# Binational Summary Report: Bisphenol A

## 1. Overview:

Annex 3 - Chemicals of Mutual Concern commits the Parties to identify and designate, on an on-going basis, Chemicals of Mutual Concern (CMCs) in the Great Lakes which originate from anthropogenic sources and that are agreed to by both Parties as being potentially harmful to the environment or human health.

As such, the Annex 3 Subcommittee (C3) has charged an Identification Task Team (ITT) with reviewing and critically evaluating relevant existing data and information, in accordance with the *Binational Considerations* developed by the C3, in order to determine which of a suite of seven candidate chemicals / classes should be recommended as CMCs.

This *Binational Summary Report* documents the application of the *Binational Considerations* to the candidate CMC Bisphenol A (BPA). This report was developed with input and review of the entire ITT and the recommendation regarding designation was reached by a vote of the full ITT.

With respect to BPA, the ITT was not able to come to a 2/3 majority decision as to a designation recommendation. There was an even split among members who felt that BPA should be recommended Not a CMC and those who felt BPA should be recommended as insufficient information on which to base a determination. There was a minority dissenting view that BPA should be recommended as a CMC. The IIT Co-Chairs voted insufficient information on which to base a determination, which is therefore, absent a majority decision of the ITT, is the default recommendation. The following summarizes the discussions of the ITT:

With regard to levels and trends of BPA in the Great Lakes Environment:

- There is little data presently available with which to evaluate BPA against available benchmarks or to establish trends over space and time in the Great Lakes basin. This includes air, sediment, wildlife, water, wastewater treatment effluents and human biomonitoring data.
- Available environmental quality benchmarks for interpreting environmental occurrence data are limited; however, Environment Canada is presently developing Canadian Federal Environmental Quality Guidelines for BPA.
- A review of the limited existing sediment data from the Great Lakes basin shows no exceedances of available, albeit limited, benchmarks. Data was too limited to establish temporal trends.
- A review of surface water data does show some exceedances (10%) of the Canadian SAR PNEC value. Most exceedances were found in Hamilton Harbor. Data too limited to establish temporal trends.
- A considerable volume of new water, wastewater, wildlife and sediment data for BPA in Canada (including the Great Lakes basin) is forthcoming under the Canadian Chemicals Management Plan and in original articles soon to be published in peer-reviewed literature;

With regard to risk management:

- There are ongoing risk management actions in the Canada and US; however their performance has not been adequately evaluated with regard to reducing levels in the Great Lakes basin.

## 2. Chemical background:

### *Chemical Identity:*

Common Name: Bisphenol A (BPA)

CAS Registry Number: 80-05-7

CA Index Name: Phenol, 4,4'-(1-methylethylidene)bis-

BPA is a high production volume chemical that is primarily used as a monomer to produce polycarbonate plastic and epoxy resins. Little monomeric BPA, typically less than 100 parts per million, remains in the finished materials. Most other smaller scale uses of BPA also involve conversion of BPA to specialty plastics, resins, or other chemicals.

The physico-chemical properties of BPA are summarized in Table 1 below (EC & HC 2008a).

| Property | Type | Value | Temperature (°C) |
|---|---|---|---|
| **Melting point (°C)** | Experimental | 150-157 | |
| | Modelled | 132 | |
| **Boiling point (°C)** | Experimental | 220-398 | |
| | Modelled | 364 | |
| **Density ($kg/m^3$)** | Experimental | 1195 | 25 |
| **Vapour pressure (Pa)** | Experimental | $5.3 \times 10^{-6}$ | 25 |
| | Modelled | $3.0 \times 10^{-5}$ ($2.27 \times 10^{-7}$ mm Hg) | 25 |
| **Henry's Law constant ($Pa \cdot m^3/mol$)** | Experimental | $1.0 \times 10^{-6}$ ($1.0 \times 10^{-11}$ $atm \cdot m^3/mol$) | |
| | Modelled | $9.3 \times 10^{-7}$ ($9.16 \times 10^{-12}$ $atm \cdot m^3/mol$) Water solubility 120 mg/L: $4.0 \times 10^{-5}$ ($3.95 \times 10^{-10}$ $atm \cdot m^3/mol$) Water solubility | 25 |

| Property | Type | Value | Temperature (°C) |
|---|---|---|---|
| | | 257 mg/L: $4.7 \times 10^{-6}$ ($4.7 \times 10^{-11}$ atm·$m^3$/mol) | |
| **Log $K_{ow}$ (Octanol-water partition coefficient) (dimensionless)** | Experimental | 3.32 | |
| | Modelled | 3.64 | |
| **log $K_{oc}$ (Organic carbon-water partition coefficient - L/kg) (dimensionless)** | Experimental | 2.53-2.85 (pH 4.5-5.9) | |
| | Calculated | 2.85 | |
| | Modelled | 4.88 | |
| **Log $K_{oa}$ (Organic carbon-air partition coefficient) (dimensionless)** | Modelled | 12.7 | |
| **Water solubility (mg/L)** | Experimental | 253-257 | 22-24 |
| | | 301 | room temperature |
| | | 120 | 25 |
| | Modelled | 173 | 25 |
| **Other solubilities (g/L)** | Experimental (alcohol) | soluble | |
| **$pK_a$(Acid dissociation constant) (dimensionless)** | Experimental | 9.59 - 11.30 | |
| | Modelled | 9.73-10.48 | |

**Table 1:** Chemical – Physical Properties of BPA identified in the final Canadian *Screening Assessment for The Challenge: Phenol, 4,4' -(1-methylethylidene)bis- (Bisphenol A)*. (EC & HC, 2008a)

## *Canadian Domestic Program Status:*

In Canada, BPA was evaluated as a Challenge substance under the Chemical Management Plan, which resulted in a final Screening Assessment Report (SAR) published in October 2008 (EC & HC, 2008a). The final screening assessment report concluded that BPA may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (EC & HC, 2008a). The final SAR also concluded that BPA is entering or may be entering 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 (EC & HC, 2008a). It is therefore concluded that BPA meets the criteria in paragraphs 64(a) and 64(c) of CEPA 1999 (EC & HC, 2008a).

As such, several environmental and human health risk management actions were identified and have been implemented or are underway (EC & HC, 2008b).

## *US Domestic Program Status:*

USEPA published an Action Plan for BPA in March 2010. Several risk management actions were identified and have been pursued (US EPA, 2010). In October 2014, BPA was added to the list of chemicals for the US EPA Work Plan program, which is the successor to the Action Plan program. Under this program it is expected that a risk assessment of BPA will be conducted. The limited basis for adding BPA to the Work Plan list was focused on human health hazard and exposure to BPA from non-FDA regulated products. The scope and timing of the assessment have not yet been announced (US EPA, 2014).

Human health assessment of BPA is largely the responsibility of the U.S Food and Drug Administration (FDA) since the primary source of human exposure to BPA is from food packaging or other food contact materials (US FDA, 2014). To support FDA's safety assessment, BPA has been the subject of extensive research conducted in a joint program between FDA and the U.S. National Toxicology Program (US FDA, 2014).

## 3. Review of existing scientific data and a qualitative evaluation of their significance:

### *Is the candidate chemical present in the Great Lakes ecosystem and does it present a potential threat to ecological or human health in the Great Lakes Basin?*

### *Canadian Releases, Sources, and Uses:*

The CEPA 1999 s.71 survey indicated that no BPA was manufactured in Canada in 2006 at quantities > 100kg. However, 26 companies reported using BPA in Canada in the range of 100,000 – 1,000,000 kg or importing approximately half a million kg into Canada either alone, in a product, in a mixture or in a manufactured item. (EC & HC, 2008a) The extent to which the reported values represent quantities of BPA present in finished and semi-finished goods entering Canada from other parts of the world is unknown, as these uses would be unlikely to meet the reporting criteria for the s.71 survey (EC & HC, 2008a). Since 2006, imports of BPA have decreased by 75% and major industrial facilities, such as those producing resins, have stopped importing and using BPA in Canada, therefore eliminating significant sources of BPA releases through industrial effluent (EC & HC, 2008b).

