

Binational Summary Report: Chlorinated Paraffins (Short, Medium and Long Chain)

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 Chlorinated Paraffins (CPs). 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 CPs, including Short Chain (C10-C13, SCCPs), Medium Chain (C14-C17, MCCPs) and Long Chain (\geq C18, LCCPs), the ITT has concluded that there is insufficient data and/or information available to effectively apply the *Binational Considerations*. Therefore, **the ITT has recommended that CPs be identified as insufficient information on which to base a determination.** With respect to SCCPs and MCCPs, the recommendation was reached by 2/3 majority of the ITT and with respect to LCCPs, the recommendation was unanimous.

With respect to LCCPs, extremely limited data from the Great Lakes exists to conclude whether relevant guidelines and/or benchmarks are being exceeded or to establish whether any spatial or temporal trends exist. Therefore the ITT cannot determine whether they pose a threat to the environment and/or human health of the Great Lakes basin at this time. Data on environmental occurrence in the Great Lakes basin, and in Canada and the US more broadly, are not readily available. This is largely due to the unreliability and the high-cost of analytical and measurement methods presently available for LCCPs.

With respect to SCCPs and MCCPs, there are some data to suggest that SCCP concentrations in top-predator fish from Lake Ontario are generally below draft Canadian Federal Environmental Quality Guidelines and that concentrations in these fish have recently (post 2005) begun to decline. For MCCPs there are some data available to suggest similar patterns. Fish data from the other Great Lakes were not readily available; however, some exceedances of the draft Canadian Federal Environmental Quality Guidelines were identified in limited data from Lake Michigan and Isle Royale. The concentrations of SCCPs and MCCPs in sediment have not shown similar declines. It should be noted that forthcoming fish biomonitoring data from the Minnesota Pollution Control Agency, mainly for Lake Superior, will soon be available. As such, the ITT determined that the body of evidence was insufficient to determine whether concentrations of SCCP and MCCP in fish from the other Great Lakes are similar to those in Lake Ontario and whether we could expect recently observed declines from Lake Ontario to continue over the long

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term or to be occurring in the other Great Lakes, especially when the present lack of risk management actions for SCCPs in the US and for MCCPs and LCCPs in both Canada and the US is taken into consideration.

While a determination for CPs could not be reached, a number of needs and opportunities for additional activities were identified, many which could provide information necessary to reach a determination, for example:

- Begin and/or continue to undertake monitoring of air, sediment and fish (including top-predator species and others with a significant benthic component to their diet) to confirm and continue tracking long-term trends in the Great Lakes environment, estimate atmospheric loadings from within and outside of the basin and to measure the performance of ongoing and forthcoming risk management activities;
- Support research to improve the measurement of LCCPs, in order to increase the availability and reliability of environmental occurrence data for these substances; and
- Implement and measure performance of existing and forthcoming Canadian and US federal risk management activities for all CPs.

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2. Chemical background:

Chemical Identity:

Chlorinated Paraffins (CPs) are a group of synthetic organic chemicals consisting of n-alkanes with varying degrees of chlorination, usually between 30 and 70% by weight. There are no known natural sources of CPs. CPs are produced by chlorination of n-alkane feedstocks. CPs are typically viscous oils with low vapor pressures; they are practically insoluble in water but are soluble in chlorinated solvents or mineral oils (EC & HC, 2008a).

CPs consist of extremely complex mixtures allowing for many possible positions of the chlorine atoms. Depending on the degree of chlorination, they are grouped into low (<50%) and high (>50%) chlorine content. Depending on the chain length, the commercial products of CPs are often subdivided into SCCPs (C10–C13), MCCPs (C14–C17) and LCCPs (C>18). CPs may also contain epoxy-enhanced soya oil, glycid ethers or organotin compounds (Coelhan and Higler 2014).

Production of SCCPs in the EU, USA and Canada ranged from 7,500-11,300 tons in 2007 (Fiedler 2010). Although production has decreased dramatically in North America and Europe, SCCP production has risen exponentially in China (Fiedler 2010). Coelhan and Hilger (2014), estimate that current global annual CP production in China (2007), India (2010), EU (2011) and the US (2007) is ~990,000 tons. Total production capacity of CPs in China alone is now reported to be over 1,000,000 tons annually, with actual output of 600,000 tons (WCC 2012). While Russia does not produce SCCPs, the production of MCCPs in Russia has increased from 23,000 tonnes in 2007 to nearly 30,000 tonnes in 2011 (WCC 2012). European production was constant at 45,000 tonnes of MCCCCP and LCCP with SCCP products at less than 500 tonnes (WCC 2012).

CPs are valued as extreme pressure additives in metalworking fluids because they reduce metal tool wear and are extremely cost-effective (Canter 2014). CPs are used worldwide in a wide range of applications such as plasticizers and flame retardants in a wide range of plastics and sealants. More highly chlorinated CPs are used as flame retardants and water-repellents. As flame retardants, they can be used in conjunction with antimony trioxide. As a secondary plasticizer, they can be added to PVC resins and pastes, wire, cables, toys, footwear, paints, adhesives, plasticizer extender in synthetic rubber, chlorinated rubber, nitrocellulose polystyrene, polyurethane, polysulfide, acrylic and butyl based sealants used in building and construction, PVC gardening and industrial pipes, PVC flooring, films/sheets, rubber belts, vinyl flooring, carpet backing, textiles and fabric coatings and inks (Coelhan and Hilger 2014 *inter alia*). CPs may constitute 4-15% by weight of paints, especially those based on vinyl copolymers, acrylics, and chlorinated rubber. They can also be used in intumescent flame retardant paints. CPs can be added to low-density polyethylene and as a coupling agent in mineral-filled polypropylene composites. Their use outdoors includes traffic paints because they improve adhesion and resistance to water, oil and fuel. CPs may be used in the leather industry as fatting and softening agents (Coelhan and Hilger 2014 *inter alia*). MCCPs are particularly valued for their use in the paint and coating, adhesives (including adhesives on food packaging), sealants, and rubber and elastomer industries because their improved flexibility and thus durability of the coating and reduced the drying time (EC and HC, 2008b).

