

Appendix A  
 Toxic Pollutant Strategy Team  
 Recommendation Cost Estimates

Recommendation/Actions	Implementation	Current Funding	Supplemental Funding Needs	Total Funding
<b>1. Finish the Job on Priority Pollutants</b>		<b>\$1.5M/yr +</b>	<b>\$12M/yr</b>	<b>13.5M/yr</b>
Mercury Utility Reductions	Private Sector	NA	NA	NA
Basin-Wide Mercury Stewardship Plan	Eight GL States	NA	Minimal	Minimal
PCB Decommissioning	Private Sector	NA	NA	NA
Burn Barrel Initiatives	Fed/State Funding	< 100K	\$10M/yr	\$10M/yr
Clean Sweeps	Eight GL States	\$1.4M/yr	\$2M/yr	\$3.4M/yr
WI		700K/yr*	\$250K/yr	\$950K/yr*
MI		260K/yr**	\$400K/yr	\$660K/yr*
OH		Unknown	\$250K/yr	\$250K/yr
MN		\$200K/yr	\$200K/yr	\$400K/yr
IL		0	\$150K/yr	\$150K/yr
IN		0	\$150K/yr	\$150K/yr
NY		\$50K/yr	\$300K/yr	\$350K/yr
PA		Unknown	\$300K/yr	\$300K/yr
<b>2.Prevent New Toxics</b>		<b>\$884K +</b>	<b>\$15.12M/yr +</b>	<b>\$16M/yr +</b>
Manufacturing Extension Partnerships	US DOC	NA	\$8M/yr	\$8M/yr
State Technical Assistance Providers	Eight GL States	884K***	\$7.12M/yr	\$8M/yr
Revolving Loan Fund	States	NA	\$50M	\$50M
P2 in Regulations	Feds/States	NA	Minimal	Minimal
<b>3. Filling in the Knowledge Gaps</b>		<b>\$300K/yr +</b>	<b>\$5-10M/yr****</b>	<b>\$5-10M/yr****</b>
Bald Eagle Monitoring	USFWS	NA	20K/yr	\$20K/yr
Mussel Toxicity Testing	USGS	NA	\$250K/yr - 5 yrs	\$250K/yr - 5 yrs
GLI Clearinghouse	EPA	NA	\$30K/yr	\$30K/yr
Great Lakes Human Biomonitoring.	Various	NA	\$1M/yr	\$1M/yr
Model intercomparison study	Various	NA	\$200K/yr	\$200K/yr
PTS Database	Various	NA	\$500K/yr	\$500K/yr
Fish Program Emerging Contaminants	EPA	\$150K/yr	\$350K/yr	\$500K/yr
Modeling Development	Various	NA	\$300K/yr	\$300K/yr
WWTP Surveillance	Private Sector	NA	\$300K/yr	\$300K/yr
Open Water Monitoring Emerging	EPA	\$150K/yr	\$150K/yr	\$300K/yr
<b>4. Public Education and Outreach</b>		<b>\$4.2M/yr +</b>	<b>\$11.7M/yr</b>	<b>\$15.9M/yr</b>
Fish Advisory Programs	Eight GL States	\$4.2M/yr	\$6.2M/yr	\$10.4M/yr
Outreach Campaign	Feds/States/Tribes	Unknown	\$5.5M/yr	\$5.5M/yr
<b>5. International Source Reduction</b>		<b>\$1.725M/yr</b>	<b>\$6M/yr</b>	<b>\$7.725M/yr</b>
Artisinal Mining	Feds	\$50K/yr	\$2.95M/yr	\$3.0M/yr
UNEP POPs Mgmt and Monitoring	Feds	\$425K/yr	\$575K/yr	\$1M/yr

UNEP Mercury Support	Feds	\$250K/yr	\$750K/yr1M	\$1M/yr
CEC SMOC Support	Feds	\$1M/yr	\$1M/yr	\$2M/yr
6. Tribal Support	Tribes	Unknown	<b>20M/yr</b>	<b>\$20M/yr</b>
Total		<b>8.6M/yr</b>	<b>69.9M - 74.8M/yr +</b>	<b>77.4M/yr-82.4M/yr +</b>

\* - WI program includes household Hazardous Waste Collection

\*\* - MI program varies from year to year

\*\*\* - EPA P2 support to States is \$4.5M/yr. Region 5 supplemented this by \$164K for its six States.

\*\*\*\* - Not all items included in cost estimate

## Appendix D

### Links to PBT Websites and Documents

#### 1) National PBT Program Links

USEPA P2 Home Page

<http://www.epa.gov/p2/>

USEPA PBT Home Page

<http://www.epa.gov/pbt/>

National List of Fish Advisories Home Page

<http://www.epa.gov/ost/fish/>

EPA National Waste Minimization Program Home Page

<http://www.epa.gov/epaoswer/hazwaste/minimize/>

EPA Toxics Release Inventory Home Page

<http://www.epa.gov/tri/>

#### 2) Great Lakes PBT Policy Documents

Great Lakes Water Quality Agreement, (*see Annexes 10-12, 15*)

<http://www.ijc.org/rel/agree/quality.html>

A Strategy for Virtual Elimination of Persistent Toxic Substances - Volume 1

<http://www.ijc.org/php/publications/pdf/ID1052.pdf>

A Strategy for Virtual Elimination of Persistent Toxic Substances - Volume 2

<http://www.ijc.org/php/publications/pdf/ID1051.pdf>

The Canada-US Great Lakes Binational Toxics Strategy

<http://www.epa.gov/glnpo/p2/bns.html>

Ann Arbor Statement February, 2004 (Long Range Transport) –

<http://delta-institute.org/pollprev/lrtworkshop/AnnArborStatement.PDF>

City of Buffalo Resolution for PBT-Free Purchasing

[www.rachel.org/library/getfile.cfm?ID=485](http://www.rachel.org/library/getfile.cfm?ID=485)

#### 3) Chemicals of Emerging Concern

Policy Statement on a New Chemicals Category for Persistent, Bioaccumulative, and Toxic Chemicals

<http://www.epa.gov/opptintr/newchems/pbtpolcy.htm>

Lake Michigan LaMP 2004 Update - Pollutant Discussion Paper - For Comment (Good Summary of Chemicals of Emerging Concern)

[http://www.epa.gov/grtlakes/lakemich/2004update/lmlamp04\\_3a.pdf](http://www.epa.gov/grtlakes/lakemich/2004update/lmlamp04_3a.pdf)

American Public Health Association (APHA): 2004-05 Preventing Human Exposure to Polybrominated diphenyl ether (PBDE) Flame Retardants to Protect Public Health

[www.apha.org/legislative/policy/2004/2004-5.pdf](http://www.apha.org/legislative/policy/2004/2004-5.pdf)

4) Great Lakes Monitoring Programs

Fish Indicators

<http://www.epa.gov/grtlakes/glindicators/fish.html>

Air Monitoring

<http://www.epa.gov/grtlakes/monitoring/air/index.html>

Great Lakes Air Toxics Emissions Inventory for years 1996,1997,1998,1999, and 2001 (2002 will be completed in spring '05)

<http://www.glc.org/air>

The Centralized Air emissions Repository On-Line (CAROL) for reporting emissions data from the above inventories

<http://mds.glc.org/carol/index.php>

5) Great Lakes Environmental/Indicator Reports for PBTs

State of the Great Lakes 2003

[http://cfpub.binational.net/solec/solec2003\\_e.cfm](http://cfpub.binational.net/solec/solec2003_e.cfm)

The Effects of Great Lakes Contaminants on Human Health – Report to Congress

<http://www.epa.gov/glnpo/health/index.htm>

Lake Ontario LaMP 2002 Report, (*see Chapter 4, Critical Pollutants*)

<http://www.epa.gov/grtlakes/lakeont/2002highlight/ontLamp2002web.pdf>

6) PBT Sources and Loads to Great Lakes

Atmospheric Deposition of Toxic Substances to the Great Lakes: IADN Results Through 2000

[http://www.epa.gov/glnpo/monitoring/air/iadn/reports/IADN\\_1999\\_2000.pdf](http://www.epa.gov/glnpo/monitoring/air/iadn/reports/IADN_1999_2000.pdf)

Lake Michigan Mass Balances for Mercury, PCBs, Atrazine

<http://www.epa.gov/grtlakes/lmmb/results/mercury/index.html>

<http://www.epa.gov/grtlakes/lmmb/results/pcb/index.html>

[http://www.epa.gov/grtlakes/lmmb/results/atra\\_datarpt.html](http://www.epa.gov/grtlakes/lmmb/results/atra_datarpt.html)

Lake Erie LaMP 2004 Update, Sources and Loads,  
[http://www.epa.gov/grtlakes/lakeerie/2004update/Section\\_5.pdf](http://www.epa.gov/grtlakes/lakeerie/2004update/Section_5.pdf)

Lake Michigan LaMP 2000, Chapter 5, Stressor Sources and Loads  
<http://www.epa.gov/grtlakes/lakemich/lmlamp2000/LM%20chapter%205.pdf>

Lake Ontario LaMP 2002 Report, (*see Chapter 5, Sources and Loads*)  
<http://www.epa.gov/grtlakes/lakeont/2002highlight/ontLamp2002web.pdf>

7) Great Lakes Pollution Prevention and Voluntary Programs and Policies

Great Lakes Region Pollution Prevention Roundtable  
<http://www.glrppr.org/>

The Canada-US Great Lakes Binational Toxics Strategy Draft 2004 Annual Report -  
<http://www.epa.gov/glnpo/bns/reports/2004progress/index.html>

The Canada-US Great Lakes Binational Toxics Strategy Step 3 Reports (*Options for reducing level 1 substances*)- <http://www.epa.gov/greatlakes/bns/workgroups.html>

The Lake Superior Binational Program, Stage 3 Report: Reducing Critical Pollutants -  
<http://www.epa.gov/greatlakes/lakesuperior/stage3/index.html>

The Lake Superior LaMP 2000, Chapter 4, Critical Pollutants -  
<http://www.epa.gov/greatlakes/lakesuperior/lamp2000/LS%20chapter%204.pdf>

The Lake Superior LaMP 2004 updates, Chapter 4, Critical Pollutants  
[http://www.epa.gov/grtlakes/lakesuperior/2004/LSLaMP2004\\_04a.pdf](http://www.epa.gov/grtlakes/lakesuperior/2004/LSLaMP2004_04a.pdf)

Lake Erie LaMP 2000, <http://www.epa.gov/grtlakes/lakeerie/lamp2000/index.html>

7) PBT Risk Assessment

Papers Addressing Scientific Issues in the Risk Assessment of Metals  
(External Review Draft)  
<http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=59052>

8) Sediments

SERDP and ESTCP Expert Panel Workshop on Research and Development Needs for the  
In Situ Management of Contaminated Sediments  
<http://docs.serdp-estcp.org/viewfile.cfm?Doc=SedimentsFinalReport.pdf>

9) PBT Research and Development

The Great Lakes Air Deposition (GLAD) program supports research projects relating to atmospheric deposition of toxic substances to the Great Lakes. Current projects include monitoring and modeling projects concerning mercury, dioxins, PBDEs, PAHs, and many others.

<http://www.glc.org/glad>

10) Mercury Rule

On March 15, 2005, EPA issued the Clean Air Mercury Rule to permanently cap and reduce mercury emissions from coal-fired power plants.

<http://www.epa.gov/CAMR/index.htm>

On March 10, 2005, in a separate but related action, EPA issued the [Clean Air Interstate Rule](#) (CAIR), a rule that to reduce air pollution that moves across state boundaries.

<http://www.epa.gov/CAIR/>

## Great Lakes Regional Collaboration Toxic Pollutant Strategy Team White Paper Summary of Human and Environmental Toxicology Research in the Great Lakes

**Human Health Protection** - Summarized from ATSDR's "The Effects of Great Lakes Contaminants on Human Health" Report to Congress,  
<http://www.epa.gov/glnpo/health/index.htm>

Several epidemiologic investigations have been conducted to investigate the association between water pollutants in the Great Lakes and the health of people in the Great Lakes states. These studies have demonstrated increased tissue levels of toxic substances (body burdens) in these populations that may be associated with or potentially result in reproductive, developmental, behavioral, neurologic, endocrin, and immunologic effects.

Epidemiologic studies of exposed human populations provide the most convincing evidence of human health effects. Of the three major routes of human exposure in the Great Lakes -- air, drinking water, and fish consumption -- fish consumption is generally thought to present the greatest risk of exposure. The most direct evidence for adverse human health effects from environmental pollution is found in a series of studies linking PCB exposure to consumption of contaminated fish (Fein *et al.* 1983, 1984; Jacobson *et al.* 1984a; Jacobson and Jacobson 1988). Replicating, improving upon, and continuing these types of epidemiologic studies should provide the most relevant and convincing evidence of the status of human health from exposure to Great Lakes pollutants.

The following research has been or is being conducted to clarify the relationships among exposure, contaminant levels in human biological tissues and fluids, and human health effects. Below are specific research data gaps that are in the process of being filled, which will provide necessary information for assessing human risk from exposure to Great Lakes contaminants.

2. **Past Great Lakes Studies** – most focused on chlorinated organics (i.e. PCBs, DDT & isomers, and general exposure due to proximity to the Great Lakes)
  - a. *Michigan Sport Fishermen Cohort Study* (Humphrey 1976-1989, 5 papers)
  - b. *Wisconsin Sports Fish-Consumers Study* (Fiore *et al.* 1989; Sonzogni *et al.* 1991)
  - c. *Minnesota Ecologic Epidemiologic Study* (Schuman *et al.* 1982)
  - d. *Michigan Maternal and Infant Study* (Many related papers, 1980s)
  - e. *Wisconsin Maternal and Infant Study* (Smith 1984, Dar *et al.* 1992)
  - f. *New York Ecologic Epidemiologic Study* (Kagey and Stark 1992)
3. **Current Program Areas of Research**
  - a. *Characterization of exposure and determination of the profiles and levels of Great Lakes contaminants in human biologic tissues and fluids*
    - i. Obtain tissues and fluids from exposed and referent populations for congener - specific analyses.
    - ii. Biological tissues and fluids that are being analyzed include serum, adipose tissue, cord blood, placenta, and breast milk in females;

- serum, adipose tissue, and seminal fluid in males; and serum and adipose tissue in their children.
- iii. Determine the levels of accumulated contaminants in human tissues and fluids over time from established cohort(s) from previous studies.
  - iv. Determine partitioning of contaminants within human tissues and fluids.
    - v. Determine of release of contaminants into the bloodstream from body tissues, especially adipose tissue.
    - vi. Determine excretion of contaminants from the body.
    - vii. Compare toxicokinetic data among males, females, and their children.
- b. *Identification of sensitive and specific human reproductive end points*
- i. Identify study subjects (male) from a cohort of fish consumers
  - ii. Examine sperm morphology, number, viability, and motility in seminal fluid
  - iii. Examine blood samples for circulating levels of follicle stimulating hormone, leutenizing hormone, and testosterone.
  - iv. Correlate body burdens of contaminants with levels of hormonal activity linked to adverse reproductive health outcomes.
- c. *Determination of the short- and long-term risk(s) of adverse health effects in the children of exposed parent*
- i. Comparing profiles of contaminants found in biological tissues and fluids of parents with the profile found in offspring.
  - ii. Correlating infant exposure history in utero with adverse health effects.
  - iii. Correlating the exposure history of mothers and fathers with observed adverse developmental effects in their children.
  - iv. Evaluating the potential of developmental effects in children due to paternal exposure.
  - v. Investigating transgenerational effects in children.
- d. *Feasibility of Establishing registries and/or surveillance cohorts in the Great Lakes*
- i. Identify subgroups of particular concern such as pregnant females, nursing females, fetuses and nursing infants
  - ii. of mothers who consume contaminated fish, infants and children, and subsistence anglers including Native Americans, the urban poor, and the elderly.
  - iii. Conduct (transgenerational) epidemiologic studies in identified fish-consuming populations from the Great Lakes region with emphasis on disease and symptoms.
  - iv. Conduct (transgenerational) exposure studies using available monitoring methods to assess mixtures of contaminants present in the cohorts.

- v. Establish a database that can provide prospective information about people's health status for use in future health studies, including the use of validated biomarkers.