The type of mixture, product or manufactured item reported for 2006 in response to the CEPA 1999 s.71 survey included resins, curing agents, epoxy curing agents, hardeners, plastic resin formulations, monomer, paperboard packaging, metal cans, phenolic resins, industrial coatings, plasticizers, adhesives, two part epoxy adhesives, chain oil, brake fluid, heat transfer fluid and lubricant formulations (EC & HC, 2008a).

Information voluntarily submitted in 2007 in response to the Challenge Questionnaire and other information submitted by industry additionally include use in epoxy polymer flooring, as a laminating adhesive, in custom color powder coating and as a curing agent for resurfacing concrete (EC & HC, 2008a).

The remaining BPA (~6%) is used in a variety of smaller-scale uses, most of which convert BPA into another chemical or a polymer. Included are various specialty plastics and resins, along with flame retardants (e.g., tetrabromobisphenol A) and other substances. BPA is used as a wax in investment casting and as a color developer in thermal paper applications, for example in cash register receipts. Bisphenol A-based polymers may also be used in the production of cosmetics, such as lipsticks, face and eye makeup and nail lacquer (EC & HC, 2008a)

### *US Releases, Sources, and Uses:*

Within the U.S., BPA is a high production volume chemical, produced at greater than 1 million lbs (approximately $4.5 \times 10^5$ kg). Essentially all production is believed to fall within the jurisdiction of the Toxic Substances Control Act (TSCA) (US EPA, 2014). BPA is manufactured at 6 facilities in the US, none of which are located in the Great Lakes Basin (GLB). Two of the facilities are located in states that border the Great Lakes, but the facilities are not in the GLB itself (i.e., both are located in the Ohio River basin).

BPA is primarily used as a monomer in the production of polycarbonate plastic and epoxy resins. In 2003, consumption patterns of BPA in the U.S. indicated that approximately 72% of BPA was used to manufacture polycarbonate, 21% was used in epoxy resins and 6% was used in other applications (US EPA, 2010). Most epoxy resin manufacturing facilities are also integrated into BPA manufacturing facilities in the US and are also not in the GLB.

## *Changes in use/production over time:*

Global production of BPA was 4 billion kg in 2007, with estimated US production accounting for 25%, or approximately 1.2 billion kg.

No detailed data on production and use of BPA over time is publicly available. According to the Chemical Economics Handbook (IHS Chemical, February 2014), BPA consumption in the US ranged from 939 thousand metric tons in 2000 to 973 thousand metric tons in 2013, with considerable year-to-year variability depending on general economic factors (e.g., consumption in 2009 dropped to 746 thousand metric tons). The report states that "The BPA market in the United States is advanced and is not expected to grow significantly in the next five years; the average annual growth rate is estimated to be less than 1% in the next five years." However, this analysis does not include BPA entering the two countries in finished products. Data are not available on total BPA entering in finished products.

Similar information for Canada is not presented in the Chemical Economics Handbook. However, since most BPA is used to make polycarbonate plastic and epoxy resins, both of which are manufactured in the US but not in Canada, it is likely that the same general perspective on future growth in use of BPA would apply to both the US and Canada.

## *Proportion of use/production occurring within the GLB region:*

All 3 polycarbonate plastic manufacturing facilities in North America are integrated into BPA manufacturing facilities, none of which are located in the GLB itself or Canada. In these facilities, BPA is generally piped from the BPA manufacturing unit to the polycarbonate manufacturing unit with little opportunity for releases of BPA.

As such, BPA is not produced in the GLB itself. Although no specific data is available on use of BPA in the GLB region, most BPA is used at the site of production to make polycarbonate plastic or epoxy resins. Thus, the industrial use of BPA in the GLB region is expected to be very low compared to the total industrial production and use of BPA across the US and Canada.

## *Volume of releases to water and air:*

Releases of BPA may occur during production, processing, use or disposal of the substance or products containing it.

Based on its moderate water solubility and low vapor pressure, wastewaters and washing residue generated during production and processing of application materials such as polycarbonates and epoxy resins are the most likely industrial sources of release of BPA into the environment.

Unintentional release of fugitive dust from closed systems during handling and transportation of the substance may also occur.

BPA has low vapor pressure at typical environmental temperatures; however, elevated temperatures occurring during some processing operations may increase the vapor pressure, resulting in formation and possible emission of gaseous BPA from plastics manufacturing facilities.

BPA may enter the environment through physical and chemical degradation of end products during product use, disposal and recycling operations. Releases from product use would include releases to surface water via waste water treatment effluent, releases from disposal and recycling operations would

be primarily to soil, and to a lesser extent, to water and air; however these are not quantified under the Canadian National Pollutant Inventory (NPRI) or the U.S. Toxics Release Inventory (TRI).

The Canadian NPRI has tracked the release and disposal of BPA from industrial facilities since the 1990s. Total reportable release of BPA in Canada in the 2000-2012 timeframe ranges from 0 to 11 tons. Disposal volumes are significantly greater. Release of BPA is highly variable year-to-year and is essentially all to air – refer to Tables 1 and 2 below (EC, 2014a). Since BPA has low volatility, releases to air are likely to be in the form of particulate matter. Since releases are only tracked for facilities meeting established criteria, it is possible that NPRI data may underestimate total Canadian industrial releases of BPA (EC, 2014a). As well, releases from in-use products are not tracked by release data (EC, 2014a).

| | 2000 | 2001 | 2002* | 2003 | 2004* | 2005 | 2006 | 2007* | 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Canada | 0.651 | 2.9 | 0 | 8.8 | 4.5 | 0.12 | 0.159 | 0.126 | 0.314 | 0 | 0.278 | 0.315 | 0.01 |
| Ontario | 0.651 | 2.9 | 0 | 8.8 | 4.5 | 0.12 | 0.159 | 0.126 | 0.314 | 0 | 0.278 | 0.315 | 0.01 |

**Table 2:** NPRI Releases of BPA to Air 2000 – 2012 (all values in tons). (EC, 2014a)

| | 2000 | 2001 | 2002* | 2003 | 2004* | 2005 | 2006 | 2007* | 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Canada | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.162 | 0 | 0 | 0 | 0 |
| Ontario | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.162 | 0 | 0 | 0 | 0 |

**Table 3:** NPRI Releases of BPA to Water 2000 – 2012 (all values in tons). (EC, 2014a)

For certain years, because the total releases of BPA (an NPRI Part 1A substance) were less than one tonne, only the total releases may be reported by the facilities (EC, 2014a).