MCCPs and LCCPs appear to have been used as alternatives to SCCPs in some of the more demanding metal working applications (HELCOM, 2002). LCCPs also appear to have potential as an alternative in leather, paints and coatings, sealants and rubber applications. A number of other potential alternatives are available for specific applications, e.g. nitroalkanes, alkyl phosphate and sulfonated fatty acid esters

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and vegetable oil based products. These alternatives are considered less harmful than CPs (UNECE, 2006). However, these non-CP alternatives are often more expensive and may require special handling. A UK estimated cost for completely converting the use of SCCPs to non-SCCPs in metal working was predicted to be four million £ per year (IRTA, 2004). An analysis conducted in California found that overall metal working processing costs were more expensive for the SCCP alternatives, however including other associated costs (clean up and waste removal) made the non-SCCP alternatives competitive (IRTA, 2004).

CPs may be released into the environment from their industrial use such as improperly disposed metalworking fluids containing CPs. The very wide range of uses of CPs in infrastructure (pipes), building materials, exterior paints, and sealants provides opportunities for direct losses to air and water through volatilization and leaching, respectively. The use of CPs as flame retardants and plasticizers in indoor applications (textile and fabric coatings, leather, sealants, and carpet backing) suggests the opportunity for release to indoor air and dust, and from there, to wastewater treatment plants (WWTPs) and outdoor air and surface waters. CPs have been identified in house and office dust (Hilger et al. 2013, Coelhand and Hilger 2014). For example, Hilger et al. (2013) found MCCPs in the dust of all residences sampled and SCCPs in 9 of 11 residences. They reported median levels of SCCPs and MCCPs of 5 (4-27) and 176 (9-892) µg/g, respectively. Fridén et al. (2011) found levels in indoor air of <5-210 ng/m³ of SCCPs and MCCPs and levels in dust at low µg/g levels in Stockholm. Of all organohalogen compounds measured in 15 kitchen hoods in Stuttgart, Germany, Bendig et al. (2014) found the highest levels, by far, of CPs (140-15,000 ng/g fat) compared to, for example, PCBs at 4-1610 ng/g fat. They attributed the abundance of CPs in kitchen hoods to their presence in food and indoor products.

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:

Sources and Uses:

From: Environment Canada and Health Canada, 2008a and 2008b

Canadian production and usage data for CPs were collected by means of a Notice, issued pursuant to section 71 of CEPA 1999 that was published in the *Canada Gazette*. CPs are no longer produced in Canada. Pioneer Chemicals Inc. (formerly ICI Canada), Cornwall, Ontario, was the only Canadian producer of CPs. However, this plant was sold to Dover Chemical Corporation and it is currently not producing CPs. This Cornwall plant previously produced MCCPs and LCCPs with a chlorine content of up to 56% under the trade name Cereclor. The capacity for production was 5.0, 5.0, 8.5 and 8.5 kilotonnes in 1997, 1998, 1999 and 2000, respectively: the corresponding imports to Canada in these years were 2.0, 2.0, 1.7 and 1.8 kilotonnes, respectively.

Total reported annual usage of CPs in Canada (production + imports - exports) was approximately 3,000 tons in 2000 and 2001. As production of CPs in Canada has stopped, CPs are now imported into Canada as chemical formulations from foreign producers or as formulations in products such as paints, sealants, plastics and metalworking fluids.

The vast majority of CP consumption in Canada in 2001 was MCCPs, while much smaller quantities of SCCPs and LCCPs were also being consumed in specific applications. SCCPs are no longer in commerce in Canada. At this time, the two dominant end-use applications for CPs in Canada were the formulation of metal working fluids such as cutting oils and high pressure lubricating oils used in the metal working industry (estimated at 1.2 kilotonnes) and as a secondary plasticizer and sometimes as a flame retardants in polyvinyl chloride (PVC) applications (estimated at 1.2 kilotonnes) (Figure 2). The use of CPs (on a volume basis) in PVC applications was primarily MCCPs and has historically been restricted to floor manufacturing, wire and cable sheathing and insulation and in wall coverings and emulsions. In 2001, an additional 0.4 kilotonnes of CPs were used in various plastics or formulated chemical products (e.g. adhesives, paints, sealants). Again, the majority of CPs consumed in these applications were MCCPs, along with small amounts of LCCPs.

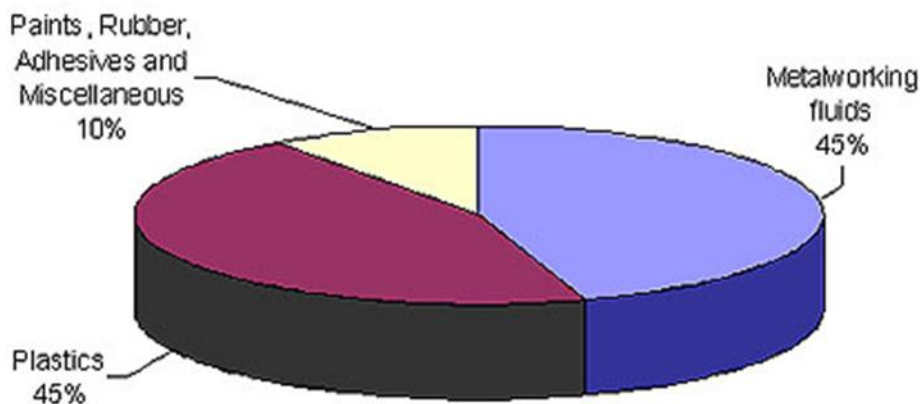


Figure 1: Approximate uses of CPs in Canada in 2001. Source: EC &HC, 2008b

Releases:

From: Environment Canada and Health Canada 2008b

There is currently no evidence of any significant natural source of CPs. Anthropogenic releases of CPs into the environment may occur during production, storage, transportation, industrial and consumer usage of CP-containing products, disposal and burning of waste, and land filling of products.

The two major sources of release of SCCPs, MCCPs and LCCPs into the Canadian environment are likely use in metalworking applications and manufacturing of products containing these CPs. The possible sources of releases to water from manufacturing include spills, facility wash-down and storm water runoff. CPs in metalworking/metal cutting fluids may also be released into aquatic environments from drum disposal, carry-off and spent bath use. These releases are collected in sewer systems and ultimately end up in the effluents of sewage treatment plants.