## **Environmental Toxicology Research**

The challenge faced by environmental toxicologists in general is trying to estimate the extent of contaminant/s exposure to specific populations over a certain time period that may lead to some measured effect. This often occurs with limited information, particularly about the environmental behavior of the contaminant/s. Environmental toxicology research is a combination of knowing the properties and environmental fate and transport routes of a contaminant or a mixture of contaminants to determine potential exposure and the dose of contaminant/s that leads to some measure of effect. How these factors link to human health has become increasingly important. Research in the past focused on measuring environmental effects in the field and measuring toxicity in a laboratory situation and trying to extrapolate to what is going on in the environment. Today, increasing effort is being done to link exposure and effect from a molecular basis up to individual and population levels. Linking ecological health to human health and being able to predict potential problems to human health from environmental contaminants by measuring or modeling effects in the environment are important challenges being focused on in current environmental toxicology research both in the Great Lakes and elsewhere. Below is an outline of some of the current research focus in environmental toxicology in the Great Lakes region:

### **1. Current Program Areas of Research**

- a. Measuring exposure to environmental estrogens (laboratory and field)
- b. Measuring exposures to polybrominated diphenyl ethers and fluorinated surfactants (laboratory and field)
- c. Research related to chemical risk assessment such as determining toxicological pathways for use in developing Quantitative Structure Activity Relationships (QSARs).
- d. Research related to developing and improving mechanistic models of water, sediment, biota interactions.
- e. Development of quantitative relationships between chemical and non-chemical stressors and the responses of freshwater ecosystems and aquatic life and wildlife species.
- f. Research to determine the fate, transport, and food web accumulation of contaminants

### **2. Some Current Research Projects**

- e. NOAA GLERL
  - i. Contaminant Effects: Investigations on the Utility of Body Residue as the Dose Metric
  - ii. Bioavailability of Sediment-Associated Toxic Organic Contaminants
- f. US EPA Mid-Continent Ecology Division

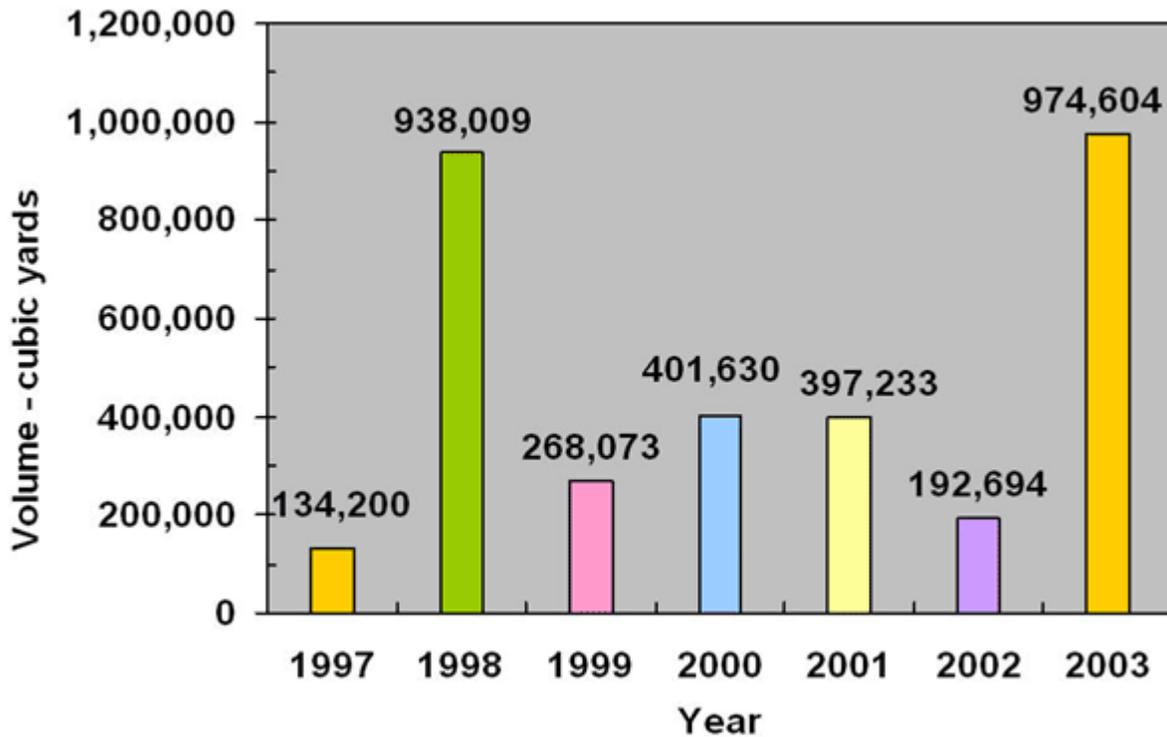
- i. Assessment of the Effects of PBT Chemicals in Aquatic Ecosystems
  - ii. Assessment of the Effects of PBT Chemicals in Aquatic Ecosystems: Indications and Influences of Metabolism among PAHs
  - iii. Development Of An Amphibian Model For Assessing Thyroid Axis Disruption
  - iv. Development of Methods for Assessing Contaminated Sediments: TIE
  - v. Evaluation of Toxicity and Accumulation of PFOS by *Rana pipiens*
  - vi. Methods for Estimating Methylmercury Effects on Avian Species and Extrapolation of Effects Among Species
- g. Available Toxicology Databases  
EPA's ECOTOX Database - source for locating single chemical toxicity data for aquatic life, terrestrial plants and wildlife. Maintained by Office of Research & Development

**Great Lakes Regional Collaboration  
Toxic Pollutant Strategy White Paper  
Remediation of Existing PBT Sediment Deposits**

Reducing persistent bioaccumulative toxins (PBTs) in the Great Lakes Basin necessitates a 2-prong approach; reducing ongoing external watershed and atmospheric loads, and mitigating existing sediment sinks of PBTs. Lake-wide mass balance modeling efforts demonstrate the current rate of reduction of banned and restricted chemicals, such as PCBs, in open water and fish are being controlled by surficial sediment feedback through resuspension processes, rather than watershed or atmospheric load reductions.

According to the *Status of Restoration Activities in Great Lakes Areas of Concern: A Special Report* (Report of the International Joint Commission, April 2003), work to remediate sediments is ongoing in 14 of the 26 United States-only AOCs, at a cost of \$160 million. The USEPA estimates that in the years 1997 through 2003, over 3.3 million cubic yards of contaminated sediment have been removed from the U.S. Great Lakes Basin. The following graph shows the progress of sediment removal; the USEPA anticipates the rate of sediment remediation activities will accelerate with the availability of Great Lakes Legacy Act funding opportunities. The estimated associated mass of PBTs removed by these removal actions are 596 tons of PCB, 519 tons of DDT in the U.S. In Canada, 34,000 cubic yards of sediment have been removed through 2002, removing 3 tons of benzo(a) pyrene, and 43 pounds of mercury (Great Lakes Binational Toxics Strategy, 2003).

**Yearly volume of sediment removed from U.S. Great Lakes Basin**



As of January 2005, USEPA Great Lakes National Program Office (GLNPO) has estimated there are 76 million cubic yards of contaminated sediment in the AOCs to be remediated, at a cost estimated between \$1.6 billion and \$4.4 billion. This estimate required by the Great Lakes Strategy 2002 and the Great Lakes Legacy Act is updated biennially. The estimate does not differentiate between likely funding sources, i.e., PRPs vs. government funds.

The wide range in the projected remediation cost is reflective of the cost differential between the basic approaches used to cleanup contaminated sediment. The three basic remedies are monitored natural recovery (MNR), capping, and dredging. At many sites a combination of these approaches will be implemented.

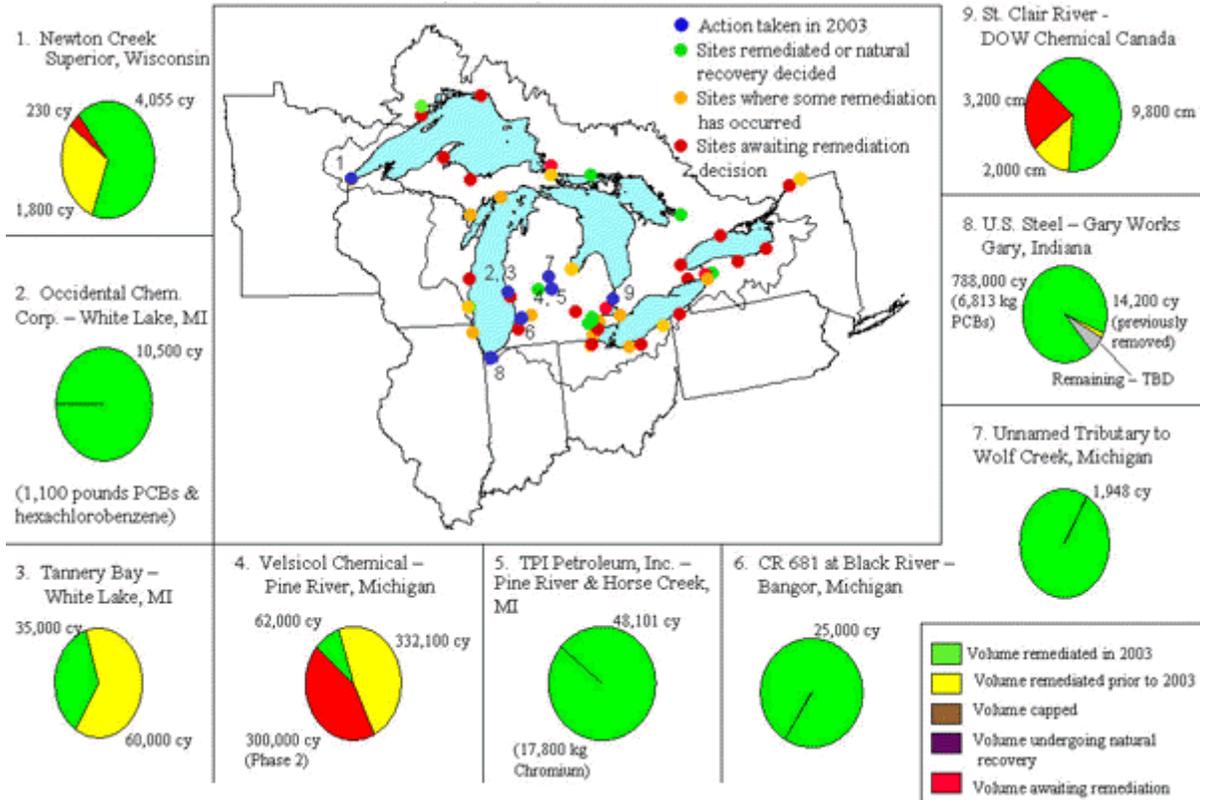
MNR is the least expensive remedy, but is likely to require more extensive and prolonged long-term monitoring. MNR uses known, ongoing, naturally occurring processes to contain, destroy, or otherwise reduce the bioavailability or toxicity of contaminants in sediment. Although burial by clean sediment is often the dominant process relied upon for natural recovery, multiple physical, biological, and chemical mechanisms frequently act together to reduce risk. MNR can be effective for low-risk sites or portions of sites where surface sediment contaminant concentrations approach surface sediment cleanup goals, and the long-term stability of the sediment bed is not a concern.

Capping refers to the placement of a subaqueous covering or cap of clean material over contaminated sediment that remains in place. Caps are generally constructed of clean sediment, sand, or gravel, but can also include geotextiles, liners, or the addition of material such as organic carbon to attenuate the flux of contaminants. A cap reduces risk by physically isolating the contaminant from the aquatic environment; by stabilizing the contaminated sediment thus preventing resuspension and transport to other sites. Additionally, capping the sediments reduces the movement of dissolved and colloiddally transported contaminants. Capping is typically much less expensive than environmental dredging but because contaminants are left in place, caps generally require long-term monitoring, and the risks of contaminant breakthrough or resuspension persist.

Dredging is typically the most expensive remedy, but results in the greatest mass removal from the aquatic environment. Currently it is the most common means of sediment remediation in the Great Lakes Basin. Removal can also be accomplished through excavation in the dry, after the water body or portion of the water body has been diverted or drained. Dredging and excavation in the dry are typically the most complex remedial approach, the components of which include removal, staging, de-watering, water treatment, sediment transport and possibly treatment, re-use, or disposal. The relatively short-term risk reduction benefits of dredging can be compromised by high surface sediment residuals and long-range transport of sediments resuspended during dredging.

The following figure shows the status of sediment remediation in the AOCs through 2003.

## Great Lakes Sediment Remediation Status at End of 2003



Source: [www.epa.gov/grtlakes/sediment/remed](http://www.epa.gov/grtlakes/sediment/remed)

## **Great Lakes Regional Collaboration Toxic Pollutant Strategy Team White Paper Regulatory Programs**

EPA's website lists 33 select environmental laws enacted by Congress through which EPA carries out its efforts, ranging in date from the 1938 Federal Food, Drug, and Cosmetic Act to the 1990 National Environmental Education Act. Cleanup enforcement authority is derived from several statutes: the Comprehensive, Environmental Response, Compensation and Liability Act (CERCLA or Superfund); the Resource Conservation and Recovery Act (RCRA), including the Underground Storage Tank (UST) Program; and the Oil Pollution Act (OPA) under the Clean Water Act. Each of these statutes deal with sites where there's been a migration or a release, or a threat of release, of hazardous substances into the environment. Most of the Areas of Concern identified in the Great Lakes Water Quality Agreement are associated with at least one cleanup enforcement site, supporting assessment (pollutant concentration and extent) of the contamination.

### Clean Air Act

Major programs of the Clean Air Act include authorization and overview of state implementation plans; performance standards for stationary sources; enforcement and permitting; ozone protection; prevention of significant deterioration of air quality; visibility protection; emission standards for mobile sources; and air quality monitoring and modeling. The 1977 Clean Air Act required EPA to set ambient air quality standards (NAAQS); EPA had to first identify the pollutants. Primary NAAQS for NO<sub>2</sub>, CO, VOCs, PM-10, SO<sub>2</sub>, and lead were set by EPA between 1977 and 1990, and the acid rain program was initiated. Attainment and non-attainment areas are identified for these NAAQS.

The 1990 Clean Air Act amendments identified 189 hazardous air pollutants (HAPs) and required EPA to regulate categories of HAP sources through a maximum achievable control technology (MACT) or specific technology. These regulations are national emission standards for hazardous air pollutants (NESHAPs). The sources are categorized as follows. "Major sources" are stationary sources emitting or having the potential to emit 10 tons per year of any HAP or 25 tons of any combination of HAPs. "Area sources" are non-major stationary sources of HAPs. "Stationary source" means any buildings, structures, equipment, installations or substance emitting stationary activities (i) which belong to the same industrial group, (ii) which are located on one or more contiguous properties, (iii) which are under the control of the same person (or persons under common control), and (iv) from which an accidental release may occur. "New source" means a stationary source constructed or reconstructed after a rule establishing an applicable HAP emission standard is proposed. The initial list of 189 HAPs (see Section 112(b)) includes many PBT substances and groups of chemicals. For example, particulate organic matter (POM) includes organic compounds with more than one benzene ring and which have a boiling point greater than or equal to 100°C. Challenges in regulating the categories include developing an accurate list of sources.

The EPA Administrator may add pollutants to the HAP list by rule *after* reviewing the pollutant's presence, route of exposure, threat of adverse human health effects (including but not limited to, *substances which are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which may cause reproductive dysfunction, or which are acutely or chronically toxic*) or adverse environmental effects through ambient

*concentrations, bioaccumulation, deposition, or otherwise* (excluding substances subject to Section 112(r)).

Section 112(m) of the 1990 Clean Air Act is specific to the Great Lakes and Coastal Waters. The Administrator of EPA and the Under Secretary of Commerce for Oceans and Atmosphere (NOAA) are required to identify and assess the extent of atmospheric deposition of HAPs to the Great Lakes. Furthermore, the Administrator of EPA is required to oversee the Great Lakes Monitoring Network in accordance with Annex 15 of the Great Lakes Water Quality Agreement. Section 112(m) also requires the Administrator to report to Congress on these monitoring programs biennially.

For a more detailed description of the Clean Air Act programs, please see *The Plain English Guide to the Clean Air Act* (EPA-400-K-93-001, April 1993), found at [http://www.epa.gov/oar/oaqps/peg\\_caa/pegcaain.html](http://www.epa.gov/oar/oaqps/peg_caa/pegcaain.html). Also, see several *Great Waters Report(s) to Congress* at <http://www.epa.gov/air/oaqps/gr8water/index.html>.

### Clean Water Act

Growing public awareness and concern for controlling water pollution led to enactment of the Federal Water Pollution Control Act Amendments of 1972. As amended in 1977, this law became commonly known as the Clean Water Act. The Act established a basic structure for regulating discharges of pollutants into the waters of the United States, the national pollution discharge elimination system (NPDES). It gave EPA the authority to implement pollution control programs such as setting wastewater standards for industry. The Clean Water Act also continued requirements to set water quality standards for all contaminants in surface waters. The Act also funded the construction of sewage treatment plants under the construction grants program and recognized the need for planning to address the critical problems posed by nonpoint source pollution. Revisions in 1981 streamlined the municipal construction grants process, improving the capabilities of treatment plants built under the program. Over the years, many other laws have changed parts of the Clean Water Act. Title I of the Great Lakes Critical Programs Act of 1990, for example, codified parts of the Great Lakes Water Quality Agreement of 1978, signed by the U.S. and Canada, where the two nations agreed to reduce certain toxic pollutants in the Great Lakes. That law required EPA to establish water quality criteria for the Great Lakes addressing 29 toxic pollutants with maximum levels that are safe for humans, wildlife, and aquatic life. (See 40 CFR Part 132.) It also required EPA to help the States implement the criteria on a specific schedule. “Hazardous substances” are defined at 40 CFR 116.4.

EPA and a predecessor agency have produced a series of scientific water quality criteria guidance documents. Early Federal efforts were the “Green Book” (FWPCA, 1968) and the “Red Book” (USEPA, 1976), and “Gold Book” (USEPA, 1986). These early efforts were premised on the use of literature reviews and the collective scientific judgment of Agency and advisory panels. However, when faced with the need to develop criteria for human health as well as aquatic life, the Agency determined that new procedures were necessary. Continued reliance solely on existing scientific literature was deemed inadequate because essential information was not available for many pollutants. EPA scientists developed formal methodologies for establishing scientifically defensible criteria. These were subjected to review by the Agency’s Science Advisory Board of outside experts and the public. This effort culminated on November

28, 1980, when the Agency published criteria development guidelines for aquatic life and for human health, along with criteria for 64 toxic pollutants. However, the individual criteria documents, as updated, are the official guidance documents. For toxic pollutants, the documents tabulate the relevant acute and chronic toxicity information for aquatic life and derive the criteria maximum concentrations (acute criteria) and criteria continuous concentrations (chronic criteria) that the Agency recommends to protect aquatic life resources. EPA continues to update and add criteria for additional chemicals.

States and Tribes typically adopt both numeric and narrative criteria. Numeric criteria are important where the cause of toxicity is known or for protection against pollutants with potential human health effects. Narrative criteria are also important -- narrative "free from toxicity" criteria typically serve as the basis for limiting the toxicity of waste discharges to aquatic species (based on whole effluent toxicity testing).

Section 303(c)(2)(B) of the Clean Water Act requires States and authorized Tribes to adopt numeric criteria for § 307(a) priority toxic pollutants for which the Agency has published § 304(a) criteria, if the discharge or presence of the pollutant can reasonably be expected to interfere with designated uses. The § 307(a) list contains 65 compounds and families of compounds, which the Agency has interpreted to include 126 priority toxic pollutants.

In addition to narrative and numeric (chemical-specific) criteria, other types of water quality criteria include: *biological criteria*, a description of the desired aquatic community, for example, based on the numbers and kinds of organisms expected to be present in a water body; *nutrient criteria*, a means to protect against nutrient over-enrichment and cultural eutrophication; and, *sediment criteria*, a description of conditions that will avoid adverse effects of contaminated and uncontaminated sediments.

For Sediment Quality Guidelines, see <http://www.epa.gov/waterscience/cs/guidelines.htm#noaa>.