Similar data from the U.S. TRI are presented below for releases in states that border the Great Lakes along with U.S.-wide data for comparison. Note that facilities in these states may not be located in the GLB itself (e.g., two BPA and polycarbonate manufacturing facilities are located in these states but neither are in the GLB) (US EPA, 2015)

| | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **U.S.** | 172730 | 151991 | 183617 | 160443 | 177502 | 204101 | 109216 | 123018 | 106110 | 105920 | 111633 | 65043 | 92386 |
| **Basin** | 82783 | 74350 | 100662 | 82720 | 89658 | 85310 | 48714 | 62067 | 46392 | 42230 | 29993 | 21713 | 54702 |
| **IL** | 3367 | 2899 | 1896 | 2705 | 4098 | 3714 | 1792 | 3228 | 3984 | 2703 | 952 | 605 | 558 |
| **IN** | 38010 | 19764 | 23750 | 9758 | 9858 | 10510 | 10260 | 27760 | 10259 | 9755 | 267 | 755 | 34645 |
| **MI** | 1450 | 1097 | 24457 | 1576 | 3690 | 3394 | 2208 | 2496 | 1833 | 1404 | 1569 | 1466 | 606 |
| **MN** | 24 | 7 | 1404 | 1660 | 1829 | 2187 | 4 | 0 | 0 | 0 | 57 | 34 | 17 |
| **NYS** | 1042 | 1024 | 500 | 10 | 15 | 10 | 10 | 10 | 350 | 469 | 464 | 362 | 381 |
| **OH** | 28316 | 40792 | 38449 | 52718 | 62334 | 57996 | 26688 | 20896 | 21947 | 18391 | 17569 | 16316 | 16016 |
| **PA** | 9843 | 8198 | 10031 | 14103 | 7603 | 7176 | 7290 | 7193 | 7523 | 9100 | 8813 | 2080 | 2426 |
| **WI** | 731 | 569 | 175 | 190 | 231 | 323 | 462 | 484 | 496 | 408 | 302 | 95 | 53 |

**Table 4:** TRI Release of BPA to Air 2000 – 2012 (all values in pounds). (US EPA, 2015)

| | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **U.S.** | 6727 | 5472 | 4591 | 3782 | 3538 | 9685 | 3410 | 6246 | 5732 | 4976 | 6240 | 4664 | 3246 |
| **Basin** | 1183 | 828 | 1480 | 2337 | 1645 | 1170 | 1139 | 796 | 1053 | 794 | 789 | 1039 | 788 |
| **IL** | 51 | 48 | 47 | 5 | 5 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **IN** | 1100 | 750 | 1400 | 2300 | 1300 | 1100 | 1100 | 750 | 1000 | 750 | 750 | 1000 | 750 |
| **MI** | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **MN** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **NYS** | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 2 |
| **OH** | 22 | 20 | 27 | 27 | 335 | 60 | 34 | 41 | 48 | 39 | 34 | 34 | 36 |
| **PA** | 5 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **WI** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

**Table 5:** TRI Release of BPA to Water 2000 – 2012 (all values in pounds). (US EPA, 2015)

For both polycarbonate plastic and epoxy resins, the manufacturing processes are closed and tightly controlled due to the use of solvents or volatile components that are reacted with BPA to make the plastic or resin. Residual unreacted BPA is present in finished polycarbonate plastic and epoxy resins only at very low levels, typically less than 100 parts per million.

## *Changes in release volumes over time:*

Although BPA is a reportable substance under Canada's National Pollutant Release Inventory, only limited data is available since releases are only required for facilities that meet established criteria. As a result, no clear time trends are discernable in the limited data (see data in tables above) (EC, 2014a).

Releases to water reported under the EPA Toxics Release Inventory fluctuate in the 2000-2012 time period with no clear trend (US EPA, 2015). Releases to air over the same time period also fluctuate but show a general downward trend (see data in tables 4 and 5 above) (US EPA, 2015).

## *Proportion of releases that are occurring within the GLB region:*

According to the NPRI data, reportable industrial releases of BPA in the 2000-2012 timeframe are all in Ontario and, thus, may be in the GLB (EC, 2014a).

According to the TRI data, approximately half of U.S. releases of BPA to air occur in states that border the Great Lakes (US EPA, 2015). As noted above, since BPA has low volatility, releases to air are likely to be in the form of particulate matter. The proportion of releases to water in states that border the Great Lakes fluctuates considerably with recent years being in the range of approximately 20% (US EPA, 2015). Most of these TRI reporter releases are likely from BPA manufacturing facilities, which are located in states that border the Great Lakes, but the facilities are not directly in the GLB (US EPA, 2015).

## *Significance of out-of-basin sources (via long-range atmospheric transport and deposition):*

As noted in Section 3.d below.

## *Environmental and Human Health Data:*

## *CEPA 1999 conclusions, US hazard classifications, and applicable international assessment findings:*

A notice summarizing the scientific considerations of the final SAR was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for BPA on October 18, 2008, under subsection 77(6) of CEPA 1999 (EC & HC, 2008a). The final SAR concluded that BPA may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (EC & HC, 2008a). The final SAR also concluded that BPA is entering or may be entering 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 (EC & HC, 2008a). It is therefore concluded that BPA meets the criteria in paragraphs 64(a) and 64(c) of CEPA 1999 (EC & HC, 2008a).

The final SAR also concluded that BPA meets the criteria for persistence in sediments under conditions of low or no oxygen, but does not meet the criteria for bioaccumulation, as defined by the *Persistence and Bioaccumulation Regulations* made under CEPA 1999 (EC & HC, 2008a).

A detailed safety assessment of BPA recently released by FDA concludes: “FDA’s current perspective, based on its most recent safety assessment, is that BPA is safe at the current levels occurring in foods” (US FDA, 2014).

## *Description of evidence or potential for harmful effects on species, populations or ecosystems:*

Many studies have been conducted to determine potential effects of BPA exposure on invertebrates, fish, amphibians, reptiles, birds, and wild mammals, and a review is provided by Crain et al. (2007). In general, studies have shown that BPA can affect growth, reproduction and development in aquatic organisms (e.g. Crain et al., 2007; EC & HC, 2008a, NTP, 1982; Picard, 2010a, b). Among freshwater organisms, fish appear to be the most sensitive species. Evidence of effects in fish, aquatic invertebrates, amphibians and reptiles has been reported at environmentally relevant exposure levels lower than those required for acute toxicity (EC & HC, 2008a).

There is controversy about whether effects seen at lower doses in animals (less than 1 mg/kg/day) are meaningful and relevant to humans. These low-dose effects include effects on puberty and developmental neurotoxicological effects (brain, behavior) at doses in animal studies as low as 2 µg/kg-bw/day. As demonstrated in numerous studies on rodents, non-human primates, and humans, BPA is efficiently converted after oral exposure to non-estrogenic metabolites (e.g., BPA-glucuronide) and rapidly eliminated from the body in urine. The most reliable urine biomonitoring studies show that human exposure to BPA is well below established human health benchmarks (e.g. Health Canada, 2013; LaKind et al., 2012).

## *Evidence of persistence in water and/or sediments:*

While BPA is not expected to hydrolyze in the environment, photolytic half-lives for BPA range from 0.5 to 10 days. Additionally, BPA is known to be readily biodegradable in aerobic environments. BPA was

found to be rapidly biodegraded by microbial communities found in many natural waters and sediments, with lag times and half-lives on the order of a few days. BPA dissipates in soil in less than 3 days, with a major route being conversion to non-extractable bound residues. The soil sorption organic carbon normalised partition coefficient values (Koc) for BPA range from 251 to 1507 L/kg, averaging 750 +/- 348 L/kg. BPA has low to moderate mobility in soil.

As concluded in the US EPA Action Plan (2010): "Based on the criteria set forth in EPA's policy statement on *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances* (64 Fed. Reg. 60194, November 4, 1999), BPA is expected to have low persistence (P1)…"

Similarly, the Canadian SAR (EC & HC, 2008a) concluded: When combined laboratory, field and model evidence are considered, there is greater reliable evidence to suggest that bisphenol A **does not meet** persistence criterion for air (half-life in air ≥ 2 days), water and soil (half-life in soil and water ≥ 182 days) as set out in the *Persistence and Bioaccumulation Regulations* under CEPA, 1999 (EC & HC, 2008). Limited and conflicting evidence suggests that BPA may not degrade or degrade only slowly under conditions of low or no oxygen. Based on the limited evidence available, the SAR concluded that BPA **does meet** the criteria for persistence in sediments (half-life in sediments ≥ 365 days) under conditions of low or no oxygen (EC&HC, 2008a).