Other releases could be associated with use of gear oil packages, fluids used in hard rock mining and equipment use in other types of mining, fluids and equipment used in oil and gas exploration, manufacture of seamless pipe, metalworking and operation of turbines on ships.

Landfilling is a major disposal route for polymeric products in Canada. CPs would be expected to remain stabilized in these products, with minor losses to wash off from percolating water. Leaching from landfill sites is likely to be negligible owing to strong binding of CPs to soils. Minor emissions of these products, which are effectively dissolved in polymers, could occur for centuries after disposal.

Polymer-incorporated CPs could also be released during recycling of plastics, which may involve processes such as chopping, grinding and washing. If released as dust from these operations, the CPs would be adsorbed to particles because of high sorption and octanol-air partition coefficients.

Another significant source of release of CPs to the environment is from losses during the service life of products containing CP polymers (PVC, other plastics, paints, sealants, etc.). These releases are predicted to be mainly to urban/industrial soil and to wastewater.

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Since 1999, on-site environmental releases of CPs used as an industrial chemical in Canada must be reported to the National Pollutant Release Inventory (NPRI) by companies meeting the reporting criteria. Based on information collected by the NPRI, very small amounts of CPs were being released to the Canadian environment by entities reporting to the NPRI. In 2002, small transfers of SCCPs for disposal to landfill (1.6 tons) and recycling by recovery of organics (2.14 tons) were reported to the NPRI from only two companies, both located in Ontario. Less than 5 kg of releases and/or transfers of CPs were reported by a third company in Ontario. In 2001, the same three companies reported similar quantities of releases/transfers of CPs to the NPRI. Since 2001, there have been no releases of CPs reported to the NPRI, with very small quantities (< 22 tons) reported annually as having been transferred for off-site disposal or recycling. It should be noted, however, that CPs are likely to be released from sources other than the industrial sectors included in the NPRI, and releases to the Canadian environment could thus be considerably higher than those reported to this inventory.

Table 1: Summary of 2001 estimated releases of CPs to the Canadian environment. Estimates are based on the demand profile of CPs and release factors taken from European risk assessment reports. Source: EC & HC, 2008b

Production/End-use Area	Estimated Annual Releases (kilotonnes)
Metalworking fluids formulation and end-use	0.3
Plastics production and end-use	<0.1
Rubber production and end-use	<<0.1
Sealants, adhesives and caulks formulation and end-use	<<0.1
Paint formulation and end-use	<<0.1
Other	<<0.1

US Releases, Sources and Uses:

Sources and Uses:

The largest use of SCCPs in the US is as a component of lubricants and coolants in metal cutting and metal forming operations. The second-largest use is as both a secondary plasticizer and a flame retardant in plastics, especially PVC. Other minor domestic SCCP uses are as a plasticizer and a flame-retardant additive to a variety of products including: rubber formulations, paints and other coatings, and adhesives and sealants (CPIA, 2009). CPs are approved by the US FDA for use in adhesives on food packaging, which may result in low concentrations of CPs being transferred to food items. For safety reasons, other countries (e.g. those in the European Union) have allowed SCCPs to be used as a flame retardant in underground mining conveyor belts (rubber formulations) and fire retardants in dam sealants (ECHA 2008a).

The current production of all CPs (SCCP, MCCP, and LCCP) in the United States is on the order of 75,000 tons per year. Production of SCCP and MCCP (C9-17) was 50,000 tons in 2007. A very small fraction of

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that number is attributable to import/export business. According to the Chlorinated Paraffins Industry Association, MCCPs represent the largest production and use of CPs in North America while SCCPs is only half that volume (CPIA, 2009). In the United States, Dover Chemical Corp. is the sole manufacturer of CPs and several companies import SCCPs (EPA, 2006).

In the United States, EPA required Dover Chemical Corp. to cease manufacturing SCCPs and to submit pre-manufacture notices (PMNs) under Toxic Substances Control Act (TSCA) section 5 for MCCPs and LCCPs in 2012. The company has since submitted the PMNs. Although MCCPs and LCCPs are included among the US EPA's list of TSCA Work Plan Chemicals, this does not restrict Dover's production or industry's use of MCCPs and LCCPs during the review period. However, US EPA took various actions beginning in 2012 to end importation and manufacturing of SCCPs in 2012, effectively eliminating all known major sources of this chemical from the marketplace.

Releases:

No CP releases have been reported to the Toxics Release Inventory (TRI). However, it should be noted that CPs are likely to be released from sources other than the industrial sectors included in TRI, and releases to the US environment could thus be considerably higher than those reported to this inventory.

Environmental and Human Health Data:

Fate Characterization Summary:

Half-lives of CPs in the environment are highly uncertain. This uncertainty is due to the complexity of the mixtures of CP compounds, the lack of measured half-lives and uncertainties associated with their estimation (e.g. Krogseth et al. 2013).

However, on the basis of the available, albeit limited, information, the half-lives of all CPs containing up to 20 carbon atoms were estimated to be greater than two days in the atmosphere and greater than one year in sediments. Furthermore, SCCPs have been detected in air samples in the high-arctic (Alert), suggesting that SCCPs may be subject to long-range atmospheric transport. Additionally, there is both modeled and empirical data which suggests that bioaccumulation factors and biomagnification factors for CPs up to 20 carbon atoms exceeds 5000. As such, CPs containing up to 20 carbon atoms are considered to meet the criteria for persistence and for bioaccumulation, as defined under the *Persistence and Bioaccumulation Regulations under the Canadian Environmental Protection Act, 1999* (CEPA 1999)(EC and HC, 2008a).

The Persistent Organic Pollutant Review Committee of the Stockholm Convention has concluded that SCCPs fulfill the persistence and bioaccumulation criteria put forth in Annex D of the Stockholm Convention on Persistent Organic Pollutants (UNEP 2009). The EU has concluded that SCCPs meet its criteria for both persistent and bioaccumulative substance and a very persistent, very bioaccumulative substance (ECHA 2008).