For a more thorough, brief introduction (66 slides) to the Clean Water Act, please visit the Watershed Academy's Web-based training module called, "Introduction to the Clean Water Act" found at <http://www.epa.gov/watertrain/cwa/>. For the current water quality criteria table, go to <http://www.epa.gov/waterscience/standards/wqcriteria.html>.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)  
CERCLA, commonly known as Superfund, was enacted by Congress on December 11, 1980. This law created a tax on the chemical and petroleum industries and provided broad Federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment. Over five years, \$1.6 billion was collected and the tax went to a trust fund for cleaning up abandoned or uncontrolled hazardous waste sites. CERCLA: established prohibitions and requirements concerning closed and abandoned hazardous waste sites; provided for liability of persons responsible for releases of hazardous waste at these sites; and established a trust fund to provide for cleanup when no responsible party could be identified.

The law authorizes two kinds of response actions: Short-term removals, where actions may be taken to address releases or threatened releases requiring prompt response; and, Long-term remedial response actions, that permanently and significantly reduce the dangers associated with releases or threats of releases of hazardous substances that are serious, but not immediately life threatening. These actions can be conducted only at sites listed on EPA's [National Priorities List](#) (NPL).

CERCLA was amended by the [Superfund Amendments and Reauthorization Act](#) (SARA) on October 17, 1986. SARA:

- stressed the importance of permanent remedies and innovative treatment technologies in cleaning up hazardous waste sites;
- required Superfund actions to consider the standards and requirements found in other State and Federal environmental laws and regulations;
- increased State involvement;
- increased the focus on human health problems;
- encouraged greater citizen participation; and,
- increased the size of the trust fund to \$8.5 billion.

The CERCLA tax has not been reauthorized by Congress, and the trust fund is only adequate to continue remedial actions at a reduced rate. (correct?)

Under CERCLA, "hazardous substance" is any material EPA has designated for special consideration under the Clean Air Act, the Clean Water Act, the Toxic Substances Control Act, or the Resource Conservation and Recovery Act (RCRA). EPA also may designate additional substances as being hazardous under CERCLA.

Programs Related to Superfund: Abandoned Mine Lands, Brownfields Economic Redevelopment Initiative, Construction Completion, Dynamic Field Activities, Emergency Response Program, Environmental Justice in Waste Programs, Environmental Response Team, Lead Workgroups, National Advisory Council on Environmental Policy and Technology (NACEPT) Superfund Subcommittee, National Risk-Based Priority Panel, Natural Resource Damages: EPA and Natural Resource Trustee Roles and Responsibilities, Post Construction Completion, Reauthorization, Risk Assessment, Site Assessment, Superfund Analytical Services/Contract Laboratory Program (CLP), Superfund Redevelopment Initiative, Superfund Reforms (all linked at <http://www.epa.gov/superfund/programs/index.htm#epa>).

#### Emergency Planning and Community Right-to-Know Act

Also known as Title III of [SARA](#), EPCRA was enacted by Congress as the national legislation on community safety. This law was designated to help local communities protect public health, safety, and the environment from chemical hazards. EPCRA establishes requirements for Federal, State and local governments, Indian Tribes, and industry regarding emergency planning and "Community Right-to-Know" reporting on hazardous and toxic chemicals. The Community Right-to-Know (Toxic Release Inventory) provisions help increase the public's knowledge and access to information on chemicals at individual facilities, their uses, and releases into the environment. States and communities, working with facilities, can use the information to improve chemical safety and protect public health and the environment.

The Extremely Hazardous Substance (EHS) profiles contain information about each of the 356 EHS currently listed as part of Section 302 of EPCRA. Each chemical profile includes physical/chemical properties, health hazards, fire and explosion hazards, reactivity data, precautions for safe handling and use, and protective equipment for emergency situations. The profiles were originally developed in 1985 for the 402 chemicals then called "acutely toxic chemicals" under the Chemical Emergency Preparedness Program. Subsequent additions and deletions resulted in 366 chemicals listed in February 1988 as extremely hazardous substances. Other chemicals may be added or deleted in the future.

### Endangered Species Act

The Endangered Species Act provides a program for the conservation of threatened and endangered plants and animals and the habitats in which they are found. The U.S. Fish and Wildlife Service of the Department of the Interior maintains the list of 632 endangered species (326 are plants) and 190 threatened species (78 are plants). Species include birds, insects, fish, reptiles, mammals, crustaceans, flowers, grasses, and trees. (Controversially, the ESA does not identify algae or protozoans that serve as the base of the aquatic food web for protection.) Anyone can petition FWS to include a species on this list. The law prohibits any action, administrative or real, that results in a "taking" of a listed species, or adversely affects habitat. Likewise, import, export, interstate, and foreign commerce of listed species are all prohibited. EPA's decision to register a pesticide is based in part on the risk of adverse effects on endangered species as well as environmental fate (how a pesticide will affect habitat). Under FIFRA, EPA can issue emergency suspensions of certain pesticides to cancel or restrict their use if an endangered species will be adversely affected. Under a new program, EPA, FWS, and USDA are distributing hundreds of county bulletins that include habitat maps, pesticide use eliminations, and other actions required to protect listed species.

### **Five Laws Affecting EPA's Pesticide Programs (August 1998)**

There are over 20,000 pesticide products registered for use in the United States. Several laws govern the Federal regulatory program for these pesticide products. Under Federal law, the Environmental Protection Agency is largely responsible for regulating the sale and use of pesticides, and the allowable levels of such pesticides in or on food. EPA's authority, and the limits to that authority, are contained in two core statutes, (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA). In 1996, both statutes were amended by the Food Quality Protection Act (FQPA). In addition, many other Environmental and procedural statutes provide shape and direction to the Agency's pesticide program. This overview covers several of the most common statutes affecting EPA's pesticide program.

1. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) FIFRA provides the overall framework for the federal pesticide program. Under FIFRA, EPA is responsible for registering, or licensing pesticide products for use in the United States. Pesticide registration decisions are based on a detailed assessment of the potential effects of a product on human health and the environment, when used according to label directions. These approved labels have the force of law, and any use which is not in accordance with the label directions and precautions may be subject to civil and/or criminal penalties. FIFRA also requires that EPA reevaluate older pesticides to ensure that they meet more recent safety standards. FIFRA requires EPA and states to establish programs to protect workers, and provide training and certification for applicators as well.

2. Federal Food, Drug, and Cosmetic Act (FFDCA) The Federal Food, Drug, and Cosmetic Act (FFDCA) governs the establishment of pesticide tolerances for food and feed products. A tolerance is the maximum level of pesticide residues allowed in or on human food and animal feed. EPA and the Food and Drug Administration (FDA) are responsible for administering the Act.

3. Food Quality Protection Act (FQPA) This law, passed in 1996, amends both FIFRA and FFDCA, setting a tougher standard for pesticides used on food. FQPA established a single, health based standard to be used when assessing the risks of pesticide residues in food or feed. The new safety standard is measured considering the aggregate risk from dietary exposure and other non-occupational sources of exposure, such as drinking water and residential lawn uses. In addition, when setting new, or reassessing existing, tolerances under the new standard. EPA must now focus explicitly on exposures and risks to infants and children. Decisions must consider whether tolerances are safe for children assuming, when appropriate, an additional safety factor to account for uncertainty in data.

Other FQPA Requirements include:

- Under FQPA, EPA may only establish a tolerance if there is "a reasonable certainty" that no harm will result from all combined sources of exposure to pesticides (aggregate exposures). FQPA also considers the combined effects of human exposure to different pesticides that may act in similar ways on the body (cumulative exposure).
- By 2006, EPA must review all old pesticides to make sure that the residues allowed on food meet the new safety standard.
- FQPA also requires that pesticides be tested for endocrine disruption potential. Endocrine disruptors may be linked to a variety of sexual, developmental, behavioral, and reproductive problems.
- EPA must distribute a brochure to supermarkets discussing pesticides on foods in order to better inform the public.

4. Federal Advisory Committee Act FACA establish policies and procedures for seeking external stakeholder input on Federal Agency activities. This law ensures that such consultation is open to the public and transparent. OPP FACA committees have included:

- Tolerance Reassessment Advisory Committee
- Food Safety Advisory Committee
- Endocrine Disruptors Screening and Testing Advisory Committee
- Pesticide Program Dialogue Committee
- FIFRA Scientific Advisory Panel (SAP) and Scientific Advisory Board
- State FIFRA Issues Research and Evaluation Group (SFIREG)

5. Safe Drinking Water Act (SDWA) The Safe Drinking Water Act was established to protect the quality of drinking water in the United States from both underground and above ground sources. In 1996, Congress amended the law to require the development of a screening and testing program for chemicals and pesticides for possible endocrine disrupting effects. EPA must develop and present a screening program to Congress and begin implementation by August 1999 to determine whether certain substances may have endocrine effects. This same requirement was contained in FQPA.

A pesticide is any substance or mixture of substances intended for:

- preventing,
- destroying,
- repelling, or
- mitigating any pest.

The term pesticide applies to insecticides, herbicides, fungicides, and various other substances used to control pests. Many household products are pesticides. Under United States law, a pesticide is also any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

Pests are living organisms located where they are not wanted or that cause damage to crops or humans or other animals. Examples include: insects, mice and other animals, unwanted plants (weeds), fungi, microorganisms such as bacteria and viruses, and prions which cause bovine spongiform encephalitis.

By their very nature, most pesticides create some risk of harm. Pesticides can cause harm to humans, animals, or the environment because they are designed to kill or otherwise adversely affect living organisms. At the same time, pesticides are useful to society. Pesticides can kill potential disease-causing organisms and control insects, weeds, and other pests. Biologically-based pesticides, such as pheromones and microbial pesticides, are becoming increasingly popular and often are safer than traditional chemical pesticides.

The U.S. definition of pesticides is quite broad, but it does have some exclusions:

- Drugs used to control diseases of humans or animals (such as livestock and pets) are not considered pesticides; such drugs are regulated by the Food and Drug Administration.
- Fertilizers, nutrients, and other substances used to promote plant survival and health are not considered plant growth regulators and thus are not pesticides.
- Biological control agents, except for certain microorganisms, are exempted from regulation by EPA. (Biological control agents include beneficial predators such as birds or ladybugs that eat insect pests.)
- Products which contain certain low-risk ingredients, such as garlic and mint oil, have been exempted from Federal registration requirements, although State regulatory requirements may still apply.

Regulatory action fact sheets discuss how EPA regulates certain chemicals or types of pesticides and other regulatory actions at [http://www.epa.gov/pesticides/factsheets/reg\\_fs.htm](http://www.epa.gov/pesticides/factsheets/reg_fs.htm).

#### Food Quality Protection Act

See FIFRA and the 'Setting Tolerances for Pesticide Residues in Food' fact sheet

In addition, Section 405(p) of the 1996 Food Quality Protection Act (FQPA) requires that EPA develop (within 2 years) and implement (within 3 years) an estrogenic effects screening program

for all pesticides using validated test methods. The FQPA also gives EPA the authority to require testing of other chemicals "that may have an effect that is cumulative to an effect of a pesticide." The FQPA states that data can be obtained via Section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Section 4 of TSCA, or an "order" if it can be shown that neither FIFRA nor TSCA can be applied. Similarly the newly amended Safe Drinking Water Act (SDWA) gives EPA authority to require testing of substances found in drinking water and to which there may be substantial exposure.

#### National Environmental Policy Act (NEPA) 1969, as amended

Through NEPA, Congress imposed the requirement on Federal Agencies to perform environmental impact statements or a finding of no *significant* impact for major federal actions. *Actions* include projects and programs entirely or partly run by federal agencies; new or revised agency rules, regulations, plans, policies, or procedures; and legislative proposals. Federal agencies are directed to use all practicable legal means to restore and enhance the quality of the *human environment* and avoid or minimize any possible adverse *effects* of their actions on the quality of the *human environment*. *Effects* include both direct effects (caused by the action, simultaneous with the action, and at the location of the action) and indirect (caused by the action, later in time, farther removed in distance). *Indirect effects* include growth inducing effects and other effects related to induced changes in the pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including ecosystems. *Human environment* includes the natural and physical environment and the interrelationship of people with that environment. *Significant* as used in NEPA requires consideration of context (society as a whole, the affected region, the affected interests, and the locality), intensity (severity of good and bad impacts, degree to which public health and safety is affected, unique characteristics of the geographic area, degree of controversy, uncertainty in the degree of human effects, whether the action is precedent-setting, relationship to other possibly insignificant actions with significant cumulative effects, adverse impact to Historic Places or significant resources, effect on endangered or threatened species, or critical habitat), and whether the action threatens a violation of law imposed to protect the environment.

#### Oil Pollution Act

The Oil Pollution Act (OPA) of 1990 streamlined and strengthened EPA's ability to prevent and respond to catastrophic oil spills. A trust fund managed by the Coast Guard and financed by a tax on oil is available to clean up spills when the responsible party is incapable or unwilling to do so. OPA requires oil storage facilities and vessels to submit to the Federal government plans detailing how they will respond to large discharges. EPA has published regulations for aboveground storage facilities; the Coast Guard has done so for oil tankers. OPA also requires the development of Area Contingency Plans to prepare and plan for oil spill response on a regional scale.

#### Pollution Prevention Act (nonregulatory; grant authority)

The Pollution Prevention Act focused industry, government, and public attention on reducing the amount of pollution through cost-effective changes in production, operation, and raw materials use. Opportunities for source reduction are often not realized because of existing regulations, and the industrial resources required for compliance, focus on treatment, and disposal. Source reduction is fundamentally different and more desirable than waste management or pollution control.

### Safe Drinking Water Act

The Safe Drinking Water Act was established to protect the quality of drinking water in the U.S. This law focuses on all waters actually or potentially designed for drinking use, whether from above ground or underground sources. The Act authorized EPA to establish safe standards of purity and required all owners or operators of public water systems to comply with primary (health-related) standards (e.g., maximum contaminant levels in treated water). State governments, which assume this power from EPA, also encourage attainment of secondary standards (nuisance-related).

### Solid Waste Disposal Act , as amended (Resource Conservation and Recovery Act or RCRA)

RCRA gave EPA the authority to control hazardous waste generation, transportation, treatment, storage, and disposal of hazardous waste. Waste is hazardous when it is ignitable, corrosive, or reactive (explosive). Also, if waste contains concentrations of 40 toxic chemicals above regulatory thresholds, it is considered hazardous. There are 500 specific hazardous wastes that have been defined by EPA. RCRA also set forth a framework for the management of non-hazardous wastes. The 1986 amendments to RCRA enabled EPA to address environmental problems that could result from underground tanks storing petroleum and other hazardous substances. RCRA focuses only on active and future facilities and does not address abandoned or historical sites. One of RCRA's goals is to clean up waste which may have spilled, leaked, or been improperly disposed and which poses a threat to human health or the environment. The Federal Hazardous and Solid Waste Amendments (HSWA) are the 1984 amendments to RCRA that required phasing out land disposal of hazardous waste.

Through national voluntary and [educational programs](#), EPA works to assure the safe management of nonhazardous household, [industrial](#), and [mining wastes](#). We promote and encourage the use of combined methods to manage solid waste. These methods are: [source reduction](#) or waste prevention, which means any practice that reduces the amount or toxicity of waste generated; [recycling](#), which conserves disposal capacity and preserves natural resources by preventing potentially useful materials from being thrown away; and [landfilling](#) and [waste combustion](#).

### Toxic Substances Control Act (U.S. EPA; U.S. Customs, Department of State; ATSDR, U.S. DHHS)

The Toxic Substances Control Act (TSCA) of 1976 was enacted by Congress to give EPA the ability to track the 75,000 industrial chemicals currently produced or imported into the United States. EPA repeatedly screens these chemicals and can require reporting or testing of those that may pose an environmental or human-health hazard. EPA can ban the manufacture and import of those chemicals that pose an unreasonable risk. Also, EPA has mechanisms in place ('Pre-Manufacture Notice' and 'Significant New Use' Rules) to track the thousands of new chemicals that industry develops each year with either unknown or dangerous characteristics. EPA then can control these chemicals as necessary to protect human health and the environment. TSCA supplements other Federal statutes.

Under TSCA, EPA has broad authority to issue regulations designed to gather health/safety and exposure information on, require testing of, and control exposure to chemical substances and mixtures. Drugs, cosmetics, foods, food additives, pesticides, and nuclear materials are exempt

from TSCA. EPA's TSCA Inventory currently contains over 70,000 existing chemicals. The TSCA Inventory is a compilation of the names of all existing chemical substances along with their respective Chemical Abstract Service (CAS) Registry numbers, production/importation volume ranges, and specific sites of production/importation. Chemicals produced in annual volumes above 1 million pounds are considered High Production Volume or "HPV" chemicals. This subset of 3,000-4,000 HPV chemicals is the main focus of OPPT's Existing Chemicals Data Collection and Data Development (Testing) activities. Data on chemicals that are collected or developed are made accessible to the public and are intended to provide input for efforts to evaluate potential risk from exposures to these chemicals.

### **Master Testing List - Executive Summary**

Section 2 of the Toxic Substances Control Act (TSCA) states, "It is the policy of the United States that adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and development of such data be the responsibility of those who manufacture and those who process such chemicals and mixtures."

*Under Section 4, EPA can by rule require testing after finding that (1) a chemical may present a hazard to human health or the environment, and/or the chemical is produced in substantial quantities that could result in significant or substantial human or environmental exposure, (2) the available data to evaluate the chemical are inadequate, and (3) testing is needed to develop the needed data.* In order to determine the hazard, EPA considers:

- Substantial production/importation (1 million pounds), and;
- Substantial release (1 million pounds or 10% of production/importation), or;
- Substantial human exposure (1,000 workers or 10,000 consumers or 100,000 general population), or;
- Significant human exposure (Determined on a case-by-case basis).

The Chemical Testing Program in EPA's Office of Pollution Prevention and Toxics (OPPT) also works with members of the U.S. chemical industry to develop needed data via TSCA Section 4 Enforceable Consent Agreements (ECAs) and Voluntary Testing Agreements (VTAs). ECAs and VTAs are usually less resource intensive than formal TSCA rule-making and allow EPA to consider agreed-upon pollution prevention and other types of product stewardship initiatives by the chemical industry as a possible substitute for or adjunct to certain types of needed testing. OPPT has been using a "Master Testing List" (MTL) since 1990 to establish its TSCA Existing Chemical Testing Program agenda. The MTL presents a consolidated listing of OPPT's Existing Chemical Testing Program priorities as well as those brought forward to OPPT by other EPA program offices, other Federal agencies, the TSCA Interagency Testing Committee, and international organizations such as the Organization for Economic Cooperation and Development (OECD). The main purposes of the MTL are to (1) identify chemical testing needs of the Federal Government (including EPA) and relevant international organizations (e.g., OECD), (2) focus limited EPA resources on the highest priority chemical testing needs, (3) publicize the testing priorities for industrial chemicals, (4) obtain broad public input on OPPT's TSCA Chemical Testing Program and its priorities, and (5) encourage voluntary initiatives by the U.S. chemical industry to fill the priority data needs that are identified on the MTL.