## *Evidence of bioaccumulation and/ or biomagnification:*

As concluded in the Canadian SAR, there is some evidence to indicate BPA may have some potential to accumulate in organisms; however, it does not meet the bioaccumulation criterion (BCF, BAF > 5000) as set out in the *Persistence and Bioaccumulation Regulations* under CEPA, 1999 (EC & HC, 2008a).

Similarly, as concluded in the US EPA Action Plan (2010): "Based on the criteria set forth in EPA's policy statement on *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances* (64 Fed. Reg. 60194, November 4, 1999), BPA is expected to have … low bioaccumulation potential (B1)." Other reported bioaccumulation factors for BPA are typically <100 L/kg (e.g. Staples et al., 1998).

## *Long range atmospheric transport potential (therefore distant international sources may be of concern to the GLB):*

At ambient temperature and atmospheric pressure, BPA has a vapor pressure between $10^{-4}$ and $10^{-5}$ Pa which means it is a semi-volatile organic compound. Its Henry's law constant calculated from vapor pressure and aqueous solubility is 3.12E-7 Pa*m3/mol. Level III Mackay-type modeling shows that nearly all BPA partitions into the water and soil compartments. Furthermore, BPA does not meet the criteria for persistence in air (half-life $\geq$ 2 days), as defined under the *Persistence and Bioaccumulation Regulations* under CEPA 1999 (EC & HC, 2008a). Accordingly, there is a limited basis to expect long range atmospheric transport of BPA; however, there is limited information available to evaluate whether long range transport does occur and confirm this expectation.

## *Evidence of significant partitioning to dissolved phase and/or sediment:*

As reported in the Canadian SAR (EC & HC, 2008a), level III fugacity modeling shows that nearly all BPA entering the environment through water will remain in water with only a small fraction (3.1%) partitioning to sediment. When released to air or soil, most BPA will partition to the soil compartment with smaller amounts partitioning to water and sediment.

## *Exposure route(s) of concern for human health (if a human health concern):*

As concluded in both the Canadian SAR (EC & HC, 2008a) and the US EPA Action Plan on BPA (US EPA, 2010), as well as numerous other assessments (e.g., US FDA, 2014), dietary intake is the primary source of human exposure to BPA. Migration of BPA from food packaging and repeat-use polycarbonate food containers has been demonstrated in numerous studies and accounts for the trace levels of BPA found in some food products. Regulatory agencies charged with assessing BPA exposure through dietary intake, including Health Canada and the U.S. FDA, have found dietary exposure to be very low and not a risk to human health. Accordingly, the exposure route of concern for human health does not occur via the GLB environment and consideration of human health data below is limited.

## *Environmental and Human Health Benchmarks Guidelines:*

Based on the extensive set of aquatic toxicity studies covering diverse taxa that are available for BPA, predicted no effect concentrations (PNECs) have been derived for freshwater by Environment Canada and others (e.g. Staples et al., 2008). $PNEC_{Freshwater}$ values identified in the literature are shown in table 6 below:

| $PNEC_{Freshwater}$ | Reference |
|---|---|
| 71 µg/L | Staples et al. 2008 - Geometric mean of LOEC and NOEC values in chronic toxicity tests calculated to derive the MATC value used in the EPA derivation of the Final Chronic Value (FCV). |
| 22 µg/L | Staples et al. 2008 - Species sensitivity distribution approach used to estimate the lower bound $5^{th}$ percentile of BPA chronic toxicity data. |
| 5 µg/L | OMOECC, 1994 |
| 0.175 µg/L | EC & HC, 2008a |

**Table 6:** Different $PNEC_{freshwater}$ values identified for BPA.

The Ontario Ministry of Environment and Climate Change have established a provisional water quality objective for BPA of 5 µg/L.

PNECs have also been derived for sediments. Picard (2010) established a PNEC of 1.2 mg/kg dw, while the final Canadian SAR (EC & HC, 2008a) established a PNEC of 0.01 mg/L for sediments.

Environment Canada is presently developing Federal Environmental Quality Guidelines (FEQGS) for BPA for water, sediment and wildlife diet.

## *Great Lakes Monitoring and Surveillance Data:*

## *Comparison of environmental concentrations relative to available benchmarks over time and geographic area:*

Available environmental monitoring data for North America, including surface waters and sediments, were compiled and analyzed by Klecka et al. (2009a). Although this analysis was not focused on the GLB and included data from throughout North America, there is no basis to expect that environmental concentrations in the GLB would be substantially different from the rest of North America since use patterns for BPA and derived products are expected to be substantially the same throughout North America.

As reported by Klecka et al. (2009a), BPA was found at concentrations above the detection limits in 20% of the samples (n=1068 weighted observations), and the median and 95$^{th}$ percentile concentrations of BPA in fresh surface waters were 0.081 µg/L and 0.47 µg/L, respectively. These values are well below the freshwater PNEC concentrations of Staples et al. (2008) which ranged from 22-71 µg/L, and are also well below the Ontario provisional water quality objective of 5 µg/L. While the median concentration is below the Canadian SAR PNEC) for BPA in surface water of 0.175 µg/L, the 95$^{th}$ percentile concentration exceeds the SAR PNEC

A report by Hull et al (2014) presented a risk-based screening exercise to evaluate the significance of chemicals of emerging concern (including BPA) measured in water and sediment of the Great Lakes basin. Based on a literature review (post 2009) the maximum reported concentration of BPA in Canadian waters of the Great Lakes was reported as 0.087µg/L and in US waters as 0.8µg/L. The Canadian maximum value is below the Canadian SAR PNEC of 0.175µg/L, while the maximum reported concentration in US waters is approximately 4.5x the SAR PNEC.

The EPA Action Plan included a similar, although more limited, summary of environmental monitoring data and reported mean values from several studies ranging from 0.012-0.14 µg/L with a range of 0.0009-12 µg/L (EPA, 2010). The high value of 12 µg/L, which was not from a location in the GLB, was characterized by EPA as an outlier. The reported mean values from these studies are l below the freshwater benchmark concentrations described in Table 5..

A report for the IJC Workgroup on Chemicals of Emerging Concern noted that BPA was detected in approximately half of the surface waters sampled at concentrations up to 0.8 µg/L (Klecka et al., 2009b) which is above the SAR PNEC of 0.175 µg/L. The report also noted that BPA was detected in 38% of the sediment samples at concentrations ranging from below the detection limit to 60 ng/g dw.

Surface water monitoring conducted under the Canadian Chemicals Monitoring Plan (CMP) from 2008 to 2012 identified 70 / 1033 (6.7%) samples across Canada which exceeded the SAR PNEC of 0.1755µg/L (EC, 2014b). More recent CMP monitoring (2013-2014) examined 343 samples from 36 sites across Canada, of which 21 samples exceeded the SAR PNEC. Of these 343 samples, 169 came from 15 locations within the Great Lakes basin: BPA was detected (> 5 ng/L) in 142 of these samples (84%), with 17 (10%) exceeding the SAR PNEC (EC, 2014b).

Regarding sediment concentrations, Klecka et al. (2009a) reported median and 90$^{th}$ percentile concentrations of 0.6 µg/kg-dw and 3.4 µg/kg-dw, respectively (insufficient data was available to calculate a 95$^{th}$ percentile value). The median value from Klecka et al. (2009a) was also cited in the US EPA Action Plan (2010). These values are well below the PNEC value of 1.2 mg/kg-dw established by Picard (2010).