A consensus analysis reported bioconcentration factors (BCFs) of MCCPs ranging from 1000 to 15000 for 2 MCCP structures and field BAFs were an order of magnitude higher than the "trigger criterion" for bioaccumulative status (Thompson and Vaughan 2014). BCFs up to 36,500 have been reported for C10 – C13 *in situ* in lake trout (POPRC). Houde et al. (2008), calculated lipid-normalized log BAFs in Lake Ontario that ranged from 4.1 to 7.0 for SCCPs, and 6.3 to 6.8 for MCCPs. In the same study, the authors calculated lipid-normalized trophic magnification factors (TMFs) for the Lake Ontario and Lake Michigan food webs. Certain SCCP isomers had a TMF >1, indicating the potential for biomagnification in food

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webs. No reliable BCF data are available for determination of a BCF for LCCPs. An estimated BCF of <2000 l/kg was put forth in a risk assessment by U.K. The Environment Agency (a public organization focused on environmental protection in England and Wales). Using this value, LCCPs are deemed unlikely to meet the UK criteria for bioaccumulative or very bioaccumulative substance (Brooke et al. 2009).

The large difference in chlorine content is primarily responsible for the large differences that are evident in measurements and estimates of the chemical and physical properties of CPs, which are present in Table 2 below (EC & HC, 2008a). **CP Class**

	Vapour pressure* (Pa)	Henry's Law Constant (Pa·m ³ /mol)	Water solubility (µg/L)	log K _{OW}	log K _{OA}	Log K _{OC}
SCCPs	2.8 × 10 ⁻⁷ - 0.028 (48 - 71% CI)	0.68 - 17.7 (48 - 56% CI)	6.4 - 2370 (48 - 71% CI)	4.39 - 8.69 (48 - 71% CI)	8.2 - 9.8 (48 - 56%CI)	4.1 - 5.44
MCCPs	4.5 × 10 ⁻⁸ - 2.27 × 10 ⁻³ (42 - 58% CI)	0.014 - 51.3 (37 - 56% CI)	9.6 × 10 ⁻² - 50 (37 - 56% CI)	5.47 - 8.21 (32 - 68% CI)	8.81 - 12.96 (32 - 68% CI)	5.0 - 6.23
C ₁₈₋₂₀ liquid LCCPs	2 × 10 ⁻⁵ - 5 × 10 ⁻⁴ (40 - 52% CI)	0.021 - 54.8 (34 - 54% CI)	0.017 - 6.1 (34 - 54% CI)	7.34 - 7.57 (34 - 54% CI) **	9.21 - 12.12 (34 - 54% CI)	-
C _{>20} liquid LCCPs	3 × 10 ⁻¹⁵ - 2.7 × 10 ⁻³ (40 - 54% CI)	0.003 (50% CI)	1.6 × 10 ⁻⁶ - 6.6 (41.9 - 50% CI)	7.46 - 12.83 (42 - 49% CI)	-	-
C _{>20} solid LCCPs	1 × 10 ⁻²³ - 3 × 10 ⁻¹⁴ (70% CI)	3.6 × 10 ⁻⁷ - 5.6 × 10 ⁻⁶ (70 - 71.3% CI)	1.6 × 10 ⁻¹¹ - 5.9 (70 - 71.3% CI)	-	-	-

* Vapour pressure values not given at a consistent temperature.

** Octanol-air partition coefficients, estimated from ratio of K_{ow}/HCL (unitless)

Table 2: Ranges of physical properties for SCCPs, MCCPs and 3 sub-classes of LCCPs. Source: EC & HC 2008a

Environmental Effects:

The available toxicity data indicate that SCCPs, MCCPs and C18-20 LCCPs may be harmful to aquatic species at low concentrations. In developing Federal Environmental Quality Guidelines for CPs, Environment Canada (2015) conducted a review of aquatic toxicity (Table 3). The aquatic toxicity data presented in Table 3 indicate a general trend of decreasing toxicity with increasing chain length of CAs. Invertebrates appear to be the most sensitive to CAs followed by fish and plants. The available data also suggest that SCCAs are more hazardous than MCCAs and LCCAs (EC 2015).

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Species	Group	Endpoint	Concentration (µg/L)	Reference
SCCAs				
Mussel (<i>Mytilus edulis</i>)	●	84d MATC (growth)	4.6*	Thompson and Shillabeer (1983)
Water Flea (<i>Daphnia magna</i>)	●	21d MATC (mortality)	6.7*	Thompson and Madeley (1983a)
Mysid shrimp (<i>Mysidopsis bahia</i>)	●	28d NOEC (growth, dev., mort)	7.3*	Thompson and Madeley (1983b)
Japanese medaka (<i>Oryzias latipes</i>)	■	20d MATC (development)	23*	Fisk et al. (1999)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	■	60d LOEC (growth)	40*	Madeley and Maddock (1983)
Algae (<i>Skeletonema costatum</i>)	▲	4d EC ₅₀ (growth)	42.3*	Thompson and Madeley (1983c)
MCCAs				
Water Flea (<i>Daphnia magna</i>)	●	21d MATC (mortality)	13.4	Thompson et al. (1997a)
Algae (<i>Selenastrum capricornutum</i>)	▲	3d NOEC (growth)	49*	Thompson et al. (1997b)
Bleak (<i>Alburnus alburnus</i>)	■	14d NOEC (mortality)	125*	Bengtsson et al. (1979)
Mussel (<i>Mytilus edulis</i>)	●	60d NOEC (mortality)	220	Madeley and Thompson (1983a)
Japanese medaka (<i>Oryzias latipes</i>)	■	20d NOEC (development)	1600	Fisk et al. (1999)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	■	60d NOEC (growth, mort.)	4500	Madeley and Maddock (1983)
LCCAs				
Water Flea	●	21d LOEC	68	Frank (1993)

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Species	Group	Endpoint	Concentration (µg/L)	Reference
SCCAs				
(<i>Daphnia magna</i>)		(reproduction, mort.)		
Mussel (<i>Mytilus edulis</i>)	●	60d NOEC (mortality)	1330	Madeley and Thompson (1983b)
Rainbow trout (<i>Oncorhynchus mykiss</i>)	■	60d NOEC (mortality)	>4000	Madeley and Maddock (1983)

Legend: ■ Fish; ● = Invertebrate; ▲ = Plant

Table 3: Toxicity endpoints for aquatic life exposed to CPs considered in the derivation of the Federal Water Quality Guideline. Source: EC, 2015

Behavioral changes and severe lesions on the livers of juvenile lake trout were noted following dietary exposure to high concentrations of CPs (C10- 14) (Cooley et al. 2001). In that study, concentrations in whole fish were in the same range as concentrations measured in wild fish, but the dietary exposures were likely much higher than would occur in the environment. The authors also noted a general trend of decreasing toxicity with increasing carbon-chain length of CPs.