*The identification of testing needs on the MTL provides an opportunity for responsible companies to initiate voluntary activities to develop the needed data for their own MTL-listed chemicals. In those instances in which companies decline to take this opportunity, EPA is put in a position of having to initiate formal, resource intensive, regulatory actions such as promulgating TSCA Section 4 Test Rules. Issuance of such rules can be viewed as "forcing"*

*chemical companies to adhere to their own professed standards of product stewardship and corporate responsibility.*

The MTL contains over 500 individual existing chemicals and more than 10 existing chemical categories and presents EPA's TSCA Chemical Testing Program priorities for 1996-1998.

Testing actions are currently being developed on more than 200 chemicals listed on the MTL while testing is currently underway on almost 300 chemicals identified on the MTL. In addition, more than 100 chemicals are being removed from the MTL at this time, over 70 of those because their testing programs have been completed.

It is also important to note that the Chemical Testing Program and the MTL are integral components of the TSCA Existing and New Chemicals Programs. These programs are responsible for assessing and managing health and environmental risks that may be posed by existing and new chemicals covered by TSCA. The "universe" of existing chemicals on the TSCA Chemical Substances Inventory that may present the greatest potential health and/or environmental concerns have been and continue to be identified and refined through various existing chemical screening activities within OPPT.

EPA must make statutory TSCA Section 4 "[data inadequacy](#)" and "[testing is necessary](#)" findings.

TSCA Section 4 testing must be conducted via [EPA-approved test methods/guidelines](#).

The relationship with industry can be somewhat adversarial.

[TSCA Section 12\(b\)](#) export notice requirements are triggered by TSCA Section 4 test rules.

**Great Lakes Regional Collaboration  
Toxic Pollutant Strategy White Paper  
Preventing Pollution: A Tool to Reduce and Eliminate Persistent Toxic Substances  
in the Great Lakes Basin**

**Background**

Innovative sustainability requires radical change. Improving the health of the Great Lakes Ecosystem presents challenges that must include the reduction of wastes containing persistent toxic substances (PTS). If a substance is harmful or toxic to a natural system, preventing its introduction into the system is integral to the long-term viability and environmental integrity of that system.

Pollution prevention is a cost effective strategy that can reduce PTSs at the source. If a persistent toxic substance is reduced or eliminated at its source, the long-term capital investment in regulation, control and clean up of that PTS is also reduced. Often pollution prevention efforts impact multiple toxic substances and result in synergies that positively impact the natural environment, economic growth and equitable social conditions at the same time.

Pollution prevention (P2) requires individual and collective action, continuous improvement, and taking ownership and responsibility for its implementation and growth potential. By creating an atmosphere of collaboration, shared value, and applied problem solving, P2 is able to influence the management of PTSs for municipalities, industries and individuals by:

- Reducing treatment, transport, and disposal costs.
- Minimizing compliance issues and cost associated with regulated wastes.
- Reducing future liability through reduced risks to workers, communities, and the environment.
- Avoiding costs of accidents and spills.
- Improving production times.
- Enhancing public image and community relations.

Examples of successful P2 practice in the Great Lakes Basin include a variety of programs such as Household Hazardous Waste Collections, Tribal Burn Barrel Strategies, Pesticide Cleansweep Programs and Mercury and PCB Reduction . The 1990's resulted in several Great Lakes States and Canada taking action to eliminate sources of PTSs. Mercury, for example, is present in a wide variety of consumer products. By targeting specific sources of use, such as schools, hospitals, end-of-life automobiles and dental offices, elemental mercury is being removed from the waste stream and replaced with alternative raw materials. For example, in 2000 New York reported a reduction of 505 lbs. of elemental, free flowing mercury recovered from auto switches bound for crushing and shredding operations. In 2004, Michigan reported collecting 8,187 mercury

containing devices from households, school laboratories, doctor's offices and clinics reclaiming 621 lbs. of mercury.

## **Current and Future Considerations**

As the global market for manufactured goods becomes more competitive, improved efficiency in the use of natural resources is integral to a sustainable economy and society in the Great Lakes Basin. Waste reduction and the elimination of potentially harmful substances in the design of products is now becoming a dominant principal in how things are made. Performance indicators that include environmental and social impacts are beginning to define, rate and hold corporations accountable and responsible for their actions. Corporate Social Responsibility (CSR) performance is an excellent indicator of management quality and is a driver of stock returns. CSR is challenging companies to work with other stakeholders to achieve system change.

Programs such as Environmental Management Systems, Green Engineering, Green Chemistry, Design for the Environment, Environmentally Preferred Purchasing and others are shifting the paradigm of historical support for unsustainable, independent practices to one of interdependence and shared values. The cyclical use of materials and the targeting of specific toxic chemicals for replacement are now being considered as a valuable component of new product development by companies. Defining materials flows is resulting in the creation of products designed to be recycled. Service oriented programs are also being created to take back product at the end of use so raw materials can be recovered and reused for new or different products. The use of alternative fuel and energy sources is also considered a marketable indicator in new the Green Label Initiative.

The waste reduction and elimination models now being practiced in some industries provide a new vision for all stakeholders in the Great Lakes Basin. If we consider that in all natural systems, waste equals food, ecosystem sustainability is an easy concept to grasp. Innovative solutions through strong partnerships is what it will take to finally recognize that in both, human and natural systems, sustainability is an outcome of relationships among the parts.

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**Great Lakes Regional Collaboration  
Toxic Pollutant Strategy White Paper  
Existing Great Lakes Chemical Monitoring Programs**

The Great Lakes region is fortunate to have a number of programs that monitor for PBTs and other toxic substances. A number of major programs, mostly those that are ongoing, are listed below. This list is by no means 100% comprehensive; many one-time projects are not included.

Include RAPIDS (emissions inventory) and TRI?

## **AIR**

The **Integrated Atmospheric Deposition Network (IADN)**, a joint U.S.EPA-Environment Canada program, monitors concentrations of PCBs, pesticides, PAHs, and trace metals in the air and precipitation of the Great Lakes basin. Limited monitoring has been conducted for dioxins and furans, mercury, and PBDEs.

The **National Air Pollution Surveillance (NAPS)** network collects data on ambient air levels of toxics at rural, suburban, city-centre, and industrial sites in Canada. This effort is carried out by Environment Canada in cooperation with provincial environmental and municipal agencies. The program includes measurement of volatile organic compounds (VOC), including toxics and ground-level ozone precursors, polar volatile organics (PVOC) such as aldehydes and ethers, components of fine particulate matter (PM), including metals and inorganic and organic ions, and persistent, toxic semi-volatile organic compounds (SVOC) such as benzo(a)pyrene and polychlorinated dibenzo-p-dioxins (CDDs) and furans (CDFs).

The **Mercury Deposition Network (MDN)** began in 1995 and measures total mercury (and in some cases, methylmercury) in precipitation. Over 85 sites currently are in operation, including sites in most of the Great Lakes states (excluding Michigan and Ohio) and in Ontario.

The **Michigan Mercury Deposition Network**, run by Michigan DEQ and University of Michigan (Dr. Jerry Keeler), has been in operation in some form since late 1994. The network monitors speciated mercury in air and precipitation at rural and urban sites in Michigan.

In 1996, Environment Canada initiated the **Canadian Atmospheric Mercury Measurement Network (CAMNet)**, which consists of 11 sites that span the country. Tekran mercury analyzers are used to monitor total gaseous mercury (TGM) concentrations, and RGM is monitored at some sites. Precipitation mercury measurements are taken at some of the sites through the MDN.

Atmospheric concentrations of dioxins, furans, and coplanar PCBs are monitored by the **National Dioxin Air Monitoring Network (NDAMN)**, with a focus on meat and poultry-producing areas. NDAMN stations in the Great Lakes region include Fondulac, MN; Lake Dubay, WI; and Jasper, NY. Funding for this network is currently ending (as of March 2005).

## WATER AND SEDIMENTS

Since 1980, the Ontario Ministry of the Environment (OME) **Enhanced Tributary Monitoring Program (ETMP)** has been collecting water samples (and biota?) near the mouths of 16 strategically chosen watersheds throughout the Great Lakes Basin representing approximately 50% of the total flow into the Great Lakes from Canadian watersheds. Currently, approximately 20 samples per year are collected at each station with an emphasis on the spring freshet, which typically accounts for a significant proportion of annual contaminant loadings. Samples are analysed for trace organics (PCB congeners, organochlorines, chlorobenzenes, and PAHs), physical parameters, nutrients, and metals, as well as other in-use pesticides at selected locations.

Through the **Great Lakes Index Station Network Monitoring** program, OME samples at 66 stations in summer to determine concentrations of priority toxic contaminants in sediment and suspended particulate material. Summer species composition and abundance of benthic invertebrates are monitored as a biological indicator of overall ecosystem health and as a general stress response indicator.

Through Environment Canada Ecosystem Health Division's (EHD) **Great Lakes Surveillance Program**, water quality is monitored in the Great Lakes via cruises alternated between the lakes except Lake Michigan so that each is monitored biennially. Water quality information (for both organic and inorganic compounds) is collected along with supporting information.

EHD conducts **water quality monitoring on the Interconnecting Channels** of the Great Lakes (i.e. St. Lawrence, Niagara, St. Clair and Detroit Rivers) to assess upstream/downstream loadings of pollution. Water and suspended sediment samples are collected to determine concentrations and loadings of trace organics (pesticides, chlorobenzenes, PCBs, PAHs, and chemicals of emerging concern).

EHD also operates the **Tributary Track-down Program**, which screens sediments in Lake Erie and Lake Ontario tributaries for contaminants to determine the extent of contamination as well as to help indicate if ongoing sources may be present in watersheds.

For the above EHD programs, see <http://www.on.ec.gc.ca/monitoring/water-quality/intro-e.html>

U.S. EPA-GLNPO initiated the **Great Lakes Aquatic Contaminant Surveillance (GLACS)** program in 2003 to monitor levels of PCBs, organochlorine pesticides, PAHs, mercury, dioxins and furans, and pollutants of emerging concern (PBDEs and PFOS/PFOA) in Great Lakes water. Similar monitoring for organochlorines had been undertaken by GLNPO in the mid-1990s. Monitoring will most likely rotate among the Lakes, with a focus on one Lake each year (following the U.S-Canada Cooperative Monitoring program).

The **Great Lakes Sediment Assessment Program**, begun in 1997, assesses contaminant concentrations in sediment in the Great Lakes.

[www.nwri.ca](http://www.nwri.ca)

In order to determine the nature and extent of sediment contamination, GLNPO uses the R/V Mudpuppy to conduct sampling to perform **sediment assessments at in Great Lakes AOCs** in the U.S.

The Lake Erie-Lake St. Clair Basin is one of more than 50 study units that are part of the U.S. Geological Survey's **National Water-Quality Assessment (NAWQA) Program**. Sediment and water samples from this unit have been analyzed for organic contaminants as well as in-use pesticides.

<http://oh.water.usgs.gov/nawqa/index.html>

## **FISH**

The Canadian **Department of Fisheries and Oceans (DFO) Great Lakes Fish Contaminants Surveillance Program** was developed jointly with the U.S. EPA and the U.S. Fish and Wildlife Service (FWS) and was initiated in 1977. Lake trout (or walleye for western Lake Erie) are collected in cooperation with the Ontario Ministry of Natural Resources and DFO collects prey fish species (alewife, sculpin, smelt) and invertebrate diet items (Mysis, Diporeia, plankton) at a subset of the monitoring sites annually. Fish are collected at 10 sites annually, but the sites rotate among 4 sites on each Lake. Whole fish are analyzed for PCBs, OC pesticides, and mercury. A subset of the samples is analyzed for non-routine contaminants (toxaphene, dioxins and furans, chemicals of emerging concern) by the EC Ultra-trace Laboratory at Burlington. DFO also measures a limited number of metals (arsenic, copper, cadmium, lead, nickel, and zinc) in selected forage fish. DFO maintains a tissue bank for retrospective analysis.

The U.S. EPA Great Lakes National Program Office (GLNPO), in cooperation with the eight Great Lakes States and USGS Biological Research Division, monitors PBTs in fish in the open waters and tributaries of the Great Lakes through the **Great Lakes Fish Monitoring Program (GLFMP)**. The program has been operating in some form since the 1960s. The first element of the program monitors contaminants in whole lake trout (walleye in Lake Erie) to assess temporal trends in the open waters of the Lakes, as well as to assess the risks of such contaminants on the health of the fishery and on the wildlife that consume them. The second element monitors contaminants in skin-on fillets of popular sport fish, coho and chinook salmon (rainbow trout in Lake Erie), to assess human exposure.

The **Great Lakes States and Tribes** also operate their own **fish contaminant monitoring** programs, which are used to determine fish consumption advisories. Fish advisory guidance varies from state to state.

## **OTHER WILDLIFE**

Long-term monitoring of contaminant levels in mussels, zebra mussels, juvenile fish, and selected sport fish is undertaken via the **Ontario Biomonitoring Program** to track levels of PBTs across the Great Lakes. Sport fish results track trends over the basin as a whole, as well as forming the basis of the Guide to Eating Ontario Sport Fish. Mussel and juvenile fish data provide a means of identifying problem zones and potential contaminant sources. The **Ontario Sport Fish Contaminant Monitoring Program** is part of this effort.

The Canadian Wildlife Service (CWS) of Environment Canada has been monitoring levels of persistent toxics (including organochlorines and mercury) in **herring gull eggs** at 15 Great Lakes sites since 1974. The Michigan Department of Environmental Quality (MDEQ) began a similar annual gull egg monitoring project in 1999, augmenting the CWS work. In addition to Herring gull egg monitoring, the CWS occasionally measures contaminants in eggs from double-crested cormorants, ring-billed gulls, black-crowned night herons, great black-backed gulls and several species of terns. CWS has also performed periodic contaminant monitoring in **amphibians and ospreys**.

For more than 20 years, the Canadian Wildlife Service (CWS) has periodically collected **Snapping Turtle eggs** and examined the species' reproductive success in relation to contaminant levels on a research basis.

Populations of **bald eagles** nesting on the shores of Lakes Erie and Ontario have been monitored annually by Ontario Ministry of Natural Resources, Canadian Wildlife Service, and Bird Studies Canada since 1983. Between 1988-1999, blood and feather samples were taken from eaglets to monitor levels of PCBs, organochlorine pesticides, and heavy metal contaminants.

Environment Canada initiated the **Fish and Wildlife Health Effects and Exposure Study** in 2001. The goal of this systematic assessment in Canadian AOCs is to determine if there are fish and wildlife health effects, similar to those reported for the human population, that are associated with contaminants in the aquatic environment. Phase I (2001-2005) of the study investigates conditions in the Canadian AOCs of the lower Great Lakes. Upon completion, the need for assessments at AOCs in the upper Great Lakes will be determined.

## **HUMAN BIOMONITORING**

A recent study conducted by the Wisconsin Department of Public Health (WiDPH) analyzed the level of bioaccumulative toxic chemicals in women of childbearing age (18 – 45) in the Great Lakes Basin. Samples were collected from women who used 3 different Women Infant and Child (WIC) clinics located along Lakes Michigan and Lake Superior.

A similar study was conducted by a partnership of the Assembly of First Nations, Health Canada and First Nations in the Great Lakes basin between 1990 and 2000 to examine the effects of contaminants on the health of the Great Lakes Aboriginal population. The Contaminants in Human Tissues Program (CHT) identified three main goals:

- To determine the levels of environmental contaminants in the tissues of First Nations people in the Great Lakes Basin;
- To correlate these levels with freshwater fish and wild game consumption; and
- To provide information and advice to First Nations people on the levels of environmental contaminants found in their tissues.

In 2000, Health Canada compared the incidence of morbidity and mortality in human populations in the 17 Areas of Concern (AOCs) in Ontario to rates for the province as a whole. The Health Canada studies were based primarily on hospital and census databases. For each

AOC, specific data were compiled on a variety of diseases and disorders, such as cancer incidence, reproductive disorders, and congenital deformities. A second, independent analysis of the Health Canada data focused on two highly industrialized AOCs, Windsor and Hamilton [see *Environmental Health Perspectives* 109 (6): 827-843 (2001)].

Initiated in 1992, the Agency for Toxic Substances and Disease Registry (ATSDR) Great Lakes Human Health Effects Research Program (GLHHERP) is designed to characterize exposure to contaminants via consumption of Great Lakes fish and investigate the potential for short- and long-term adverse health effects via grants to researchers.

While there have been many small-scale human biomonitoring studies, no Great Lakes regional human biomonitoring program, which could be conducted similarly to the CDC National Health and Nutrition Examination Survey (NHANES) project, has been undertaken.

**Great Lakes Regional Collaboration  
Toxic Pollutant Strategy White Paper  
Indicators of Persistent Toxic Substances in the Great Lakes Basin**

Developing strategies for reducing the impacts of persistent toxic substances in the Great Lakes basin requires the ability to define goals and assess progress toward meeting them. Such goals and assessments must be based on indicators that are 1) quantifiable; 2) able to be measured consistently across time and geography; and 3) adequately reflect the state of the environment with regard to the impacts in question.

**Defining goals and indicators**

A first step in defining indicators is to define the types of goals toward which progress must be indicated. With regard to persistent toxic substances, the Great Lakes Water Quality Agreement has set a goal of “virtual elimination.” In addition, Annex 2 to the Agreement defines 14 “impairments of beneficial use” which are to be avoided. Among these 14, many are or may be caused by PTSs, including restrictions on fish and wildlife consumption, degradation of fish and wildlife populations, fish tumors and other deformities, bird or animal deformities or reproduction problems, restrictions on dredging activities, restrictions on drinking water consumption, added costs to agriculture or industry, and degradation of phytoplankton and zooplankton populations. Whereas “virtual elimination” is a long-term goal, these beneficial uses point toward a more proximate goal of reducing emissions and environmental concentrations of PTSs to levels at which they do not pose observable risks to human or wildlife populations.