Chu et al. (2005) reported BPA was detected in 65% of sediment samples from Lake Erie (n = 55) at concentrations ranging up to 6.1 ng/g dw. Tertuliana et al. (2008) detected BPA in 11% of the samples from Tinkers Creek, with estimated concentrations ranging from 20 to 60 ng/g dw.

Recent monitoring conducted under the CMP sediment monitoring program indicate that sediment concentrations (2011-2015) found concentrations across Canada ranged from <1 – 40ng/g-dw, with a mean of 7.0ng/g-dw (n=31) (EC, 2014c). Two of the sites were located in the lower Great Lakes basin, with concentrations of 5 and 14ng/g-dw (EC, 2014c). Another report for the IJC Workgroup (Uslu et al., 2011) noted that BPA was detected in wastewater treatment plant effluents and in drinking water treatment plant source and treated drinking water from Windsor and Detroit at concentration ranges of 7-42 ng/L, 1-1967 ng/L and 0.3-26 ng/L and detection frequencies of 50%, 50%, and 40%, respectively.

Focused more specifically on drinking water and source waters (i.e., surface water and groundwater) Arnold et al. (2013) evaluated the relevance of drinking water as a source of human exposure. Based on data from 31 papers, the fraction of drinking water measurements reported as less than the detection limit is 95% in North America. The maximum quantified (in excess of the detection limit) BPA concentration in North America was 0.099 µg/l. Accordingly, BPA in drinking water represents a minor component of overall human exposure.

BPA was also detected in source water and drinking water from 17 drinking water systems in Ontario at frequencies of 22% and 12 %, respectively. The maximum concentrations of BPA in source water and drinking water were 87 and 99 ng/l, respectively.

With regards to human biomonitoring, while not specific to the Great Lakes, concentrations of BPA in urine of the Canadian population have been evaluated under the Canadian Health Measures Survey (CHMS) cycles 1 and 2 - see table 7 below (HC, 2013.) However, it should be noted that the primary route of human exposure to BPA is through dietary intake as a result of various sources including migration from food packaging and repeat use polycarbonate containers (EC & HC, 2008a).

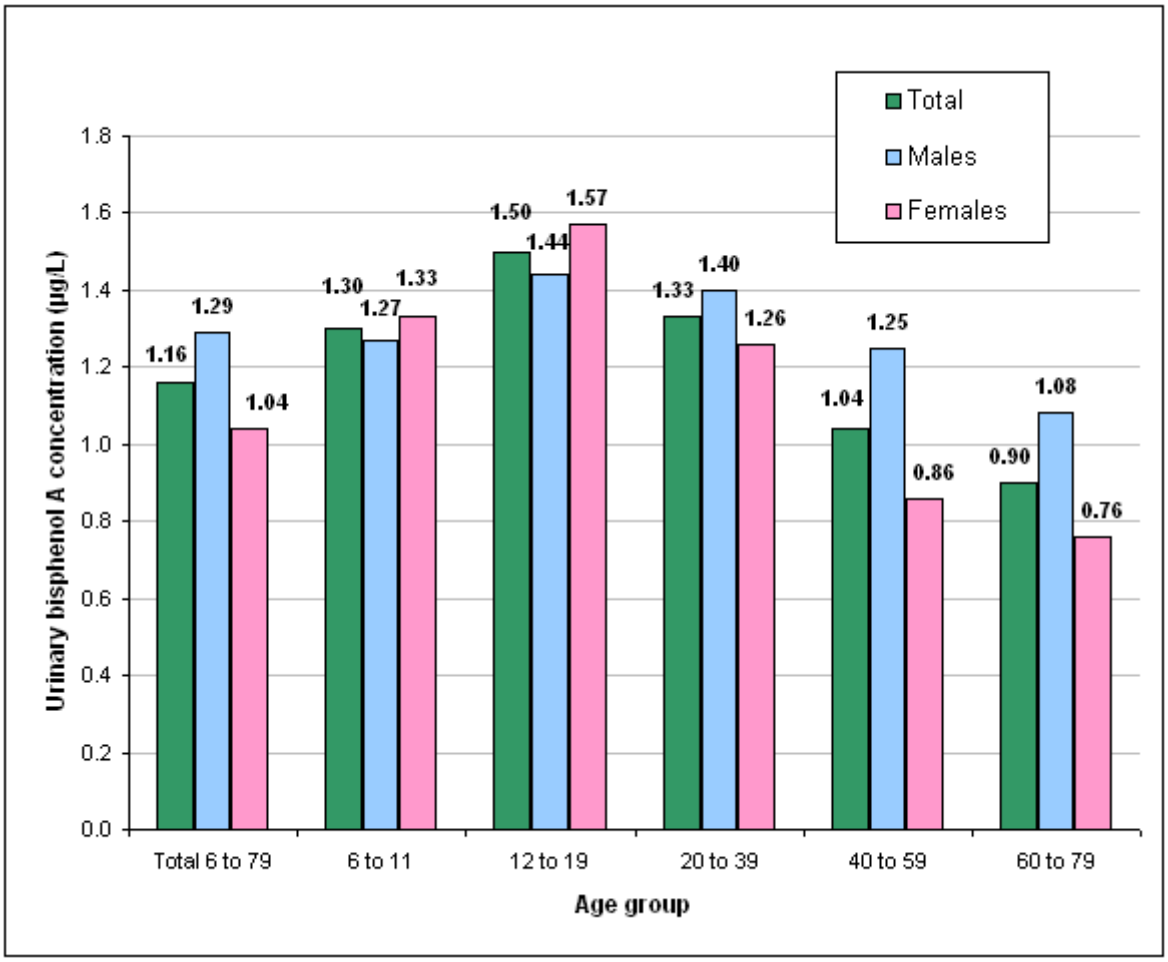


**Figure 1:** BPA – Geometric means and selected percentiles of urine concentrations (µg/L) for the Canadian population aged 6 -79 years, Canadian Health Measures cycle 1 (2007-2009) and cycle 2 (2009-2011). (HC, 2013)

The First Nations Biomonitoring Initiative (FNBI) examined the concentration of BPA in urine of the Canadian First Nations populations in 2011 (AFN, 2013). The analyses included a breakdown by ecozones, one of which was the Great Lakes – see table 8 below (AFN, 2013). Concentrations in the Great Lakes ecozone were comparable to those of the entire FNBI study (all ecozones) and to the results of the CHMS.

| FNBI Ecozone | Age group | n | % < LOD | A.M. 95%CI | G.M. 95%CI | 10th 95%CI | 25th 95%CI | 50th 95%CI | 75th 95%CI | 90th 95%CI | 95th 95%CI |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Great Lakes | Total | 71 | 2.8 | 3.44<br>2.63 - 4.25 | 1.87<br>1.60 - 2.17 | F<br>F | 0.95<br>0.84 - 1.07 | 1.53E<br>0.54 - 2.51 | 3.73<br>3.57 - 3.89 | 8.20E<br>5.29 - 11.10 | 11.31<br>10.67 - 11.95 |
| Great Lakes | 20-39 | 25 | 0.0 | 3.53E<br>2.08 - 4.99 | 2.17<br>2.08 - 2.27 | 0.87<br>0.73 - 1.02 | 1.07E<br>0.69 - 1.46 | 1.52E<br>0.61 - 2.43 | 3.51E<br>2.34 - 4.69 | 5.27E<br>1.95 - 8.59 | 16.53<br>.- . |
| Great Lakes | 40-59 | 33 | 6.1 | F<br>F | F<br>F | 0.12<br>0.09 - 0.16 | F<br>F | 0.95<br>0.65 - 1.25 | F<br>F | 3.99E<br>2.47 - 5.51 | 5.63<br>.- . |
| Great Lakes | 60-99 | 13 | 0.0 | 6.70E<br>2.90 - 10.51 | 5.21E<br>3.12 - 8.70 | 1.55<br>1.53 - 1.58 | 2.76E<br>1.53 - 4.00 | 4.46<br>3.32 - 5.59 | .<br>. | .<br>. | .<br>. |

E – Survey estimates should be used with caution. Their associated co-efficient of variation are between 16.6% and 33.3%

F – Survey estimates were too unreliable to be published. Their associated coefficient of variation were above 33.3%

**Table 7:** Arithmetic and geometric means of urine concentrations (µg/L) for on reserve and crown land First Nations populations aged 20 years and older, Great Lakes ecozone, by age distribution. (AFN, 2013)

## *Conclusions:*

Overall, typical reported concentration of BPA in sediment in North America are generally very low and well below the limited available benchmarks. Surface water concentrations do show some exceedances of the Canadian SAR PNEC value. Insufficient environmental monitoring data is currently available to analyze time trends. However, there does not appear to be any indication of any significant time trends, in particular to increasing environmental levels.