LCCPs do not appear to be as toxic to aquatic life as SCCPs and MCCPs; however, toxicity data for LCCPs is rather limited. A handful of laboratory studies (between 1976 and 1983) examined the effects of aqueous exposure of fish to LCCPs. No effects were seen at solubility in any of the studies. There are a few studies that examined aquatic toxicity of LCCPs to *Daphnia magna*. The study with the lowest toxicity value indicated a chronic NOEC of 0.029 mg/L (EUC 2005) and chronic LOEC of 0.068 mg/L (EC 2015). Given the low solubility of LCCPs, exposure to LCCPs in water is not likely to be the most important route of exposure to aquatic life. Sediments are likely to be the most relevant environmental compartment for LCCPs. Studies of toxicity to benthic invertebrates are lacking.

Human Health Effects:

CPs have been measured in human liver, kidney, adipose tissue and breast milk (UNEP 2009). Although adequate information related to humans is not available, toxicokinetic studies in experimental animals indicate that distribution of CPs is expected to occur mainly in the liver, kidney, intestine, bone marrow, adipose tissue, and ovaries (IPCS 1996). In addition, CPs may cross the blood-placental barrier. Elimination of CPs shows an inverse relationship to chlorine content, that is, CPs with greater degrees of chlorination are not excreted as readily as CPs that are less chlorinated (IPCS 1996).

The U.S. National Toxicology Program reviewed the toxicity of CPs (C12, 60% chlorine). They found that acute toxicity of SCCPs (C10-13) is very low: SCCPs may cause skin and eye irritation upon repeated application, but do not appear to induce skin sensitization.

There is no experimental evidence using human data that demonstrates the carcinogenicity of SCCPs. In the 13th Report on Carcinogens, NCI lists CPs (C12, 60 percent chlorine) as reasonably anticipated to be human carcinogens based on sufficient evidence of carcinogenicity in experimental animals. They are

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classified by the IARC as Group 2B - possibly carcinogenic to humans based on sufficient evidence of carcinogenicity in experimental animals and mechanistic considerations.

No fertility or developmental effects data are available for humans. Developmental effects were observed in rats dosed at 2000 mg/kg/day (UNEP 2009).

A recent compilation of toxicity data indicates the acute toxicity of MCCPs to humans is low and that they are not likely to be genotoxic.

Additional or Other Factors to Consider:

SCCPs and MCCPs have undergone detailed risk assessments (ECD 2000, ECB 2005, ECB 2008), including two risk assessments conducted by the Government of Canada in 1993 and 2008 (EC & HC 1993; EC & HC 2008a). In addition, El-Sayed and Legler (2010) summarized mammalian and environmental toxicity of CPs.

CPs were assessed under CEPA 1999, including SCCPs (containing 10 to 13 carbons), MCCPs (containing 14 to 17 carbons and LCCPs (containing 18 to 20 carbons) (EC & HC 2008a). The assessment concluded that:

- SCCPs, MCCPs and LCCPs are 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, and thus meet the definition of “toxic” under paragraph 64(a) of CEPA 1999; and
- SCCPs and MCCPs are entering or may be entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health, and thus meet the definition of “toxic” under paragraph 64(c) of CEPA 1999);

Some CPs appear to have similar physicochemical properties to other chemicals of concern, such as toxaphene and PCBs (Muir et al. 2000).

Several reports include CPs among their evaluation of chemicals of emerging concern in the Great Lakes region (Eyles et al., 2011; IJC 2009; Klaper and Welch, 2011). CPs are identified as an “emerging contaminant threat” to the Great Lakes in a report by the Alliance for the Great Lakes (Klaper and Welch, 2011). Houde et al. (2008) expressed the need for additional evaluation of CPs: “Given the prominence of CPs, particularly in lake waters and in lower food web organisms, further investigation is needed to evaluate the magnitude of their distribution and accumulation/magnification in the Great Lakes environment.” CELA and Lowell Center report to IJC: “The lack of early action to reduce short chain CPs based on the initial assessment has contributed to CPs being detected in the Great Lakes today. Similarly, the prohibitions which will include exemptions and not address imported products that may contain CPs will contribute to the continued release of CPs to the aquatic environment.”

Environmental and Human Health Benchmarks Guidelines:

Environment Canada (2015) has developed draft Federal Environmental Quality Guidelines for CPs in various environmental media (Table 4).

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Homologue	Water (µg/L)	Fish Tissue (µg/g lipid)	Sediment* (mg/kg dw)	Mammalian Wildlife Diet (mg/kg food ww)
SCCPs	2.4	2.7	1.8	18
MCCPs	2.4	0.76	5.4	0.54
LCCPs	2.4	–	100 ^a	18 ^b , 770 ^c
SCCPs = short chain chlorinated paraffins (C ₁₀₋₁₃) MCCPs = medium chain chlorinated paraffins (C ₁₄₋₁₇) LCCPs = long chain chlorinated paraffins (C _{≥18}) *values normalized to 1% organic carbon ^a C ₁₈₋₂₀ liquid; ^b C _{>20} liquid; ^c C _{>20} solid dw = dry weight; ww = wet weight				

Table 4: Draft Canadian Federal Environmental Quality Guidelines for CPs. Source: EC, 2015

Great Lakes Monitoring and Surveillance Data:

CPs occur in complex mixtures that are very difficult to analyze in environmental matrices. There are an enormous number of possible homologues with varying carbon-chain lengths and chlorination patterns. Authentic surrogate standards that capture the vast range of potential CPs occurring within any given mixture do not exist. Furthermore, PCBs can sometimes be mistaken for CPs in environmental samples if care is not taken to identify chromatographic patterns associated with CPs. Data are often reported from analytical laboratories as “maximum estimated” concentrations.