Tracking progress toward PTS reduction goals requires a thorough knowledge of current and past PTS concentrations throughout the basin. The Great Lakes basin is a large area with diverse environmental characteristics. Lake depths, water and air temperatures, chemical characteristics, ecosystem structure and many other factors vary widely both within and among the five Great Lakes and their connecting waterways. PTSs possess a similarly broad diversity with regard to their physio-chemical properties which determine their behavior in the environment and in biota. Because of these differences in environmental and chemical characteristics, it is problematic to extrapolate observations made for an individual chemical and geographic area to another chemical or geographic area.

Indicators must therefore be evaluated separately for each PTS of concern and with high spatial resolution. At a minimum, indicators should be assessed individually for the five lake basins. Many indicators will require a finer spatial scale of assessment. Indicators to be monitored can be grouped into three categories: 1) concentrations in environmental compartments and biota; 2) releases, emissions and out-of-basin transport; and 3) human and wildlife health impacts and biological markers. Each of these indicators must be assessed at a temporal resolution adequate to determine trends and patterns. Although reporting might be done on an annual or biennial basis, assessments will need to be based on data that adequately resolves seasonal patterns.

**Concentrations in environmental compartments and biota**

The most direct indicators of progress toward reducing or eliminating PTSs are the amounts of these compounds found in the Great Lakes environment, biota and humans. Environmental

## **Potential PTS Indicators**

### DRAFT PARTIAL LIST

#### **Concentrations in environmental compartments and biota**

- Concentration in Great Lakes water
- Concentration in inland waters
- Concentration in sediment
- Concentration in soil
- Concentration in air
- Concentration in phytoplankton, algae and microorganisms
- Concentration in invertebrates
- Concentration in forage fish
- Concentration in piscivorous fish
- Concentration in piscivorous birds
- Concentration in piscivorous mammals
- Concentration in terrestrial plants and animals
- Concentrations in humans

#### **Emissions, loading and out-of-basin transport**

- Emissions to water
- Emissions to air
- Emissions to soil
- Atmospheric deposition (dry, wet and gaseous)
- Tributary inputs
- Recovery trajectory
- Contribution of long-range transport

#### **Human and wildlife health impacts and biological markers**

- Predicted impacts on microorganisms
- Predicted impacts on invertebrates
- Predicted impacts on forage fish
- Predicted impacts on piscivorous fish
- Predicted impacts on piscivorous birds
- Predicted impacts on piscivorous mammals
- Predicted cancer impacts on human
- Predicted non-cancer impacts on humans
- Sediment toxicity by laboratory test
- Estrogenic / Androgenic activity of sediments
- Additional biological markers

Each of the above indicators would require data collection and assessment that adequately covers: 1) all PTSs of concern; 2) the full geographic scope and diversity of the Great Lakes basin; and 3) a temporal scale and resolution adequate to monitor trends and observe patterns.

compartments for which PTS concentrations should be tracked include water, soil, air and sediments, many of which can be divided into multiple sub-components. Although these compartments contain the majority of chemical mass, it is the biota and human concentrations that are ultimately of concern.

Biota concentrations are directly impacted by environmental concentrations. However, significant variations and uncertainties are present in this relationship due to the diverse and complex ecosystem structures and exposure routes involved. It is therefore desirable to have an indicator of PTS concentrations at each of many representative portions of the Great Lakes ecosystem and aquatic foodchain, including—but not limited to—phytoplankton, algae, and microorganisms; invertebrates; forage fish; piscivorous fish, birds, and mammals; and humans.

#### **Emissions, loadings and out-of-basin transport**

Tracking concentrations in the ambient environment and biota will provide information on current and past levels. However, to gain information on how these levels are likely to change in the near and somewhat distant future, it is important to have information on PTS emissions to the water, air and soil of the Great Lakes region; the PTS loadings to the lakes from all relevant routes; and the atmospheric transport of PTSs to the Great Lakes region from further abroad. Tracking of these characteristics for each PTS will enable mass balances to be established and recovery trajectories to be determined under various future loading scenarios. These indicators are important for informing management decisions.

#### **Human and wildlife health impacts and biological markers**

Additional indicators include observations and predictions of the actual impacts of PTSs on human and wildlife receptors and markers that illustrate the biological response to individual chemicals or mixtures. Indicators of impacts can be divided into two categories: prediction of impacts and observation of impacts. The former category involves the collection of environmental or biota concentrations

and an estimation of impacts based on known dose-response models. In this way, the impacts of chemical concentrations can be determined and compared both between chemicals and over time. The second category involves the collection of environmental or biota concentrations along with indicators of ecosystem, wildlife or human health and assessing the correlation of the two categories.

In addition to indicators of health impacts, indicators of biological or physiological response to PTSs are desirable in a number of cases. Whole sediment toxicity testing is an example of such an experimental indicator. In addition to whole organism toxicity tests, recent advances in cellular biotechnology have made available a wide variety of tests for biological response. Using such tests, sampled environmental media, such as water or sediments, can be tested for their ability to cause adverse cellular responses, such as estrogenic and androgenic gene expression or induction of liver cytochromes. These types of tests have an advantage in that they can account for the toxicological interactions of the complex mixtures of chemicals present in the actual environment.

### **Monitoring, modeling and information management**

Each of the indicator types described above require information to be gathered to support their assessment. In many cases, this will require monitoring of contaminants in the ambient environment and biota. In some cases, modeling can supplant a portion of this monitoring by using known chemical and ecosystem parameters—such as partition coefficients, bioaccumulation factors and foodchain structure—to fill gaps in monitored data. However, monitoring efforts must be sufficiently intensive to help formulate, validate and inform these models. In addition to monitoring and modeling data, many other information types are required for various indicators, including emissions information and toxicity data. To allow assessment of comparable indicators across time and space, consistent data collections and management protocols are an important consideration.

### **Current Indicators – SOLEC**

The major mechanism for reporting on environmental conditions in the Great Lakes is the State of the Lakes Ecosystem Conference (SOLEC) and associated reports. Under this collaborative effort of the U.S. EPA and Environment Canada, a conference is held and a report issued on a biennial basis, each reporting on nearly 100 indicators of ecosystem status in the Great Lakes basin. The indicators included on the 2004 revised list which are most directly related to PTSs are listed in the following table. There are many additional indicators that impact or are impacted by PTSs, but less directly.

<b>ID</b>	<b>SOLEC Indicator Title</b>	<b>2000 Status</b>	<b>2001 Status</b>	<b>2002 Status</b>	<b>2003 Status</b>
114	Contaminants in Young-of-the-Year Spottail Shiners	NR	NR	Mixed, improving	Mixed, improving
115	Contaminants in Colonial Nesting Waterbirds	Good	Good	Mixed, improving	Mixed, improving
117	Atmospheric Deposition of Toxic Chemicals	Mixed, improving	Mixed, improving	Mixed	Mixed

118	Toxic Chemical Concentrations in Offshore Waters	Mixed	Mixed	Mixed, improving	Mixed, improving
119	Concentrations of Contaminants in Sediment Cores	NR	NR	Mixed, improving	Mixed, improving
121	Contaminants in Whole Fish	New indicator <sup>†</sup>			
351 5	Cosmetic Pesticide Controls	New indicator <sup>†</sup>			
417 7	Chemical Contaminants in Human Tissue	NR	NR	NR	NR
420 1	Contaminants in Sport and Commercial Fish (*Contaminants in Edible Fish Tissues 4083)	Mixed, improving	Mixed, improving	Mixed, improving	Mixed, improving
450 6	Contaminants in Snapping Turtle Eggs	Mixed	Mixed	Mixed	Mixed
813 5	Contaminants Affecting Productivity of Bald Eagles	Mixed, improving	Mixed, improving	Mixed, improving	Mixed, improving
814 2	Sediment Available for Coastal Nourishment	NR	NR	NR	NR
814 7	Contaminants Affecting the American Otter	NR	Insufficient data	Mixed	Mixed
TB D	Contaminant Accumulation in Coastal Wetlands	New indicator <sup>†</sup>			
351 4	Commercial/Industrial Eco-Efficiency	New indicator <sup>†</sup>			
705 7	Energy Consumption	NR	NR	Mixed, deteriorating**	Mixed, deteriorating**
706 4	Vehicle Use (*Mass Transportation 7012)	NR	Insufficient data	Mixed	Mixed

\* Replaced by new indicator in 2004

\*\*Assessment is for Lake Superior only

† Indicator Added in 2004

The current list of SOLEC indicators includes many, but certainly not all, indicators identified above as desirable for tracking progress toward reducing and eliminating PTSs in the Great Lakes basin. Some notable omissions are the bottom portions of the food-chain (phytoplankton, microorganisms and invertebrates), terrestrial ecosystems, emission levels, tributary loadings, long range transport and biological markers (estrogen activity, etc.). Expansion of the SOLEC PTS indicator list to fill such gaps will in many cases require significant additional monitoring, modeling and data collection. In addition to expanding the list, the current indicator suite should be evaluated to determine the adequacy of their coverage of temporal and spatial scales and chemicals of concern.

### Current Indicators - Other

In addition to SOLEC process, there are other efforts in the region to assess and report on indicators of PTS contamination in the Great Lakes. One additional effort is the Great Lakes Environmental Indicators (GLEI) program being conducted by the Natural Resources Research

Institute at University of Minnesota Duluth, in cooperation with numerous partners around the region. Among the numerous indicators currently being developed by this program, two are directly related to PTSs. One of these indicators assesses the risk of larval fish to PAH contamination, particularly with regard to increased risk due to photo-activation of these compounds in areas with high UV penetration. The second indicator associates elevated levels of specific chemicals with increased expression of an estrogen-induced protein in male fish.

**Great Lakes Regional Collaboration  
Toxic Pollutant Strategy Team White Paper  
Existing Great Lakes PBT Programs**

While a variety of national and statewide programs exist that promote the reduction and proper disposal of PBT chemicals, there are some programs that are specific to the Great Lakes. The following three programs are especially prominent.

Great Lakes Binational Toxics Strategy (BTS)

This program originated as a 1997 agreement between the United States and Canada known as the *Canada - United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes*. It was a response to concerns that the governments needed to take more direct action on the virtual elimination policy described in Article II of the *Great Lakes Water Quality Agreement (GLWQA)*. The BTS agreement established a series of reduction challenges. For example, the U.S. challenge for mercury is to “Seek by 2006, a 50 percent reduction nationally in the deliberate use of mercury and a 50 percent reduction in the release of mercury from sources resulting from human activity.”

The BTS has become the overarching PBT program for the Great Lakes and it integrates reduction efforts from a variety of stakeholders. Implementation of the BTS is being carried out by an Integration Workgroup and some specialized chemical workgroups. The 2003 progress report notes “Of seventeen GLBTS reduction goals set forth for the twelve Level I persistent toxic substances in April 1997, nine have been met, four will be met by the target timeline date of 2006, and the remaining four will be well advanced toward meeting their targets by 2006.”

Lakewide Management Plans (LaMPs)

LaMPs originate in Annex 2 of the GLWQA. Originally intended to address critical pollutants in the open waters of each Great Lake, LaMPs have evolved to include not only the critical pollutants, but other aspects of water quality improvement via the ecosystem management approach. While the LaMPs are planning programs, they are also implementing a variety of PBT voluntary reduction projects. For example:

- *Lake Superior*: As part of the Lake Superior LaMP’s *Zero Discharge Demonstration*, a 2004 project identified transformers suspected of containing PCBs at four utilities in the Minnesota portion of the basin and removed 71% of those transformers.
- *Lake Michigan*: Three Indiana steel mills participated in a Mercury Agreement Reduction Program that resulted in guidance for performing a mercury inventory and resulted in the removal of 3,700 pounds of mercury between 1999 and 2003 (roughly 80% of the mercury believed to be present in these facilities).
- *Lake Erie*: The P3ERIE Program in Pennsylvania has removed over three tons of mercury from businesses, schools and citizens in the greater Erie area since the inception of the program.

- *Lake Ontario*: Monroe County, New York, Department of Health implemented a mercury pollution prevention program for hospitals and dental offices that won a USEPA Region 2 Environmental Quality Award in 1999.

Note: While Lake Huron does not have a formal LaMP, the new Lake Huron Binational Partnership released the Lake Huron Binational Partnership Action Plan – 2004 to address basinwide concerns in Lake Huron.

### Remedial Action Plans (RAPs)

Areas of Concern (AOCs) are addressed in a different section of the report (see Section ???). Unlike LaMPs, which focus on open waters, the AOCs represent the nearshore contaminated areas. According to the GLWQA Annex 2, the United States and Canada will develop Remedial Action Plans (RAPs) for each AOC. RAPs are expected to address the impairment of 14 beneficial uses at each AOC. PBTs can cause the following beneficial use impairments:

- Restrictions on fish and wildlife consumption;
- Tainting of fish and wildlife flavour;
- Degradation of fish and wildlife populations;
- Fish tumors or other deformities;
- Bird or animal deformities or reproduction problems;
- Degradation of benthos;
- Restrictions of dredging activities;
- Restrictions on drinking water consumption, or taste or odour problems;
- Added costs to agriculture or industry;
- Degradation of phytoplankton or zoo plankton populations; and
- Loss of fish and wildlife habitat.

RAP activities that address PBT impairments are mostly focused on sediment remediation although RAPs include other aspects of PBT management, including stormwater management and local source reductions.

**Great Lakes Regional Collaboration  
Toxic Pollutant Strategy Team White Paper  
Ongoing efforts in PBT education and outreach**

The reduction of PBT chemicals entering into the Great Lakes basin is a priority. A variety of organizations work to develop both outreach materials and waste reduction opportunities which are directed to the public and industry. The organizations include multiple levels of government from the federal to the municipal level, citizen groups, environmental groups, as well as industry. These organizations use many different outreach techniques ranging from websites to newspaper advertisements in order to educate the public on issues involved with PBT chemicals. The purpose of this whitepaper is to outline many of the recent and/or on-going PBT reduction education and outreach efforts in the Great Lakes basin.

Because there is such a wide variety of education and outreach programs throughout the basin ranging from small communities to national programs, only general topics of education and outreach are addressed in the white paper.

*Great Lake Workgroup and Forum Activities:*

Many of the Great Lakes have individual workgroups and forums dedicated to addressing a wide array of Great Lake issues. Many of the workgroups have communication/public involvement committees which have a long-term commitment to communications, public involvement/ outreach, and education. The Great Lake Forums (Superior, Michigan, and Erie) have worked collectively with the workgroups to focus on a series of projects that educate the citizens of the basin on PBT issues through education and outreach techniques that include: 1) traveling displays, 2) websites. 3) newspaper inserts, and 4) mailing lists as a means to deliver information. Below are a list of the types of programs conducted in the basin which involve both waste reduction as well as education and outreach and activities:

- Voluntary installation of amalgam separators in all Minnesota dental offices statewide;
- Local programs to recover mercury switches from new and used automobiles, including a sponsored auto switch-the-switch event, an event to remove fluids and batteries from abandoned cars and the development an abandoned car ordinance;
- Establishment of collection depots for thermostats which were sent to a processor where mercury is removed. Also, there are proposed state programs which offer a mercury free thermostats in exchange for an older thermostat;
- Mercury thermometer collections and swaps have been implemented. In many cases outreach materials were available to the public;
- Local programs established to purchase sodium vapor security lighting to replace the old mercury vapor lamps;
- Abandoned waste collections were carried out in areas of the basin. In addition, periodic curbside white goods collections have been carried out;
- Cities and environmental groups have partnered to divert mercury bearing products including button batteries, fluorescent lights and thermostats from landfill disposal;

- Local school districts have signed the mercury free pledge, .Clancy (the mercury detecting dog) has assessed schools for mercury contamination and programs have been established to educate students, teachers and school faculty of the risks of mercury. Programs have included includes technical assistance and facility audits and collection of mercury devices and other hazardous waste;
- Various workshops on a number of PBT subjects including, the hazards of burn barrels, mercury reduction, and development of a dental best management practices manual for mercury disposal and management;
- Statewide publication of PBT articles in natural resource magazine;
- Development of PBT posters for mercury, PCB and the hazards of burn barrels;
- Dedicated staff to work with the community on mercury reduction and burn barrel projects;
- Forum development of fish consumption outreach materials to address environmental justice concerns. Over 17,750 brochures have been distributed.

#### *Great Lakes States and Tribal fish consumption advisories*

Great Lakes states and tribes have extensive fish contaminant monitoring programs and issue advice to their residents about how much fish and which fish are safe to eat through a variety of mediums including printed material, websites, and public outreach. This advice ranges from recommendations limiting consumption of specific sizes, species, and or water bodies to unlimited consumption of fish from various locations. Advice from these agencies to limit consumption of fish is mainly due to levels of PCBs, mercury, chlordane, dioxin, and toxaphene in fish and tribal advisories in particular are issued to be culturally sensitive.

#### *Educational Tools for educators*

There are many useful online resources for educators to learn new information to share with students and to download teaching and presentation materials. Information ranges from teaching aids for elementary and highschool students (T.E.A.C.H. program) to materials that can be used to educate communities (Enviro Tools).

#### *NOAA National Sea Grant Program*

Sea Grant is a nationwide network (administered through the National Oceanic and Atmospheric Administration [NOAA]), of 30 university-based programs that work with coastal communities. The National Sea Grant College Program engages this network of the nation's top universities in conducting scientific research, education, training, and extension projects designed to foster science-based decisions about the use and conservation of our aquatic resources.

#### *Federal Programs*

A variety of federal agencies provide PBT educational information to the public via their websites. This information includes such items as data and reports (SOLEC), a clearing house for Great Lakes information (GLIN), and public friend fact sheets on a variety PBTs (ATSDR ToxFAQs).

### *Great Lakes Mid-Atlantic Center for Hazardous Substance Research*

The Center places strong emphasis on technology transfer through its two community outreach programs: Technical Outreach Service to Communities (TOSC), and Technical Assistance to Brownfields Communities (TAB). These programs are making a significant impact by providing information and education to communities faced with environmental challenges such as clean-up of Superfund sites and redevelopment of Brownfields.