Based on the limited data and environmental guideline or benchmarks available for the Great Lakes there are no discernable temporal trends in environmental concentrations at this time. As noted in Section 3.1, the BPA market in the United States, and presumably Canada, is advanced and is not expected to grow significantly in the next five years. However, this does not account for BPA in finished imported goods. Since BPA is readily biodegradable and is not persistent, in particular in surface water, environmental concentrations of BPA are considered unlikely to increase; however, data are needed to confirm and further assess temporal trends.

Although BPA has been well studied, it continues to be the subject of additional research. Of particular relevance are studies that monitor environmental media for the presence of BPA (and typically many other substances). Additional studies will continue to be valuable to further document environmental concentrations and to identify any areas of potential concern.

| Media | Summary |
|---|---|
| **Air** | - There is no air monitoring data or benchmarks with which to assess potential threats from BPA to the Great Lakes. |
| **Water** | - Data somewhat limited<br>- Available data indicated that concentrations are generally below benchmarks: Recent CMP monitoring (2013-2014) examined 169 samples from 15 sites within the Great Lakes basin: BPA was detected (> 5 ng/L) in 142 samples (84%), with 17 samples (10%) exceeding the SAR PNEC of 0.175 µg/L. |
| **Sediment** | - Data and available benchmarks somewhat limited;<br>- Measured concentrations of BPA are below available benchmarks. |
| **Wildlife** | - There was no wildlife data identified with which to assess BPA in the Great Lakes basin. |
| **Biomonitoring** | - There is limited human biomonitoring data specific to the Great Lakes basin with which to assess trends in concentrations of BPA. What is available indicates urine |

| Media | Summary |
|---|---|
| | concentrations in Great Lakes are comparable to the rest of Canada. Furthermore, fish consumption and other environmental exposures not considered to be a significant source of human exposure to BPA. |

**Table 8:** Summary of ITT environmental findings and conclusions.

## 4. Review of past, present and/ or planned science and risk management actions:

### *Is there a need for additional risk management and/or science activities and are there resources and/or tools available to support the delivery of such activities?*

### *Canadian Federal Risk Management Activities:*

As an outcome of the conclusions of the final SAR in Canada, a Risk Management Approach for BPA was established, which included several risk management actions related to BPA in the environment. Along with ongoing monitoring programs and continuing to require reporting of BPA releases under NPRI, Environment Canada established a requirement for preparation and implementation of Pollution Prevention Plans for BPA in industrial effluents (EC & HC, 2008b). A complete summary of Canadian risk management actions for BPA for both human health and the environment is provided below.

The human health risk management objective established in the Canadian Risk Management Approach is to reduce the release of BPA from infant formula containers and from polycarbonate baby bottles to the lowest level that is technically and economically feasible (EC & HC, 2008b). The established ecological risk management objective is to reduce as much as possible, within what is technically and economically feasible, BPA releases to water (EC & HC, 2008b).

To meet the ecological and human health risk management objectives for BPA, many different actions have been implemented, are underway or are planned for the future in Canada. These are summarized in the table below:

| Authority | Risk Management Actions | Most Recent Milestone |
|---|---|---|
| *Hazardous Products Act*<br><br>*(Now the Canada Consumer Product Safety Act)* | Prohibit the importation, sale and advertising of polycarbonate baby bottles that contain bisphenol A. | An Order Amending Schedule I to the *Hazardous Products Act* was published March 2010. |
| *Food and Drugs Act (cosmetics)* | Addition to the Cosmetic Ingredient Hotlist. | The Cosmetic Ingredient Hotlist has been amended. |
| *Food and Drugs Act (medical devices)* | Survey all currently licensed Class II, III and IV medical devices that contain bisphenol A that come into contact with the patient or the patient fluids. | Underway. |
| *Food and Drugs Act (foods)* | Evaluation of pre-market submissions for infant formula to ensure the lowest levels of bisphenol A in the food packaging for these products. | In effect as of October 2008. |
| *Food and Drugs Act (foods)* | Facilitate the assessment of proposed industry alternatives to bisphenol A used in can linings. | In effect as of October 2008. |
| *Food and Drugs Act (foods)* | Develop stringent migration targets | In development. |

| Authority | Risk Management Actions | Most Recent Milestone |
|---|---|---|
| | for bisphenol A in infant formula cans. | |
| *Food and Drugs Act (foods)* | Support industry in the development and implementation of codes of practice to reduce, to as low as reasonably achievable, the levels of bisphenol A in existing food packaging for canned infant formula. | Consultations are underway (Health Canada - Food and Nutrition Web site). |
| *Food and Drugs Act (foods)* | Exploration of establishing migration targets for bisphenol A in canned foods. | In development. |
| *Food and Drugs Act (foods)* | Bisphenol A will be added to the list of chemicals regularly monitored in the 2009 cycle of the Canadian Total Diet Study (TDS). | In effect as of October 2008. Will be published with the 2009 TDS results. |
| *Food and Drugs Act (foods)* | Gather additional data to fill information gaps by testing a variety of foods for bisphenol A presence, including liquid and powdered infant formulas, as well as foods for infants and children aged 1-4 years. | Underway. Studies are being published on Health Canada's Food and Nutrition - Bisphenol A Web site. |
| *CEPA 1999* | Further information on human exposure will be collected through research projects, including the Maternal-Infant Research on Environmental Chemicals (MIREC) Study and the P4 study: Plastics and personal care product use in pregnancy. | Underway. |
| *CEPA 1999* | The Canadian Health Measures Survey (CHMS) is measuring bisphenol A concentrations in Canadians. | The first Report on Human Biomonitoring of Environmental Chemicals in Canada was released in August, 2010.<br><br>The second Report on Human Biomonitoring of Environmental Chemicals in Canada was released in April, 2013.* |
| *CEPA 1999* | Further research on the mechanism of action of bisphenol A and potential fetal exposures. | Underway. |
| *CEPA 1999* | Regulatory approach to minimize risks from releases of bisphenol A into the environment. | A final Pollution Prevention Planning Notice (P2 Notice) was published in the *Canada Gazette*, Part I |

| Authority | Risk Management Actions | Most Recent Milestone |
|---|---|---|
| | | on April 14, 2012.<br><br>An *Environmental Performance Agreement Respecting BPA in Paper Recycling Mill Effluents* was established in 2013 and remains in effect until 2017 |
| *CEPA 1999* | Continuation of reporting releases of bisphenol A through the National Pollutant Release Inventory. | Ongoing. Data is being released on the National Pollutant Release Inventory Web site. |
| *CEPA 1999* | Environmental monitoring of bisphenol A in wildlife, fish and receiving waters, as well as monitoring of wastewater and landfill leachates | Initiated in 2008 and is ongoing. |
| *CEPA 1999* | Bisphenol A will be included in future information gathering initiatives. | In development. |

* HC, 2013

**Table 9:** Summary of Canadian federal risk management actions for BPA. (EC, 2013a)

In 2012, the *Pollution Prevention Planning Notice with Respect to Bisphenol A in Industrial Effluents* came into force. The RM objective targeted by this measure is to reduce and maintain BPA releases to the lowest total concentration that is economically and technically feasible. It also seeks to reduce the BPA releases to less than 1.75 µg/L in effluent (i.e. process wastewater from an industrial facility released into off-site wastewater systems or to surface waters) released at the final discharge point of the facility. In order to meet this target, industries subject to the Notice are required to develop and implement pollution prevention plans and to report on their progress. This notice applies, under specific conditions, to any person who owns or operates an industrial facility that manufactures or uses a certain quantity of BPA or mixture containing BPA (EC, 2012).

