer alternatives for priority toxic chemicals;
- the lack of full accountability by government 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 the virtual elimination in the BTS framework, which is inconsistent with the interpretation outlined in the *Great Lakes Water Quality Agreement*;
- the lack of clarity in the use of the precautionary principle in the BTS, which may result in actions that do not achieve elimination and preventative measures on toxic chemicals (that are not data rich but that have been demonstrated to impact health or environment); and
- the governments’ reliance on the existing national programs to identify and evaluate the chemicals that require action, since this approach is limiting and not comprehensive. There is no guarantee that national programs in either country will identify and prioritize appropriately all chemical substances for action (including virtual elimination) that are a threat to the Great Lakes Basin ecosystem.<sup>197 198</sup>

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<sup>196</sup>Environment Canada and U.S. Environmental Protection Agency Region V, “Great Lakes Binational Toxic Strategy Path Forward,” (2008).

<sup>197</sup> See: “Chemical Selection Framework for the Binational Toxics Strategy NGO Proposal,” Prepared by the Canadian Environmental Law Association, Great Lakes United, Indiana Toxics Action and National Wildlife Federation, (August, 2008).

<sup>198</sup> See: “Comments on Binational 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 Binational Toxics Strategy Sector Work Group and Binational 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.<sup>199</sup> 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 taken 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.*<sup>200</sup>

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 precautionary 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 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 US 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.

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<sup>199</sup> See: "EPA and Environment Canada BTS framework," presented in September submissions by CELA, GLU, NWF and Indiana Toxics Action (September 2008).

<sup>200</sup> 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 propose the following recommendations to the Multi-Board Work Group on Chemicals of Emerging Concern in the Great Lakes.

***Establish a Binational Strategy on Emerging Chemicals of Concern based on precaution and prevention.***

**Recommendation 1**

The IJC should urge the Parties to establish an intergovernmental taskforce on emerging chemicals of concern to develop a binational strategy for such chemicals that spans jurisdictional boundaries and focuses on approaches to ensure redesign of such chemicals toward safer alternatives. The taskforce would establish processes and authorities to implement the actions described below.

***Establish a Great Lakes rapid identification and screening process for chemicals of concern.***

**Recommendation 2**

Building on existing national programs of Canada and the U.S. as well as the GLWQA List and reviewing data from other jurisdictions for identification and screening substances of concern, the IJC should seek to establish a Great Lakes screening process for emerging chemicals of concern. The IJC process should use the criteria established under the GLWQA for persistence, bioaccumulation and/or toxicity, which would include carcinogenicity, reproductive and developmental toxicity, neurodevelopmentality, genotoxicity, respiratory toxicity, skin sensitization, 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 should be based on the most conservative criteria adopted internationally.

### **Recommendation 3**

Similarly, the IJC or another Great Lakes binational agency should apply an identification and screening process to chemicals used in drugs, other pharmaceutical products and nanomaterials that effectively characterizes their uses, possible exposures, and fate in the environment.

#### ***Publish a Great Lakes List of Chemicals of Concern.***

### **Recommendation 4**

Building on the work of government scientists, Muir and Howard, and those of the national programs, substances should be identified and ranked as to their potential to become a chemical concern in the Great Lakes Basin as high, medium, or low concern.<sup>201</sup> Substances with inadequate data needed for making such a categorization should be automatically considered as high concern. The results of this process should be widely publicized as a Great Lakes List of Chemicals of Concern. This list would be a tool to inform regulatory-, market-, research and innovation, and educational activities that support implementation of safer alternatives. A timeframe of two years to complete this process should be required.

***Action plans should be developed and implemented for chemicals identified under the Great Lakes List of Chemicals of Concern to achieve the goals outlined under the GLWQA, particularly prevention and application of safer alternatives.***

### **Recommendation 5**

The IJC should recommend that Parties commit to the development and implementation of mandatory action plans to substitute or prohibit chemicals of high concern listed in the Great Lakes List of Chemicals of Concern as well as develop action plans to reduce and ultimately substitute with substances of medium and low concern.

All action plans should include time-limited mandatory processes and programs that achieve pollution prevention through substitution with safer, technologically feasible alternatives, product redesign, and mandatory restrictions where necessary. Such action plans should prioritize high concern chemicals for preventive actions. Action plans should also consider end of life take-back considerations for products containing chemicals of concern. Given the variety and number of such chemicals, action plans should be developed in as expedient a manner as possible.

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<sup>201</sup> 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 Binational Toxics Strategy Meeting, Chicago, IL, 2008).

### **Recommendation 6**

To support these action plans, the IJC should urge the Parties to establish a binational 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.

#### ***Establish a Public Database and Clearinghouse of Information on Chemicals of Concern for the Great Lakes Basin.***

### **Recommendation 7**

The IJC should recommend to the Parties, the development 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. Such a database can provide government agencies and the public a vital source of information to track flows of emerging chemicals of concern in the Great Lakes Basin. This database would supplement existing pollutant inventories in Canada and in the United States, which apply to chemicals in medium to large scale manufacturing.

#### ***Ensure greater accountability by producers, users, vendors, importers, and disposers of chemicals, drugs, and nanomaterials in the Great Lakes Basin.***

### **Recommendation 9**

The IJC should urge the Parties to 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.