SCCPs and MCCPs have been analyzed in Great Lakes prey fish, predator fish, invertebrates, plankton, sediment, water and air. Table 4 summarizes Great Lakes CPs concentration data. Given the problematic nature of CP analysis in different laboratories as discussed above, care must be taken when making comparisons. However, the following generalizations are suggested from the values in Table 3.

- Lake Ontario had the greatest diversity of sampling media. Quite a few samples were taken in Lake Michigan as well. There was only sediment sampling in Lake Erie and Lake St. Clair. There are no CP data from Lake Huron. The only data relevant to Lake Superior are for fish collected in a small lake on Isle Royale.
- One placeholder has been left in Table 3. The Annex 3 committee should track this study to add to the knowledge base of CP concentrations in the Great Lakes basin.
- In the same sample, SCCP concentrations are typically higher than MCCPs. There are some exceptions. In the 16 summary results in Table 3 where both SCCPs and MCCPs were analyzed, Houde et al. (2008) found MCCP exceeded SCCP in alewife, sculpin and rainbow smelt. Ranges for some other results suggest there could be other samples where MCCPs exceed SCCPs.

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Ismail et al. (2009) reported concentrations of Σ SCCP and Σ MCCP in archived samples of lake trout from Lake Ontario collected from 1979 to 2004. They found an increasing but non-significant trend from 1979 to 1988 followed by a significant decrease until 2004 (Figure 3). They calculated a half-life for the decrease of 6 years ($p < 0.001$).

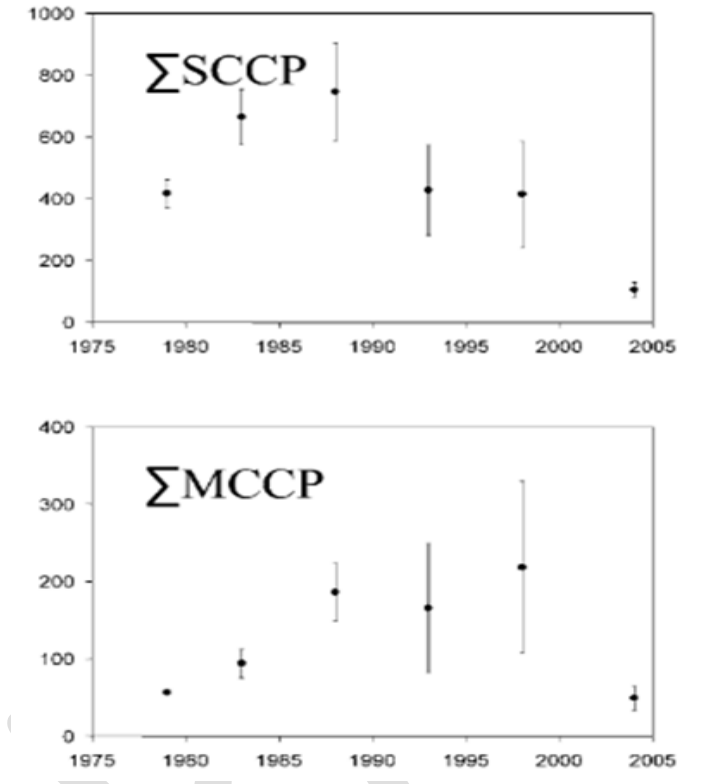


Figure 1: SCCP and MCCP (ng/g wet lipid) measured in archived samples of Lake Trout from Lake Ontario. Source: Ismail et al. (2009).

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Sampling Medium	Location	SCCP Concentration	MCCP Concentration	Unit	N	Other Info	Reference
air	Egbert, ON	65 to 924		pg/m ³		1990	Tomy 1997; Tomy et. al. 1998a
air	over Lake Ontario	120 to 1,510		pg/m ³		1990 and 1999	Muir et al. 2001
alewife	Northern Lake Michigan	37	5.6	ng/g whole organisms	2		Houde et al. (2008)
alewife	Western Lake Ontario	4.6	35	ng/g whole organisms	2		Houde et al. (2008)
catfish	Detroit River		0.904	mg/kg wet wt			Tomy and Stern 1999
Diporeia	Northern Lake Michigan	24 ± 19	nd	ng/g whole organisms	3		Houde et al. (2008)
Diporeia	Western Lake Ontario	5.9 ± 5.5	4.2 ± 7	ng/g whole organisms	3		Houde et al. (2008)
lake trout	Northern Lake Michigan	123 ± 35	5.6 ± 4.8	ng/g whole organisms	7		Houde et al. (2008)
lake trout	Western Lake Ontario	34 ± 37	24 ± 26	ng/g whole organisms	7		Houde et al. (2008)
lake trout	Lake Ontario	107 ± 23 to 748 ± 158 (17 ± 3 to 91 ± 18)	50 ± 16 to 187 ± 37 (7.9 ± 2 to 34 ± 15)	ng/g lipid (ng/g ww)		part of a study of archived fish tissue 1979-2004	Ismail et al. (2009)
lake trout	Great Lakes	not available	not available			placeholder until data are available	Saborido-Basconcillo (Sverko, Muir, Backus coauthors)
Mysis	Northern Lake Michigan	7.5 ± 3.9	nd	ng/g whole organisms	3		Houde et al. (2008)
Mysis	Western Lake Ontario	2.4 ± 3.3	nd	ng/g whole organisms	3		Houde et al. (2008)
northern pike	Richie Lake - Isle Royale (in Lake Superior)	nd – 2.78	nd – 5.0	µg/g lipid (filet)	10	2011 (unpublished data)	Streets, S.
plankton	Northern Lake Michigan	23 ± 16	nd	ng/g whole organisms	3		Houde et al. (2008)
plankton	Western Lake Ontario	1.02 ± 0.33	nd	ng/g whole organisms	3		Houde et al. (2008)
rainbow smelt	Western Lake Ontario	19	109	ng/g whole organisms	2		Houde et al. (2008)
sculpin	Northern Lake Michigan	69	2.9	ng/g whole organisms	2		Houde et al. (2008)
sculpin	Western Lake Ontario	25	108	ng/g whole organisms	2		Houde et al. (2008)