The pollution prevention notice for BPA contained certain exemptions for different sectors, including paper recycling mill effluents, which have been identified as a source of BPA. As such, an *Environmental Performance Agreement Respecting Bisphenol A in Paper Recycling Mill Effluents* was established in 2013 between the Government of Canada and 13 paper recycling companies, to minimize the risk of environmental impacts from their effluent releases of BPA to the greatest extent practicable. This agreement sets in place specific performance objectives for paper recycling mills that deposit directly to the environment of into off-site wastewater treatment systems, and remains in effect until March 5, 2017 (EC, 2013b). The first annual progress report summarizing the reports provided by the mills after the first year of the agreement has been published (EC, 2015). There were 21 paper recycling mills from the 13 companies that originally signed the Agreement: as of 2015, 14 of these paper recycling mills were meeting the objectives of the Agreement and one mill had ceased operations and withdrawn from the Agreement (EC, 2015). In the remaining six mills, work is ongoing towards achieving the objective (EC, 2015).

## *U.S. Federal Risk Management Activities:*

*Source: US EPA 2010, 2014 & US FDA, 2014:*

As an outcome of US EPA's Action Plan, several actions were identified. These include several Design for the Environment (DfE) projects on certain uses of BPA, consideration of rulemaking under section 4(a) of TSCA to develop additional environmental testing or monitoring data, and consideration of rulemaking under section 5(b)(4) of TSCA to identify BPA on the Concern List.

One of the DfE projects focused on the use of BPA and alternatives in thermal paper has been completed. An Advanced Notice of Proposed Rulemaking under section 4(a) of TSCA was published in 2011 to solicit public comments on the need for additional environmental data. Further steps have not yet been proposed. Rulemaking under section 5(b)(4) was considered but was withdrawn. Additional details on these actions are provided below.

Based on US EPA's screening-level review of hazard and exposure information, including the uncertainties surrounding the low-dose studies, the chemical action plan for BPA called for the US EPA to:

1. Consider initiating rulemaking under section 5(b)(4) of the TSCA to identify BPA on the Concern List as a substance that may present an unreasonable risk of injury to the environment on the basis of its potential for long-term adverse effects on growth, reproduction and development in aquatic species at concentrations similar to those found in the environment. As noted above, this action was considered but was withdrawn.

2. Consider initiating rulemaking under section 4(a) of TSCA to develop data with respect to environmental effects relevant to a further determination that BPA either does or does not present an unreasonable risk of injury to the environment. This may include testing or monitoring data in the vicinity of landfills, manufacturing facilities, or similar locations to determine the potential for BPA to enter the environment, including surface water, ground water, and drinking water, at levels of potential concern particularly for environmental organisms, pregnant women, and children. US EPA released an advance notice of proposed rulemaking on July 26, 2011 but further steps have not yet been proposed.

3. Initiate collaborative alternatives assessment activities under its Design for the Environment (DfE) program to encourage reductions in BPA releases and exposures. One of these activities, released in 2014, addressed alternatives to BPA in thermal paper coatings used in such applications as cash register receipts. The report is now available on the DfE website.

Additionally, EPA intends to initiate alternatives analyses for BPA used in foundry castings since foundries are accountable for large releases of BPA as reported under the Toxic Release Inventory (TRI), and for BPA-based materials lining water and waste water pipes since this application may have a potential for human and environmental exposure.

As noted in the Action Plan, US EPA does not intend to initiate regulatory action under TSCA at this time on the basis of risks to human health. EPA remains committed to protecting human health and will continue to consult and coordinate closely with US FDA, the Centers for Disease Control and Prevention, and the National Institute of Environmental Health Sciences to better determine and evaluate the potential health consequences of BPA. The results of this work will factor significantly in any future EPA

decisions to address potential risks to human health resulting from uses within EPA's jurisdiction. As noted above, US FDA has recently released a detailed safety assessment on BPA.

As part of US EPA's efforts to address BPA, it also intends to evaluate the potential for disproportionate impact on children and other sub-populations through exposure from TSCA uses.

## *Provincial, State and Other Actions:*

The Ontario Ministry of Environment and Climate Change have established a provisional water quality objective of 5 µg/L for BPA (OMOECC, 1994).

The Minnesota Department of Health has developed a guidance values for BPA in drinking water of 20µg/L (MDOH, 2014).

Michigan has established Water Quality Standards values for BPA to protect humans, wildlife and aquatic life. The final chronic value is 20 µg/L, the aquatic maximum value is 180 µg/L and the final acute value is 350 µg/L.

Many environmental non-government organizations have identified BPA as being a chemical of concern, including the Canadian Environmental Law Association (e.g. CELA, 2008) and the David Suzuki Foundation (e.g. Paglaro, 2013), among others.

## *Identification of Gaps in Management and/or Science Activities:*

BPA has been extensively tested and evaluated by regulatory agencies in both Canada and the US. Concentrations of BPA in environmental media show some exceedances of the draft FEQG for water, but not sediment. There is no data on which to judge trends in concentration over time. Human exposure to BPA is very low and well below safe intake limits established by US FDA and Health Canada.

1. ***Are environmental levels below applicable benchmarks and are there any discernable environmental trends****?*

Environmental concentrations in the Great Lakes are *generally* below benchmark values (e.g. SAR PNEC values); however some exceedances have been reported in surface waters (e.g. CMP Monitoring and Surveillance)

Forthcoming monitoring and surveillance data (e.g. CMP M&S results) should fill knowledge gaps identified with regards to present BPA concentrations and trends over space and time.

Furthermore, Federal Environmental Quality Guidelines for BPA are under development in Canada and will soon provide a standard benchmark against which to evaluate observed environmental concentrations in the forthcoming work described above.

2. ***Is the GLB-relevant human health exposure being adequately addressed?***

The primary exposure route of concern for human health (i.e., dietary exposure resulting from migration of BPA from food packaging) does not occur via the GLB environment.

3. ***Are applicable/available objectives for the substances being met?***

Risk management actions identified under the EPA Action Plan and the Canadian risk management approach are completed or in progress. However, there is limited data available to assess the performance of these actions.

***4. If no objectives exist for the substance, is progress being made towards reducing levels in the environment, generating needed data, etc.?***

While there is some evidence to indicate that presently levels of BPA in the environment are generally below available benchmarks, with some exceedances observed in surface waters, there are insufficient data available to establish trends over time and correlate any observed decreases in concentrations to reduced releases.

***5. If progress is not being made, are actions in place to expect progress (e.g., regulations that have yet to take effect);***

N/A

***6. Gaps in risk management, research or monitoring for the substance (e.g., ongoing releases of concern, knowledge needs, lack of monitoring data) and possible actions that would fill these gaps:***

Monitoring and surveillance to establish trends over time and to evaluate the performance of Canadian and US risk management measures could be considered a knowledge gap, as could the development of national environment quality guidelines, which is underway in Canada.