### *National Pollution Prevention Roundtable*

The P2 roundtable provides forums for the direct exchange of ideas and expertise as well as through a number of programs designed to disseminate the most current data on pollution prevention policy developments, practices and resources. Information is exchanged through workgroups, national meetings, a publication program, and topic specific electronic listserves.

### *Great Lakes Tribes*

#### Great Lakes Indian Fish and Wildlife Commission

- Produces GIS-based color coded maps that point tribal members to inland lakes with walleye that are lower in mercury;
- Published articles in its quarterly newspaper (Masinaigan or "talking paper") on how to enjoy fish safely by choosing to eat fish species that are lower in contaminants, smaller fish, to trim away fat and skin tissues, and cooking methods that can also reduce contaminants;
- Currently working on ways that can better educate tribal members on how to avoid contaminants in fish and still maintain their cultural lifeways, and particularly to educate sensitive populations on these issues. This may include educating tribal health care professionals and having more discussions on tribal radio stations, TV stations, and at tribal meetings.

Many tribes are involved in educating their members on the hazards associated with burn barrels.

## Ongoing efforts in PBT education and outreach Reference material

ATSDR ToxFAQs – <http://www.atsdr.cdc.gov/toxfaq.html>

The ATSDR ToxFAQs™ is a series of summaries about hazardous substances developed by the ATSDR Division of Toxicology. Information for this series is excerpted from the ATSDR Toxicological Profiles and Public Health Statements. Each fact sheet serves as a quick and easy to understand guide. Answers are provided to the most frequently asked questions (FAQs) about exposure to hazardous substances found around hazardous waste sites and the effects of exposure on human health.

Enviro Tools - <http://www.envirotools.org/about.shtml>

The EnviroTools materials are aimed at community assistance leaders, outreach assistance providers and citizen leaders. Through the Internet, we provide easy access to the materials in a form that can be distributed to communities. Many of the materials are written for folks who have little or no background in site cleanup, and all of the materials have been "pilot tested" through community assistance carried out under the EPA-funded [TOSC](#) and [TAB](#) programs.

Great Lakes States and Tribal fish consumption advisories

Great Lakes states and tribes have extensive fish contaminant monitoring programs and issue advice to their residents about how much fish and which fish are safe to eat. This advice ranges from recommendations limiting consumption of specific sizes, species, and or water bodies to unlimited consumption of fish from various locations. Advice from these agencies to limit consumption of fish is mainly due to levels of PCBs, mercury, chlordane, dioxin, and toxaphene in the fish.

*Minnesota-* <http://www.health.state.mn.us/divs/eh/fish/index.html>

*Wisconsin-* <http://dnr.wi.gov/org/water/fhp/fish/pages/consumption/>

*Illinois-* <http://www.idph.state.il.us/envhealth/fishadv/fishadvisory04.htm>

*Indiana-* [http://in.gov/isdh/dataandstats/fish/fish\\_2001/using\\_advisory.htm](http://in.gov/isdh/dataandstats/fish/fish_2001/using_advisory.htm)

*Ohio-* <http://www.epa.state.oh.us/dsw/fishadvisory/>

*Michigan-* [http://www.michigan.gov/documents/FishAdvisory03\\_67354\\_7.pdf](http://www.michigan.gov/documents/FishAdvisory03_67354_7.pdf)

*Pennsylvania-*  
<http://www.dep.state.pa.us/dep/deputate/watermgmt/wqp/wqstandards/fishadv/fishadvisory.htm>

New York- <http://www.health.state.ny.us/nysdoh/fish/fish.htm>

*Great Lakes Indian Fish and Wildlife Commission* - <http://www.glifwc.org/>

1. GLIFWC produces GIS-based color coded maps that point tribal members to inland lakes with walleye that are lower in mercury
2. GLIFWC currently has a grant designed to further enhance and develop our ability to communicate fish contaminant information to its member tribes.
3. Other tribal organizations and many individual tribes in the Great Lakes region provide or are in the process of developing their own culturally sensitive fish consumption advice.
4. Many tribes are involved in educating their members on the hazards associated with burn barrels.

More detailed info on GLIFWC's work:

1. GLIFWC has been very active in education and outreach, particularly related to fish consumption with our member tribes in northern WI, MI, and MN. Tribal harvest of walleye in spring is a very important cultural and subsistence activity. Because tribal members expressed concerns over mercury contamination in fish, GLIFWC currently issues GIS-based, color-coded maps that alert tribal members to inland lakes (mostly in WI) that have walleye lower in mercury (based on our database of mercury analyses in walleye).
2. GLIFWC also conducted a five year study that looked at tribal member's fish consumption patterns throughout the year in order to determine how much people were eating and if consumption was bunched around spring harvest or spread more evenly throughout the year. The goal was to provide an extensive database to help us better assess the type of fish consumption advice we should be giving to tribal members. As you probably are aware, fish consumption by tribal people is generally greater than that by most other folks, so we don't feel other fish consumption advice that is available (i.e. from States) is practical to apply to these people.
3. GLIFWC has published articles in its quarterly newspaper (Masinaigan or "talking paper") on how to enjoy fish safely by choosing to eat fish species that are lower in contaminants, smaller fish, to trim away fat and skin tissues, and cooking methods that can also reduce contaminants.
4. GLIFWC is currently working on ways that we can better educate tribal members on how to avoid contaminants in fish and still maintain their cultural lifeways, and particularly to educate sensitive populations on these issues. This may include educating tribal health care professionals and having more discussions on tribal radio stations, TV stations, and at tribal meetings.

*Minnesota Chippewa Tribe Research Lab* -

<http://www.mnchippewatribe.org/wqd.htm>

General Assistance Program (GAP)

Funded by the U.S. Environmental Protection Agency, the GAP contract provides the following services:

- Fish tissue analysis for mercury contamination
- Preparation of (6) subsistence fish consumption guides by reservation and by lake
- Technical assistance for resource contamination issues, water quality management, quality assurance plan development, drinking water analysis, and surface water analysis
- Research and advocacy for Tribal health, environmental quality and funding issues

*Aroostook Band of Micmacs Environmental Health Department - <http://www.micmac-nsn.gov/index.html>*

*St. Regis Mohawk Tribe, Environment Division - <http://www.srmtenv.org/>*

*Cheyenne River Sioux Tribe - <http://www.sioux.org/>*

The Great Lakes Information Network <http://www.great-lakes.net/envt/pollution/toxic.html>

The Great Lakes Information Network (GLIN) is a partnership that provides one place online for people to find information relating to the binational Great Lakes-St. Lawrence region of North America. GLIN offers a wealth of data and information about the region's environment, economy, tourism, education and more. Thanks to its strong network of state, provincial, federal and regional partner agencies and organizations, GLIN has become a necessary component of informed decision making, and a trusted and reliable source of information for those who live, work or have an interest in the Great Lakes region.

Great Lakes Mid-Atlantic Center for Hazardous Substance Research - <http://www.engin.umich.edu/dept/cee/research/HSRC/index.html>

The mission of the Great Lakes Mid-Atlantic Center for Hazardous Substance Research is to foster and support integrated, interdisciplinary, and collaborative efforts that advance the science and technology of hazardous substance management to benefit human and environmental health and well-being.

The Center places strong emphasis on technology transfer through its two community outreach programs: Technical Outreach Service to Communities (TOSC), and Technical Assistance to Brownfields Communities (TAB). These programs are making a significant impact by providing information and education to communities faced with environmental challenges such as clean-up of Superfund sites and redevelopment of Brownfields.

Great Lake Workgroup and Forum Activities

Lake Superior LaMP - <http://epa.gov/glnpo/lakesuperior/2004/index.html>

Lake Erie LaMP - <http://epa.gov/glnpo/lakeerie/2004update/index.html>

Lake Michigan LaMP - <http://epa.gov/glnpo/lakemich/2004update/index.html>

Lake Ontario LaMP - <http://epa.gov/glnpo/lakeont/2004/louupdate2004.pdf>

Lake Huron Binational Partnership - <http://epa.gov/glnpo/lakeont/2004/louupdate2004.pdf>

NOAA National Sea Grant Program - <http://www.nsgo.seagrant.org/>

Environmental stewardship, long-term economic development and responsible use of America's coastal, ocean and Great Lakes resources are at the heart of Sea Grant's mission. Sea Grant is a nationwide network (administered through the National Oceanic and Atmospheric Administration [NOAA]), of 30 university-based programs that work with coastal communities. The National Sea Grant College Program engages this network of the nation's top universities in conducting scientific research, education, training, and extension projects designed to foster science-based decisions about the use and conservation of our aquatic resources.

*Indiana – Illinois Sea Grant* - <http://www.iisgcp.org/>

*Minnesota Sea Grant* - <http://www.seagrant.umn.edu/>

*Wisconsin Sea Grant* - <http://www.seagrant.wisc.edu/>

*Michigan Sea Grant* - <http://www.miseagrant.umich.edu/>

*Ohio Sea Grant* - <http://www.sg.ohio-state.edu/>

*Pennsylvania Sea Grant* - <http://www.pserie.psu.edu/seagrant/seagindex.htm>

*New York Sea Grant* - <http://www.seagrant.sunysb.edu/>

National Pollution Prevention Roundtable - <http://www.p2.org/>

One of the most important roles of NPPR is to provide members with timely and accurate information on pollution prevention. We do this by providing forums for the direct exchange of ideas and expertise as well as through a number of programs designed for dissemination of the most current data on pollution prevention policy developments, practices and resources.

NPPR members have the opportunity to participate in [Workgroups](#) which help to disseminate information on cutting edge issues relating to pollution prevention amongst peers. Workgroups are the lifeblood of the organization and play a major role in

organizing tracks and sessions at national conferences and act as advisors on documents, reports and position papers issued by NPPR.

NPPR holds [National Meetings](#) that facilitate pollution prevention network building and the collaboration of ideas, resources and research on various topics. Members are able to attend these meetings with discounted registration fees, when appropriate.

Additionally, NPPR has an active [Publications Program](#) which includes newsletters and many other documents and reports. Many of the Roundtable's publications are either free to members or can be purchased at a discount.

The Roundtable also has four topic specific [Electronic Listservs](#), P2 Policy, P2 Tech, P2 Trainer and P2 Energy. All four listservs function as forums for sharing P2 information and act as discussion groups for pollution prevention practitioners. Through the listservs, subscribers have direct access to information and knowledge from hundreds of pollution prevention experts world wide. Listservs are currently available throughout the P2 community and are not limited to NPPR members.

State of the Lakes Ecosystem Conference – [http://cfpub.binational.net/solec/intro\\_e.cfm](http://cfpub.binational.net/solec/intro_e.cfm)

The State of the Lakes Ecosystem Conferences (SOLEC) are hosted by the U.S. Environmental Protection Agency and Environment Canada on behalf of the two countries. These conferences are held every two years in response to a reporting requirement of the binational Great Lakes Water Quality Agreement (GLWQA). The purpose of the Agreement is "to restore and maintain the physical, chemical and biological integrity of the Great Lakes Basin." The conferences are intended to report on the state of the Great Lakes ecosystem and the major factors impacting it, and to **provide a forum for exchange of this information amongst Great Lakes decision-makers**. However, these conferences are not intended to discuss the status of programs needed for protection and restoration of the Great Lakes basin, but to evaluate the effectiveness of these programs through analysis of the state of the ecosystem. Another goal of the conference is to **provide information to people in all levels of government, corporate, and not-for-profit sectors that make decisions that affect the Lakes**.

T.E.A..C.H. Great Lakes – <http://www.great-lakes.net/teach/>

TEACH Great Lakes features mini-lessons on many Great Lakes topics: environment, history & culture, geography, pollution and careers & business. Geared for elementary through high school students, the modules are continually expanded and updated and include links to a glossary to help explain scientific terms and acronyms. This site will continue to grow in the months ahead, so please explore now but stop by again soon!

US Fish and Wildlife Service – <http://greatlakes.fws.gov/education.htm>

The Mission of the U.S. Fish & Wildlife Service: working with others to conserve, protect and enhance fish, wildlife, and plants and their habitats for the continuing benefit of the American people.

The Great Lakes Basin Ecosystem Team has several outreach products ready for use and is in the process of completing others. The team has developed a 40-foot display (pictured) and a more portable 10-foot display for use at special events around the basin. These displays outline the U.S. Fish and Wildlife Service's primary responsibilities and roles in the Great Lakes including the management of National Wildlife Refuges, law enforcement, conservation of endangered and threatened species, and protection of migratory birds and fishes.

## Great Lakes Regional Collaboration Toxic Pollutant Strategy White Paper Chemical Screening Programs

Listed below are several primary government programs that include, at least in part, requirements and/or protocols for the screening of chemical substances for human and ecosystem health impact potential. This paper is not intended to contain a complete list of chemical screening programs. It is recognized that others also exist and may be in common use.

### I. Domestic Programs

#### **Toxic Substance Control Act (TSCA)**

Established initially in 1976, TSCA greatly expanded federal authority to require testing, as well as to regulate the production, importation, use and disposal of new and existing chemicals. Among its provisions, TSCA requires chemical manufacturers to notify EPA at least 90 days before manufacture and distribution of a new chemical substance. It also gives the Agency the authority to require testing of new chemicals before manufacture and the power to ban or restrict chemicals that pose substantial risks to human health or the environment. TSCA covers all organic and inorganic chemical substances and mixtures, both synthetic and naturally-occurring, with the exception of food, food additives, drugs, cosmetics, nuclear materials, tobacco, and pesticides which are covered under other programs. Pursuant to pre-manufacture notice requirements, manufacturers and importers must submit information on all new chemical substances that would provide EPA with the opportunity to determine if manufacture, processing, distribution in commerce, use or disposal of the substance should be delayed or prohibited because the data is insufficient to evaluate health and environmental effects, or because the substance or new use presents or will present an unreasonable risk of injury to health or the environment. TSCA also requires manufacturers and processors to collect, maintain, and (if “significant adverse reactions” [TSCA Sec. 8(c)] trigger events occur) submit information and test data to EPA. Frequently, little or no data on health or environmental effects are available for PMN substances, yet EPA must decide within 90 days if such substances are likely to present hazards to human health or the environment. TSCA Section 5(e) gives EPA the authority to regulate a new substance if the Agency concludes that a chemical *may* present an unreasonable risk. Also, TSCA Section 5(b) grants EPA the authority to require test data for new substances or significant new uses.<sup>1</sup>

#### **Pre-manufacturing Notices (PMN), Review and PMN Screening**

Since TSCA was implemented, EPA has reviewed approximately 36,600 pre-manufacturing notices (PMNs)<sup>2</sup>. The evaluation process involves many tools and models that can provide estimates and predictions on the potential hazards and exposures of a new chemical. This information allows EPA to develop an estimate of the potential risk of a new chemical based on its proposed use(s).

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<sup>1</sup> Chemistry Assistance Manual for Premanufacture Notification Submitters, Appendix, The Toxic Substances Control Act: History and Implementation, EPA 744-R97-003, March 1997. Available at: <http://www.epa.gov/oppt/newchems/chem-pmn/appendix.pdf>,

<sup>2</sup> Overview: Office of Pollution Prevention and Toxics Programs, December 24, 2003

As of November 1999, the Agency began screening the pre-manufacturing data on new chemicals that industry submits to EPA for evidence of PBT chemical characteristics. This additional level of screening -- conducted pursuant to EPA's TSCA Policy Statement on PBTs resulted in EPA identifying 36 new chemicals as potential PBTs and issuing consent orders on 13 of these substances. Permissible control actions range from banning production to prohibiting certain uses and releases, pending development of further data.<sup>3</sup>

### **TSCA Inventory Update Rule (IUR)**

The Environmental Protection Agency (EPA) promulgated a rule in 1986, often referred to as the Inventory Update Rule (IUR), for the partial updating of the Toxic Substances Control Act (TSCA) Chemical Inventory Database. The rule requires manufacturers and importers of certain chemical substances included on the TSCA Chemical Substances Inventory to report current data on the production volume, plant site, and site-limited status of these substances. Reporting under the Inventory Update Rule takes place at four-year intervals which began in 1986. The 2002 reporting period is from August 26, 2002 to December 23, 2002<sup>4</sup>.

Past IUR reports required reporting for organic chemical (except polymers) over 10,000 pounds and typically resulted in information reported on about 9,000 chemicals<sup>5</sup>. In 2002, about 1,080 companies compiled and submitted IUR reports.<sup>6</sup>

EPA recently adjusted the IUR reporting threshold, and also increased the reporting requirements to include use and exposure information, and expanded the scope of reporting to include inorganic chemicals. Chemical companies will report chemical data to the EPA under the expanded IUR requirements in 2006

### **TSCA Section 8(e)**

Section 8(e) of TSCA provides the EPA with a powerful information-gathering tool that serves as an early warning mechanism. Section 8(e) has the broadest coverage of any of the TSCA Section 8 information reporting provisions in that all chemicals and mixtures subject to TSCA itself are subject to Section 8(e). EPA has received and reviewed more than 15,000 TSCA Section 8(e) notices<sup>7</sup> covering a wide range of chemical substances and mixtures and containing new data concerning serious adverse health effects, ecotoxicological effects and exposures.

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<sup>3</sup> First Annual 1999 Accomplishments Report, Persistent Bioaccumulative and Toxic (PBT) Chemical Program, July 2000, EPA 742-R-00-003. Available at: <http://www.epa.gov/opptintr/pbt/accomp99.htm>

<sup>4</sup> <http://www.epa.gov/oppt/iur/iur02/index.htm>

<sup>5</sup> Database of the 1998 Inventory Update. Available at [www.epa.gov/opptintr/iur/iur98/index.htm](http://www.epa.gov/opptintr/iur/iur98/index.htm).