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sediment	Lake Ontario	0.049		mg/kg dry wt	26	average	Tomy et al. 1999; Stern and Evans 2003
sediment	Western Lake Erie		0.068	mg/kg dry wt			Tomy and Stern 1999
sediment	Lake St. Clair	50.8 - 935 (med = 158)	<dl - 767 (med = 14.1)	ng/g dry weight	34	2001	Gewurtz et al. 2007
surface water	Western Lake Ontario	1190 ± 430	0.9 ± 1.2	pg/L	10		Houde et al. (2008)
surface water	Western Lake Ontario	606-1935		pg/L		2000-2004	Muir et al. 2001, Houde et al. 2006
surface water	Lake Ontario		<0.5 - 2.6	pg/L		2002 and 2004, filtered	Houde et al. 2006

Table 5: SCCP and MCCP concentrations from various environmental media in the Great Lakes.

Under the Canadian national Chemicals Management Plan, a screening of SCCPs and MCCPs in fish from nine water bodies across Canada was conducted in 2010-2011 (EC 2014). These results were compared to those previously described by Houde et al. in 2008 (see Table 5). The results indicated that for lake trout in Lake Ontario, concentrations of SCCPs were significantly lower in 2011 than 2001. While the concentrations of MCCPs were also lower in 2011 than 2001, the differences were not significant. These trends are consistent with those reported by Ismail et al. (2009).

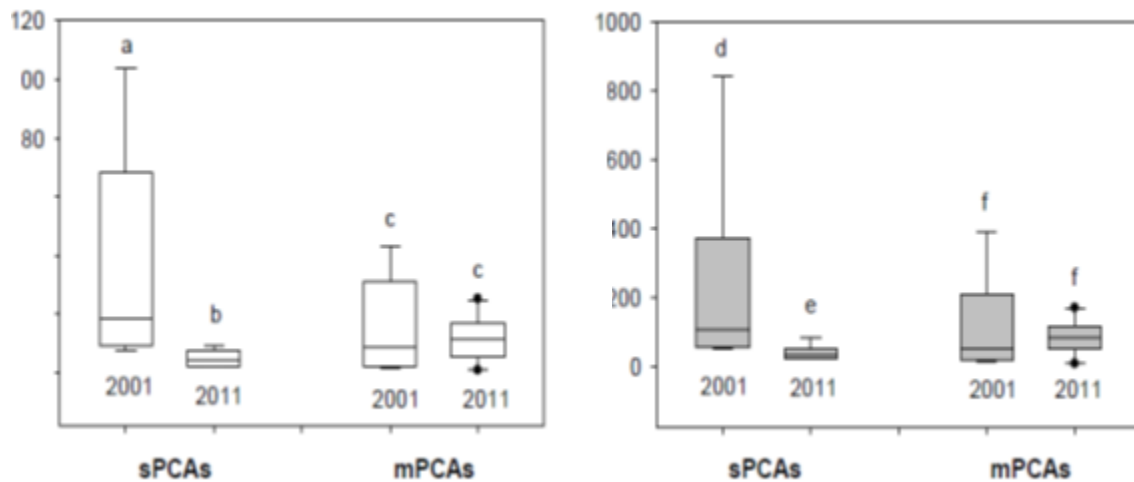


Figure 2: Concentrations of SCCPs (sPCAs) and MCCPs (mPCAs) in lake trout from Lake Ontario in ng/g wet weight (left) and ng/g lipid (right). Source: EC, 2014

Marvin et al. (2003) measured SCCP in Lake Ontario sediments. They reported an average SCCP sediment concentration of 49 ng/g (dry weight) which exceeded that of Σ DDT of 32 ng/g. The highest concentrations were measured in the western Niagara basin at 410 ng/g (Figure 5). They calculated an accumulation rate of $170 \mu\text{g}/\text{m}^2 \text{ y}$ and postulated that the source was local industry discharges. Concentrations were highest in the mid-1970s and have decreased since (Figure 6). In comparison, the estimated accumulation rate was $8.0 \mu\text{g}/\text{m}^2 \text{ y}$ from a core taken in the centre of the lake.



Figure 3: Spatial distribution of SCCPs (ng/g dry weight) in Lake Ontario surficial sediments. Source: Marvin et al. (2003).

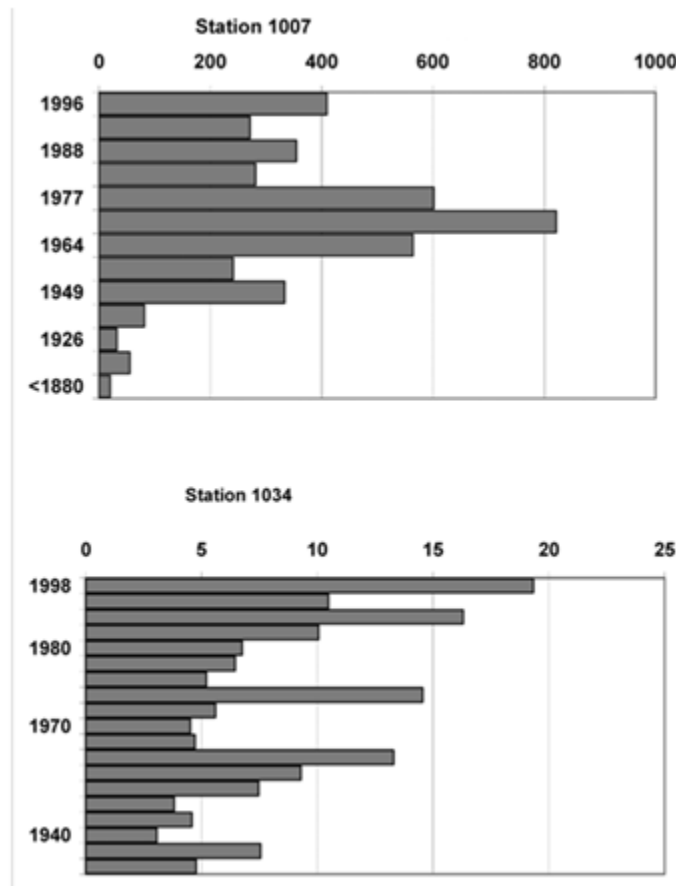


Figure 4: Concentration profiles of SCCPs in dated sediment cores (ng/g dry weight) from the Niagara Basin (Station 1007) and Mississauga Basin (Station 1034) of Lake Ontario. Source: Marvin et al. (2003).