No risk management gaps of specific relevance to the GLB are apparent at this time and the risk management actions identified in Canadian and U.S. strategies and work plans have been implemented or are in progress. However, as noted above, there is limited data available at this time to evaluate the performance of existing risk management actions.

BPA is already one of the most extensively tested of all substances in commerce for it toxicity. Environmental monitoring data is available and additional data is expected to be routinely generated in studies initiated by academic as well as government researchers (e.g. Canadian Chemicals Management Plan monitoring and surveillance and various United States Geological Survey studies).

## 5. Final Recommendation:

With respect to BPA, the ITT was not able to come to a majority as to a recommendation for designation. There was an even split among members who felt that BPA should be designated Not a CMC and Insufficient information on which to base a determination.. There was with a minority dissenting view that BPA should be designated as a CMC. The IIT Co-Chairs voted insufficient information on which to base a determination, which is therefore, absent a majority decision of the ITT, the default recommendation as per the Operational Guidance developed by the ITT.

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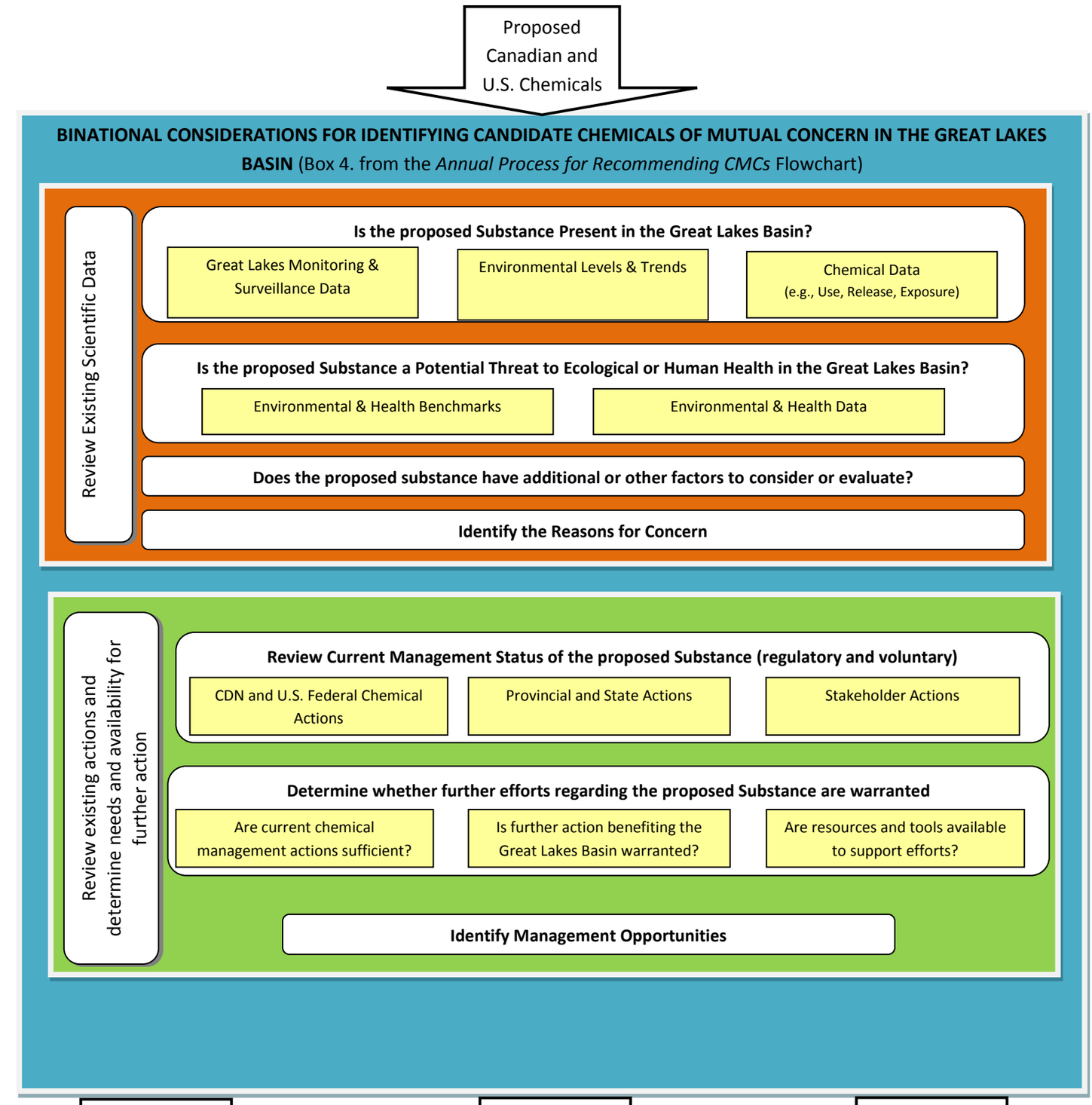
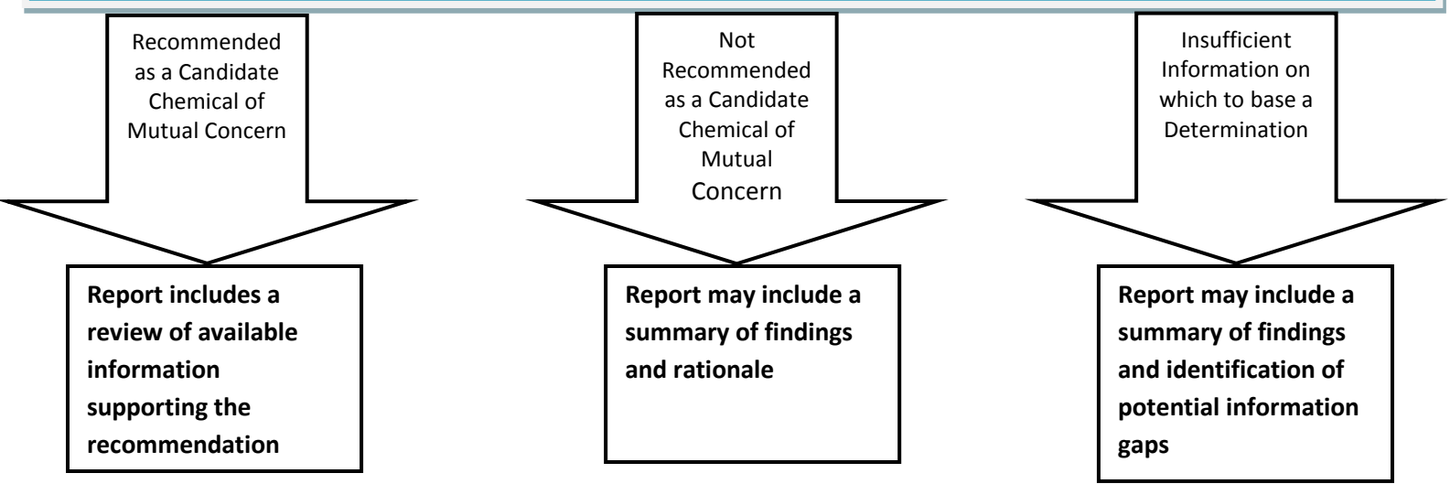
# Appendix A:

# Binational Considerations When Evaluating Candidate Chemicals of Mutual Concern




**Report includes a review of available information supporting the recommendation**

**Report may include a summary of findings and rationale**

**Report may include a summary of findings and identification of potential information gaps**

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