<sup>6</sup> September 13, 2004 e-mail from Daryl Ballard, EPA to Jim Keith, ACC

<sup>7</sup> Overview: Office of Pollution Prevention and Toxics Programs, December 24, 2003

## **TSCA Section 5**

Under Section 5, as part of its review of new chemical notifications, EPA can, and often does, require additional test data to be developed. Through September 2002, approximately 300 new chemical submissions included additional voluntary testing actions.<sup>8</sup>

### **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**

When EPA approves a particular pesticide for registration, the agency has assessed the chemical and found that, when used according to label directions, it does not pose unreasonable risk to public health and the environment. A pesticide cannot be legally used if it has not been registered with EPA's Office of Pesticide Programs. In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product. The producer of the pesticide must provide data from tests done according to EPA guidelines. Product properties must be described through:

- Analysis of product residues in foods and animals and associated affects.
- Environmental fate determinations
- Degradation studies
- Metabolism studies
- Mobility studies
- Dissipation studies
- Accumulation studies

Hazards to humans and domestic animals are assessed through:

- Acute Studies
- Subchronic Studies
- Chronic Studies
- Teratogenicity and Reproduction Studies
- Mutagenicity Studies
- Metabolism Studies
- Reentry Protection
- Pesticide Spray Drift Evaluation

Hazards to non-target organisms are assessed through:

- Short-term Studies
- Long-term and Field Studies
- Product Performance

These tests evaluate whether a pesticide has the potential to cause harmful effects on humans, wildlife, fish, and plants, including endangered species and non-target organisms, as well as possible contamination of surface water or ground water from

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<sup>8</sup> Overview: Office of Pollution Prevention and Toxics Programs, December 24, 2003

leaching, runoff, and spray drift. Potential human risks range from short-term toxicity to long-term effects such as cancer and reproductive system disorders<sup>9</sup>.

### **EPA Office of Prevention Pesticides and Toxic Substances (OPPTS)**

OPPTS has harmonized test guidelines developed for pesticides and toxic substances to minimize variations in testing procedures under the Toxic Substances Control Act and the Federal Insecticide, and Rodenticide Act. The following sets of guidelines were included in the harmonization effort<sup>10</sup>.

- Product Performance Test Guidelines
- Product Properties Test Guidelines
- Fate, Transport and Transformation Test Guidelines
- Spray Drift Test Guidelines
- Ecological Effects Test Guidelines
- Residue Chemistry Test Guidelines
- Health Effects Test Guidelines
- Occupational and Residential Exposure Test Guidelines
- Biochemicals Test Guidelines
- Microbial Pesticide Test Guidelines

### **High Production Volume (HPV) Challenge Program**

The HPV Challenge Program is an EPA initiative in which U.S. manufacturers and importers voluntarily provide basic human health and environmental effects data for 2,800 HPV chemicals; i.e., those produced or imported into the U.S. in volumes of 1 million pounds or more per year. These data comprise the HPV Screening Information Data Set (SIDS), developed by the Organization for Economic Cooperation and Development (OECD). The OECD HPV SIDS data set represents an internationally agreed upon set of studies needed to screen HPV chemicals and identify potential hazards. These include studies for physical chemical properties (e.g., water solubility), environmental fate (e.g., biodegradation), environmental toxicity to fish and other aquatic species, and mammalian toxicity (acute toxicity, genetic toxicity, repeat dose toxicity, and reproductive and developmental toxicity). The SIDS data set does not include the developmental neurotoxicity test (DNT). Consequently, the DNT is not part of the HPV Challenge Program.

EPA intends to consider specific chemicals that are not voluntarily sponsored as candidates for test rules under Section 4 of the Toxic Substances Control Act. Sponsorship entails identifying existing information and assessing its adequacy, conducting new testing only if adequate information does not exist, and providing the new and existing data to EPA. EPA is making this information accessible to the public.

### **Voluntary Children's Chemical Evaluation Program (VCCEP)**

The Voluntary Children's Chemical Evaluation Program (VCCEP) is an EPA pilot program in which companies that manufacture and/or import 23<sup>11</sup> chemicals that have

<sup>9</sup> <http://www.epa.gov/pesticides/regulating/data.htm>

<sup>10</sup> <http://www.epa.gov/opptsfrs/home/guidelin.htm>

<sup>11</sup> Acetone, Benzene, Vinylidenechloride, Methyl ethyl ketone, Trichloroethylene, *a*-Pinene, *o*-Xylene, Ethylbenzene,

been found in human blood, breast milk, and exhaled breath and in indoor air or presence in drinking water as an unregulated contaminant, are requested to volunteer to sponsor their evaluation in Tier 1 of a pilot of the VCCEP. The program is intended to provide data to enable the public to understand the potential health risks to children associated with certain chemical exposures.

The VCCEP consists of three tiers, which a sponsor may commit to separately. EPA is now asking companies to volunteer to sponsor chemical(s) they manufacture or import in Tier 1 of the VCCEP pilot. As part of their sponsorship, companies would collect and/or develop health effects and exposure information on their chemical(s) and integrate that information in a risk assessment. A "Data Needs Assessment" would also be developed by the sponsor. The Data Needs Assessment would discuss the need for additional data, which could be provided by the next tier, to fully characterize the risks the chemical may pose to children. The information submitted by the sponsor would be evaluated by a group of scientific and relevant experts with extensive and broad experience in toxicity testing and exposure evaluations, a Peer Consultation Group. This Group will forward its opinions to EPA and the sponsor(s) concerning the adequacy of the assessments and the need for development of any additional information to fully assess risks to children. EPA will consider the opinions of the Peer Consultation Group and announce whether additional higher tier information is needed. If additional information is needed, sponsors will be asked to volunteer to provide the next tier of information. If additional information is not needed, EPA and the sponsors will cooperate to conduct appropriate risk communication and, if necessary, risk management.

Companies have until June 25, 2001 to submit a commitment letter to EPA volunteering to sponsor their chemical(s) in Tier 1 of the VCCEP. For the VCCEP chemicals not sponsored, needed testing may be proposed in a future test rule under TSCA section 4.

### **PBT TRI Reporting Thresholds**

On October 29, 1999 EPA published a final rule under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), which lowers the Toxics Release Inventory (TRI) reporting thresholds for persistent bioaccumulative toxic (PBT) chemicals and adds certain other PBT chemicals to the TRI. The final rule includes lowered reporting thresholds for PBT chemicals and a special, lower, reporting threshold for dioxin. The rule also includes modifications to certain reporting exemptions and requirements for the chemicals newly subject to the lower reporting thresholds<sup>12</sup>.

### **The PBT Profiler**

The PBT Profiler is an online PBT screening methodology jointly by EPA, The American Chemistry Council, The Chlorine Chemistry Council, The Synthetic Organic Chemical Manufacturers Association and with the support and contributions of Environmental

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*p*-Dichloro,benzene, Ethylene dibromide, Ethylene dichloride, *m*-Xylene, Toluene, Chlorobenzene, *n*-Dodecane, *p*-Dioxane, Decane, Tetrachloroethylene, *m*-Dichlorobenzene, Undecane, Decabromodiphenylether, Pentabromodiphenyl ether, Octabromodiphenyl ether

<sup>12</sup> FACT SHEET ON EPCRA SECTION 313 RULEMAKING, Persistent Bioaccumulative Toxic Chemicals. Available at: <http://www.epa.gov/tri/lawsandregs/pbt/pbtrule-fs.pdf>

Defense. The PBT Profiler will predict P, B, and (fish chronic) T characteristics from chemical structure. When the user accesses the PBT Profiler on the Internet, the program prompts the user to enter the CAS Registry Numbers (RNs) of chemicals under consideration. The PBT Profiler is linked to a database containing the CAS RNs and the associated chemical structures for over 100,000 discrete chemical substances. If the CAS RN is in the database, the PBT Profiler will translate the CAS RN into a chemical structure, predict the PBT characteristics, and provide a PBT Profile in an easy to understand format.

In addition, the PBT Profiler compares the results of a profile with the PBT criteria established for Premanufacture Notices (PMNs) submitted under section 5 of TSCA; and the final rule for reporting chemicals under the Toxic Chemical Release Inventory (TRI), under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPA does not rely solely on results of screening level methods, such as the PBT Profiler, to regulate chemicals. EPA reminds users that any screening level method should be used with caution. The PBT Profiler is useful for establishing priorities for chemical evaluation when chemical-specific data are lacking. If the PBT Profiler identifies an issue of potential concern, additional data should be gathered and/or additional analyses conducted to come to an informed decision about the chemicals under review.

### **EPA Endocrine Disruptor Screening Program**

The Endocrine Disruption Screening Program (EDSP) is mandated to use validated methods for the screening and testing of chemicals to identify potential endocrine disruptors, determine adverse effects, dose-response, assess risk and ultimately manage risk under current laws. These methods or assays once developed and validated should allow EPA to identify and characterize the endocrine activity (specifically, estrogen, androgen and thyroid) of pesticides, commercial chemicals, and environmental contaminants. While EPA has some data on endocrine-disrupting pesticides, currently insufficient scientific data are available on most of the estimated 87,000 chemicals produced today to allow for an evaluation of endocrine associated risks. To address this issue, EPA is developing a two-tiered screening and testing process. In Tier 1, EPA hopes to identify chemicals that have the potential to interact with the endocrine system. In Tier 2, EPA will determine the specific effect caused by each endocrine disruptor and establish the dose at which the effect occurs. This approach will enable EPA to gather the information needed to identify endocrine disruptors and take appropriate regulatory action, as mandated by Congress. In 2001, EPA chartered the Endocrine Disruptor Methods Validation Subcommittee (EDMVS) under Federal Advisory Committee Act (FACA) and National Advisory Council for Environmental Policy and Technology (NACEPT). EDMVS provides people and organizations the opportunity to express their concerns and work to ensure that scientifically-sound validation processes are developed for animal- and non-animal-based screens and tests. EDMVS' mission is to critically examine every step of the validation process, provide advice to EPA, and suggest or consider new assays, or chemical tests<sup>13</sup>.

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<sup>13</sup> U.S. EPA, The Endocrine Disruptor Screening Program. Available at: <http://www.epa.gov/scipoly/oscp/edspoverview/primer.htm#3>

## **Approvals of FDA Regulated Products**

FDA's regulatory approaches to marketing approval of the products it regulates are varied as the products themselves. These differences are dictated by the laws FDA enforces and the relative risks that the products pose to consumers.

Some products -- such as new drugs and complex medical devices -- must be proven safe and effective before companies can put them on the market. The agency also must approve new food additives before they can be used in foods. Other products -- such as x-ray machines and microwave ovens -- must measure up to performance standards. And some products -- such as cosmetics and dietary supplements -- can generally be marketed with no prior approval.

At the heart of all FDA's medical product evaluation decisions is a judgment about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of a risk when its potential benefit is great -- especially for products used to treat serious, life-threatening conditions.

FDA reviews the results of laboratory, animal and human clinical testing done by companies to determine if the product they want to put on the market is safe and effective. FDA does not develop or test products itself. The Agency does this pre-market review for new human drugs and biologics (such as vaccines, blood products, biotechnology products and gene therapy), complex medical devices, food and color additives, infant formulas, and animal drugs.

FDA has streamlined its review process for medical products in recent years to help speed important new treatments to patients. For example, the average review time for an innovative new drug is now only 6 months, and some have been approved even faster<sup>14</sup>.

## **U.S. Department of Agriculture Food Safety and Inspection Program**

The U.S. Department of Agriculture (USDA) Food Safety and Inspection Program (FSIP) screens the human food supply for the presence of agricultural chemicals, animal drugs and environmental contaminants<sup>15</sup>. USDA takes enforcement action when individuals or firms are found responsible for repeat drug, pesticide, or other chemical residue violations in animals presented for slaughter. A repeat violator is a firm with 2 violations within a 12-month period, with the second violation occurring after receipt of the FSIS Notification. A FSIS Recall Committee reviews test information to determine if a recommendation for product recall or other action is warranted<sup>16</sup>.

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<sup>14</sup> <http://www.fda.gov/opacom/7approval.html>

<sup>15</sup> B.P. Dey and Edna Negron, Food Safety and Antimicrobial Residues in Food Animals, USDA, University of Puerto Rico. Available at: <http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/animalprod/presentations/residue/tsld012.htm>

<sup>16</sup> USDA, FSIS Directive, Recall of meat and poultry products. Available at: <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4.pdf>

## **Consumer Product Safety Commission and the Federal Hazardous Substances Act**

The Federal Hazardous Substances Act requires that certain hazardous household products ("hazardous substances") bear cautionary labeling to alert consumers to the potential hazards that those products present and to inform them of the measures they need to protect themselves from those hazards. Any product that is toxic, corrosive, flammable or combustible, an irritant, a strong sensitizer, or that generates pressure through decomposition, heat, or other means requires labeling, if the product may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonable foreseeable handling or use, including reasonable foreseeable ingestion by children. The FHSA gives the Commission authority to ban by regulation a hazardous substance if it determines that the product is so hazardous that the cautionary labeling required by the act is inadequate to protect the public<sup>17</sup>.

## **Department of Health and Human Services National Toxicology Program**

The NTP is an interagency program whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The program maintains an objective, science-based approach in dealing with critical issues in toxicology and is committed to using the best science available to prioritize, design, conduct, and interpret its studies. Three agencies form the core of the NTP:

- National Institute of Environmental Health Sciences of the National Institutes of Health (NIEHS/NIH)
- National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention (NIOSH/CDC)
- National Center for Toxicological Research of the Food and Drug Administration (NCTR/FDA)<sup>18</sup>

## **National Institute of Environmental Health Sciences**

The National Institute of Environmental Health Sciences (NIEHS) is one of 27 Institutes and Centers of the National Institutes of Health (NIH), which is a component of the Department of Health and Human Services (DHHS). Human health and human disease result from three interactive elements: environmental factors, individual susceptibility and age. The mission of the National Institute of Environmental Health Sciences (NIEHS) is to reduce the burden of human illness and dysfunction from environmental causes by understanding each of these elements and how they interrelate. The NIEHS achieves its mission through multidisciplinary biomedical research programs, prevention and intervention efforts, and communication strategies that encompass training, education, technology transfer, and community outreach. NIEHS is investigating whether exposure to certain chemicals contributes to the development of cancer or reproductive disorders<sup>19</sup>.

## **Agency for Toxic Substances and Disease Registry (ATSDR)**

ATSDR is directed by congressional mandate to perform specific functions concerning the effect on public health of hazardous substances in the environment. These functions

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<sup>17</sup> <http://www.cpsc.gov/businfo/fhsa.html>

<sup>18</sup> <http://ntp-server.niehs.nih.gov/index.cfm?objectid=7201637B-BDB7-CEBA-F57E39896A08F1BB>

<sup>19</sup> <http://www.niehs.nih.gov/external/intro.htm>

include public health assessments of waste sites, health consultations concerning specific hazardous substances, health surveillance and registries, response to emergency releases of hazardous substances, applied research in support of public health assessments, information development and dissemination, and education and training concerning hazardous substances<sup>20</sup>. ATSDR produces "toxicological profiles" for hazardous substances found at National Priorities List (NPL) sites. These hazardous substances are ranked based on frequency of occurrence at NPL sites, toxicity, and potential for human exposure. Toxicological profiles are developed from a priority list of 275 substances. ATSDR also prepares toxicological profiles for the Department of Defense (DOD) and the Department of Energy (DOE) on substances related to federal sites. So far, 275 toxicological profiles have been published or are under development as "finals" or "drafts for public comment"<sup>21</sup>.

### **National Institute for Occupational Safety and Health**

The National Institute for Occupational Safety and Health (NIOSH) is the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is part of the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services. The Occupational Safety and Health Act of 1970 created both NIOSH and the Occupational Safety and Health Administration (OSHA). OSHA is in the U.S. Department of Labor and is responsible for developing and enforcing workplace safety and health regulations. NIOSH is in the U.S. Department of Health and Human Services and is an agency established to help assure safe and healthful working conditions for working men and women by providing research, information, education, and training in the field of occupational safety and health<sup>22</sup>.

NIOSH publishes the NIOSH Pocket Guide to Hazardous Chemicals (NPG). The NPG is intended as a source of general industrial hygiene information on several hundred chemicals/classes for workers, employers, and occupational health professionals. The NPG does not contain an analysis of all pertinent data, rather it presents key information and data in abbreviated or tabular form for chemicals or substance groupings (e.g. cyanides, fluorides, manganese compounds) that are found in the work environment. The information found in the NPG should help users recognize and control occupational chemical hazards. The NPG includes the following information about chemicals.

- Chemical names, synonyms, trade names, conversion factors, CAS, RTECS, and DOT numbers
- NIOSH Recommended Exposure Limits (NIOSH RELs)
- Occupational Safety and Health Administration (OSHA)
- Permissible Exposure Limits (PELs)
- NIOSH Immediate Dangerous to Life and Health values
- (NIOSH IDLHs) (documentation for those values can be found elsewhere on this website)
- A physical description of the agent with chemical and physical properties

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<sup>20</sup> <http://www.atsdr.cdc.gov/about.html>

<sup>21</sup> <http://www.atsdr.cdc.gov/toxpro2.html>

<sup>22</sup> <http://www.cdc.gov/niosh/about.html>

- Measurement methods
- Personal Protection and Sanitation Recommendations
- Respirator Recommendations
- Information on Health Hazards including route, symptoms, first aid and target organ information<sup>23</sup>

## II. International Programs

### **Canadian Environmental Protection Act - Domestic Substances List**

One of the new initiatives in the *Canadian Environmental Protection Act, 1999* (CEPA 1999) requires the Minister of the Environment and the Minister of Health to “categorize” and then if necessary, conduct screening assessments of substances listed on the Domestic Substances List (DSL) to determine whether they are “toxic” or capable of becoming “toxic” as defined in the Act. Substances that are deemed a priority will be considered for risk management under CEPA. Under the Act, a substance is “toxic” if it is entering or may enter the environment in a quantity or concentration or under conditions that:

- Have or may have an immediate or long-term harmful effect on the environment or its biological diversity
- Constitute or may constitute a danger to the environment on which life depends
- Constitute or may constitute a danger in Canada to human life or health.

The DSL includes substances that were, between January 1, 1984, and December 31, 1986, in Canadian commerce, used for manufacturing purposes, or manufactured in or imported into Canada in a quantity of 100 kg or more in any calendar year. The purpose of the List was to define what was 'New to Canada' and it has been amended from time to time following assessment under the New Substances Notification Regulations and currently contains approximately 23,000 substances. Types of substances on the DSL include simple organic chemicals, pigments, organometallic compounds, surfactants, polymers, metal elements, metal salts and other inorganic substances, products of biotechnology as well as substances that are of “Unknown or Variable Composition, complex reaction products, or Biological materials” (referred to as UVCBs). Although “new substances” are also included on the DSL only those substances which have not or will not be evaluated as a new substance will be examined under the DSL Categorization and Screening exercise.

### **European Union (EU) REACH Proposal**

On October 29, 2003, the European Commission released a proposed a new regulatory framework for chemicals known as REACH, the Registration, Evaluation and Authorization of Chemicals. This REACH proposal is currently being actively debated within the EU system and has yet to be

<sup>23</sup> <http://www.cdc.gov/niosh/npg/npg.html>

formally considered by either the EU Council or EU Parliament both of which must review and approve any final proposal. As currently proposed REACH would establish a new program on data collection, testing and authorization for both new and existing chemicals. The REACH proposal would require the submission by industry of data on the hazards, exposure and risk assessment for up to 30,000 substances, while also setting up an authorization process that could restrict or ban certain substances deemed to pose a significant risk to public health or the environment<sup>24</sup>.

Recent reports suggest that it is too early to draw conclusions on what the final version of the program will look like. "With the European Commission signaling it is prepared to make major changes to its chemical regulatory proposal known as REACH, leading European lawmakers questioned Jan. 19 the wisdom of carrying out the legislative process until the new changes are submitted," concluded an article in a January 21, 2005 BNA newsletter. The article quotes the legislative leader responsible for the measure within the European Commission as saying, "The problem is that at the current time, there are so many uncertainties and possible new changes under consideration that it would be better for the Commission to put forward a revised proposal now before we go further<sup>25</sup>."

#### **EU Interim PBT Strategy**

The EU Institute for Health and Consumer Protection European Chemicals Bureau has identified 25 potential PBT (persistent, bioaccumulative, toxic) or vPvB (very persistent, very bioaccumulative) substances. An additional 25 substances have been identified for further review in 2004/2005<sup>26</sup>.

#### **United Nations Economic Commission for Europe (ENECE) Convention on Long Range Transboundary Air Pollution POPs Protocol**

This protocol focuses on a list of 16 substances that have been singled out according to agreed risk criteria. The substances comprise eleven pesticides, two industrial chemicals and three by-products/contaminants. The ultimate objective is to eliminate any discharges, emissions and losses of POPs. The Protocol bans the production and use of some products outright (aldrin, chlordane, chlordecone, dieldrin, endrin, hexabromobiphenyl, mirex and toxaphene). Others are scheduled for elimination at a later stage (DDT, heptachlor, hexachlorobenzene, PCBs). Finally, the Protocol severely restricts the use of DDT, HCH (including lindane) and PCBs. The Protocol includes provisions for dealing with the wastes of products that will be banned. It also obliges Parties to reduce their emissions of dioxins, furans, PAHs and HCB below their levels in 1990 (or an alternative year between 1985 and 1995).

#### **Stockholm Convention on Persistent Organic Pollutants**

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<sup>24</sup> European Union Development of New Chemicals Policy, BNA Environment Reporter, May, 12, 2004

<sup>25</sup> Parliament May Delay Work on REACH As EU Commission Pursues Major Changes, BNA Environment Reporter, January 21, 2003

<sup>26</sup> <http://ecb.jrc.it/>

The Stockholm Convention on Persistent Organic Pollutants (POPs) entered into force on 17 May 2004. Overall the Convention is focused on controlling the production, use and/or emission of 12 POPs of “historical concern<sup>27</sup>.” The treaty includes a mechanism for considering additions to the list of POPs. The majority of countries will have until May 2006 to submit National Implementation Plans (including National Action Plans for management of unintentional POPs) outlining how they will meet the Convention’s obligations.

### **The United Nations Environmental Programme Rotterdam Convention**

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was adopted in 1998. The Convention establishes the principle that export of a chemical covered by the Convention can only take place with the prior informed consent of the importing party. The Convention establishes a "Prior Informed Consent procedure," a means for formally obtaining and disseminating the decisions of importing countries as to whether they wish to receive future shipments of specified chemicals and for ensuring compliance with these decisions by exporting countries.

The Convention also contains provisions for the exchange of information among Parties about potentially hazardous chemicals that may be exported and imported. The Convention covers pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by Parties and which have been notified by Parties for inclusion in the PIC procedure.

### **United Nations Economic and Social Council Globally Harmonized System**

The Globally Harmonized System (GHS) for the classification and labeling of hazardous chemicals is an initiative to promote common, consistent criteria for classifying chemicals according to their health, physical and environmental hazards, and to develop compatible labeling, safety data sheets for workers, and other information based on the resulting classifications. In July 2003 the United Nations Economic and Social Council (ECOSOC) formally adopted the GHS and authorized its translation into official UN languages and dissemination throughout the world. The intent is that countries which lack systems for hazard classification and labeling will adopt the GHS as the fundamental basis for national policies for the sound management of chemicals, and that countries which already have systems will adapt them to be consistent with the GHS. The U.S. has been participating in GHS activities with a number of other countries and key industry, worker, and public interest stakeholders. The 1992 United Nations Conference on Environment and Development (UNCED, or Earth Summit), the 2002 World Summit on Sustainable Development (WSSD) and the Intergovernmental Forum on Chemical Safety (IFCS) have all endorsed the need for the GHS, and IFCS and WSSD have set a goal of 2008 for its implementation<sup>28</sup>

### **CEC Sound Management of Chemicals Program**

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<sup>27</sup> The 12 substances are aldrin, chlordane, dieldrin, DDT, endrin, heptachlor, hexachlorobenzene, mirex, toxaphene, polychlorinated biphenyls (PCBs), dioxins and furans.

<sup>28</sup> <http://www.epa.gov/oppfead1/international/globalharmon.htm>

The Sound Management of Chemicals (SMOC) project is an ongoing initiative to reduce the risks of toxic substances to human health and the environment in North America. The project provides a forum for: a) identifying priority chemical pollution issues of regional concern; b) developing North American Regional Action Plans (NARAPs) to address these priority issues; c) overseeing the implementation of approved NARAPs; and d) facilitating and encouraging capacity building in support of the overall goals of SMOC, with emphasis on the implementation of NARAPs<sup>29</sup>

Substance selection is pursued pursuant to recommendations of the selection criteria task force and based upon the following principles:

- All three countries should benefit in health or environmental terms from development and implementation of NARAPs
- Transboundary environmental movement is a concern.
- Concerns about human health or environmental risk are substantiated by scientific evidence
- Application of a precautionary approach to decisions to manage substances in keeping with Principle 15 of the Rio Declaration on Environment and Development
- To the extent possible, criteria should be consistent with and complementary to ones already developed as part of each country's national or international commitments
- Action should complement and help implement broader regional or international commitments
- Substance selection should also consider socio-economic factors during the choice of management strategies for action in a manner consistent with health and environmental protection, in support of sustainable development
- Substance selection should be a transparent process with a reporting system to enable public accountability and with the reasons for selection or rejection made clear
- Substance selection should be designed to utilize existing resources of the Parties and make decisions within the North American region in the most effective manner possible
- Substance selection should take account of emerging science and regional needs in the review and development of selection criteria and process<sup>30</sup>.

### **International HPV Program**

In 1998, the International Council of Chemical Associations (ICCA), in co-operation with the OECD and its member countries, launched the High Production Volume (HPV) Chemicals Initiative. Under this voluntary programme, harmonized, internationally agreed upon data and initial hazard assessments for approximately 1000 HPV chemicals, will be available by the end of 2004. The chemicals selected for this initiative represent

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<sup>29</sup> [http://www.cec.org/programs\\_projects/pollutants\\_health/project/index.cfm?varlan=english&projectID=25](http://www.cec.org/programs_projects/pollutants_health/project/index.cfm?varlan=english&projectID=25)

<sup>30</sup> CEC, Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative, Report to the North American Working Group on the Sound Management of Chemicals by the Task Force on Criteria. Available at: [http://www.cec.org/programs\\_projects/pollutants\\_health/smoc/criter.cfm?varlan=english#1](http://www.cec.org/programs_projects/pollutants_health/smoc/criter.cfm?varlan=english#1)

more than 90% of the global chemicals production. This information will provide a sound scientific basis for global, regional or national risk assessments<sup>31</sup>.

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<sup>31</sup> <http://www.icca-chem.org/section02b.html>

**Great Lakes Regional Collaboration Toxic Pollutant Strategy Team White Paper**  
**The Value of Mass Balance Modeling in Formulating a PTS Reduction Strategy for the Great Lakes**

**Background**

The value of mass balance models for both research and management purposes has long been recognized in the Great Lakes community. From chlorides to nutrients/eutrophication and more recently for toxic substances, mass balance models have served Great Lakes managers for almost thirty years with an aid to making informed decisions regarding regulation and remediation by providing a tool to simulate the concentration of important materials in various compartments of the aquatic ecosystem as a function of the loadings of those materials to the system. For example, in the 1970s mass balance models were instrumental in setting phosphorus target loads for each of the Great Lakes. Today, these same conservation of mass principles are being used to evaluate remediation alternatives for areas impacted by toxic substances, to help understand the relationship between fish productivity and nutrient loadings and fish stocking practices, and to integrate what we know about the ecological impacts of exotic species like zebra mussels within the Great Lakes ecosystem. With respect to PTS, a mass balance model can quantitatively relate the external sources of a chemical of concern (i.e., loadings) to the temporal and spatial concentrations of that chemical in each environmental compartment of interest (atmosphere, water, sediments, biota). These concentration profiles can then be input to risk assessment models to assess human and ecological health risks, thus providing a quantitative relationship between risk and the loading history for the system of interest. One can then forecast future trends in human and ecological risks as a function of a range of load reduction scenarios represented by the future implementation of alternative load reduction strategies. Appropriate use of the model can also provide a quantification of the mass transfer rates among compartments and between spatial segments of the system; in other words, these models can help quantify the relative exposure pathways connecting sources and receptors for a given system.

Despite their capability to produce mass budgets, mass balance models should not be confused with contaminant input-output budgets based strictly on field data. An input-output chemical budget merely relates a discrete measurement of the chemical output flux to its measured input flux for the time interval over which the measurements were made. It has no predictive value and does not provide information on the quantitative transport and fate of the chemical within the system. Data from a chemical budget are, of course, a necessary part of the monitoring program required for the calibration and confirmation of a mass balance model; but, in general, a more comprehensive data acquisition and experimentation program is necessary to obtain the additional benefits derivable from the mass balance model.

**Utility of Mass Balance Models**

Because mass balance models of chemicals of concern can quantify the relationship between external sources and the concentration in water, sediments and biota and can also quantify the relative importance of various pathways of exposure within the system, they have value in addressing many policy and management questions of concern. Generally, the type of analyses that these models can address include:

1. Models can quantify the linkage between loadings and in-situ concentrations of chemicals of concern, thereby providing a rational basis for regulatory and remedial actions such as establishment of a load reduction and allocation strategy to achieve a target chemical concentration within a key component of the system (e.g., chemical body burden in top predator sport fish);
2. Models can help design more effective and efficient monitoring and surveillance programs aimed at documenting the success of regulatory/remediation efforts;
3. Models can provide a reference point to define the notions of ecosystem health/integrity, restoration goals, and sustainable development;
4. Models can aid assessments for which there is not actual environmental experience, such as assessing the relative risks of chemicals of emerging concern or the impact of exogenous environmental stressors (e.g., exotic species invasions, major storm events, climate change) on risks from chemical loadings;
5. Models can help evaluate and measure the success of management programs by providing a reference state by forecasting the ramifications of no action and by providing a means to explain or normalize the small scale, stochastic variability so often present in monitoring data so that longer term, system-wide trends can be seen.

An example of the management value of mass balance models can be seen in both the Lake Michigan and Lake Ontario mass balance modeling efforts. In both of these lakes, the models explained that the current rate of reduction of banned and restricted chemicals (historical legacy chemicals like PCBs) in open lake water and in lake trout is being controlled by surface sediment feedback through resuspension processes (because chemicals in the surface mixed layer of sediments have much longer residence times than water) rather than watershed or atmospheric load reductions. That is why these exposure reduction rates appear to be quite slow and not affected by external load reductions. As the surface sediment concentrations get closer to being at steady-state with external loads, the whole-lake response will indeed become more controlled by the external load reductions that have been taking place. So, programs should continue to strive for load reductions suggested by model forecasts but we should not expect to see the fruits of these reductions on a lakewide basis for some time (15 – 30 years, depending on lake and amount of reduction).

### **Ongoing Chemical Mass Balance Modeling in the Great Lakes**

The development of chemical mass balance models in the Great Lakes began in the early 1980s. Examples of early chemical mass balance modeling efforts include: the development of MICHRIX by studying the transport and fate of heavy metals in the Flint River (Delos, et al. 1984) and the early analysis of solids dynamics and PCBs fate and transport in the Great Lakes (Thomann and Di Toro, 1983). A seminal effort in determining the feasibility and utility of using mass balance modeling in large lakes involved an IJC-sponsored project in 1987 in which three different modeling teams built models for PCBs in Lake Ontario based only on existing data. These three models were vetted at a workshop and the resulting report concluded that mass balance modeling of toxics in the Great Lakes not only was feasible but potentially had great management value (IJC Task Force on Chemical Loadings, 1988). Encouraged by this project, the USEPA Great Lakes National Program Office initiated the first major mass balance modeling pilot study in the Great Lakes, the Green Bay/Fox River Mass Balance Study (Bierman, et al. 1992; DePinto, et al. 1994; Beltran and Richardson,

<http://www.epa.gov/grtlakes/gbmb/Greenba1.htm>). The GBMBS was instrumental in expanding our knowledge of the sources, internal cycling, and exposure pathways of hydrophobic chemicals in the Great Lakes. Using the knowledge gained from the Green Bay study, GLNPO moved to a full lake mass balance study, using Lake Michigan as the whole lake study system and including atrazine, mercury, and PCBs among the chemicals investigated (GLNPO, <http://www.epa.gov/glnpo/lmmb/index.html>). A mass balance model has also been used to support the Lake Ontario LaMP in its efforts to develop a load reduction strategy for priority pollutants in that system (DePinto, J.V. et al. 2004). The ARCS program (Assessment and Remediation of Contaminated Sediments) also embraced the use of mass balance models to inform the development of remedial action plans in Great Lakes Areas of Concern (e.g., DePinto, et al. 1995). Now models are being used throughout the basin to support contaminated sediment assessments and development of remediation actions. Finally, the Great Lakes Initiative used many of the findings associated with the research and model development in the Great Lakes to establish point source loading guidelines for the bioaccumulative chemicals of concern that were identified in the Initiative. Also, the ongoing work of the Binational Toxics Strategy program is being informed by the analysis of mass balance models.

### **Recommendations for Use of Models to Support PTS Reduction**

Models can support ongoing and new reduction planning and actions for existing PTS of concern. They can also be used, although in a different way, to support identification of, prioritization of and reduction strategies for chemicals of emerging concern. Below are recommended actions for each of these classes of chemicals.

#### **Recommendations for Binational Toxics Strategy and LaMP priority chemicals**

With regard to existing PTS, we propose to continue to develop and apply models as they have been used for the Green Bay, Lake Michigan, and Lake Ontario mass balance studies. That is, we propose to develop and apply models to evaluate alternative load reduction strategies on a whole lake and on an AOC basis. The general approach for this application would be:

- Estimate loading of contaminant of concern to the lake or AOC;
- Gather available concentration data in all media of the system;
- Obtain physical-chemical property data for chemical of concern;
- Obtain system-specific environmental/limnological data;
- Run model in a steady-state to reconcile ambient data against loads; and
- Run the model in a time-dependent mode to estimate time-variable response to recommended actions to achieve targets.

Also, once an action has been implemented the same model should be used to evaluate progress in PTS reduction on a system-specific (chemical and water body) basis. For example, a model can be used in a predictive mode to provide a reference for the trend in fish concentration of a contaminant if no reduction actions had been implemented. This “reference” response will permit assessment of the benefits gained by actions that had been implemented. The model can also aid in the design of a monitoring program to measure the success of reduction actions. For example, the model forecast of system response to a proposed action can provide an estimate of when, where, and how often fish should be sampled to detect a response to the reduction action being implemented.

## **Recommendations for Chemicals of Emerging Concern**

Modeling support of activity for chemicals of emerging concern focuses on their value in making screening-level assessments. It is important for models to help screen chemicals of emerging concern to be multi-media, basin-wide modeling frameworks. The multi-media modeling framework would be structured around a simulation of air, water, and sediment transport and inter-compartmental exchange rates. A modeling framework of this structure can then provide exposure assessment of any substance for which chemical properties and emission/source rates and boundary conditions can be estimated. Possible screening assessments that could be conducted with a basin-scale modeling framework include:

- Assessment of the rate of chemical build-up within various media and spatial compartments of the system over time, along with an estimate of the steady-state concentrations that should be observed given the current emission rates and the time it should take to reach steady-state.
- Assessment of the chemical transport between air, land, and water media. For example, how important is an exposure pathway that involves a chemical air emission taking place in Chicago followed by air transport and deposition into Lake Ontario?
- Assessment of the spatial and temporal connections between source emissions and receptors within the basin.
- Assessment of the relative contributions to exposure from source inside and outside the basin.
- Assessment of inter-lake transfer of the chemical of concern.

Of course, all of these screening assessments can be made for multiple chemicals of emerging concern, thus permitting a prioritization of those chemicals with regard to emission reduction actions.

## **Gaps in PTS Modeling**

With regard to existing priority chemicals, we need to continue building loading and *in situ* compartment concentration data that is similar the database that has been developed for PCBs. The more data that can be gathered for these other chemicals, the more accurately models will be able to forecast the system response to reduction alternatives.

With regard to chemicals of emerging concern, screening these chemicals for exposure the assessments discussed above first requires that the screening model is calibrated to a chemical for which we have considerable data, such as PCBs. This calibration to PCBs gives confidence that the air and water transport and inter-compartmental exchanges are being modeled accurately. Once this is done the multi-media modeling framework can be used on other chemicals by specifying the chemical-specific data that is used as input to the model (emissions and loads from PS and NPS, boundary conditions, chemical properties (e.g.,  $K_{oc}$ , H), reaction rates) and confirmation that the exposure assessments are reasonable (concentrations in air, water, sediment, and biota). Some data are available for some chemicals of emerging concern; however, this is a major gap in assessing these chemicals. Nevertheless, it would be valuable to begin developing and applying these screening models now, because that exercise can point out data gaps and those fate and transport processes for which a chemical's behavior in the Great Lakes is most sensitive. This exercise will guide and prioritize the new data collection on a chemical-specific basis.

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