Conclusions:

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In summary, with respect to SCCPs and MCCPs, there is some, albeit limited, data to suggest that SCCP concentrations in top-predator fish from Lake Ontario are generally below draft environmental quality guidelines, and that concentrations in these fish have recently (post 2005) begun to decline. For MCCPs there is some data available to suggest declines; however, these are not significant. Fish data from the other Great Lakes was not readily available and some exceedances compared to the still draft Canadian Federal Environmental Quality Guideline were identified in Lake Michigan and Isle Royale. The concentrations of SCCPs and MCCPs in sediment have not yet begun to show similar declines.

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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:

Final Screening Risk Assessment Report Conclusions:

CPs were included on the first Priority Substances List (PSL) program under the 1988 *Canadian Environmental Protection Act* for assessment of potential risks to the environment and human health. In 1993, Environment Canada and Health Canada published an assessment report that concluded short-chain CPs constitute or may constitute a danger to human health or life as set out in the Act (EC & HC 1993).

On August 30, 2008, a notice summarizing the scientific considerations of a final follow-up assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I for chlorinated alkanes (EC & HC, 2008a). The final follow-up assessment report concluded that:

- All CPs (C10 – C38) are entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health, and thus meet the definition of “toxic” under paragraph 64(c) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999); and
- CPs containing up to 20 carbon atoms are 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, and thus meet the definition of “toxic” under paragraph 64(a) of CEPA 1999;

Furthermore, the follow-up assessment also concluded that CPs containing up to 20 carbon atoms are predominantly anthropogenic, and the available data regarding their persistence and bioaccumulation potential indicate that they satisfy the criteria outlined in the *Persistence and Bioaccumulation Regulations*, made under CEPA 1999.

Risk Management Objective and Actions:

The Government of Canada human health objective for the management of CPs is to minimize human exposure to the extent practicable. The environmental objective for CPs up to 20 carbon atoms is virtual elimination, as specified under subsection 77(4) of CEPA, 1999.

Risk management action has been initiated in Canada for CPs containing 10 to 13 carbon atoms (SCCPs). SCCPs, which are no longer in commerce, have been added to the *Prohibition of Certain Toxic Substances Regulations, 2012* (the Regulations).

The Regulations were published in the *Canada Gazette*, Part II, on January 2, 2013 under CEPA 1999 and came into force on March 14, 2013. The Regulations prohibit the manufacture, use, sale, offer for sale or import of SCCPs and products containing them with a limited number of exemptions. The Regulations

DRAFT DOCUMENT OF THE IDENTIFICATION TASK TEAM

also have reporting requirements for the manufacture or import of incidentally present SCCPs contained in a toxic substance or a product.

Presently, the Government of Canada is considering options to control releases to the environment of CPs containing 14 – 20 carbon atoms.

Draft Canadian Federal Environmental Quality Guidelines have been developed for CPs for various environmental media including water, fish tissue, sediment, and mammalian wildlife diet (Table 2) (Environment Canada 2015).

U.S. Federal Risk Management Activities:

In 2009, the US EPA published a chemical action plan for SCCPs. In conducting its review of these chemicals, EPA determined that some of the specific SCCPs, MCCPs, and LCCPs currently being manufactured and/or used in the United States are not on the TSCA Inventory. Any substance that is not on the TSCA Inventory is classified as a new chemical. Prior to manufacture or import of a new chemical for general commercial use, a notice must be filed with EPA under TSCA section 5.

EPA intends to address the discrepancy between the specific CP companies are actually manufacturing or importing and those listed on the TSCA Inventory. EPA intends to require companies to submit Pre-Manufacture Notices for the SCCP, MCCP, and LCCP fractions that are not on the TSCA Inventory and, if appropriate, would initiate action under TSCA section 5 to address their potential risks.

February 8, 2012: EPA announced a federal enforcement action requiring Dover Chemical to pay \$1.4 million and to cease manufacturing short-chain chlorinated paraffins (SCCPs), and to submit pre-manufacture notices under TSCA section 5 to EPA for various MCCPs and LCCPs, which also are persistent and bioaccumulative. Dover has the last remaining domestic CP manufacturing facilities.

August 22, 2012: EPA announced a settlement with INEOS Chlor Americas, Inc., requiring INEOS to pay \$175,000 and end the importation of SCCPs into the United States, and to submit pre-manufacture notices under TSCA section 5 for any MCCPs or LCCPs it wishes to import.

December 17, 2014: EPA issued a Significant New Use Rule (SNUR) under the Toxic Substances Control Act (TSCA) for Alkanes C 12-13, chloro, a SCCP. This SNUR requires manufacturers (including importers) and processors of this SCCP to notify EPA at least a 90 days before starting or resuming new uses of this chemical. This notification allows EPA the opportunity to evaluate the intended uses and, if necessary, to prohibit or limit that activity.

MCCPs and LCCPs and their use as metal working and compounding agents and its effect on ecological receptors are included for assessment as part of US EPA's TSCA Work Plan. The Agency has not yet completed its assessment. Such information may be relevant in the future as to whether or not the substances and particular uses pose a risk so as to inform future management activities.

Provincial, State and Other Actions:

The Minnesota Pollution Control Agency (MPCA) is currently conducting a statewide study of environmental concentrations of CPs in fish, surface water, groundwater and sediment as well as concentrations in wastewater effluents. Sample collection will be complete by June 2015. The MPCA also intends to develop Aquatic Life Screening Values for CPs in order to characterize the results of monitoring.

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SCPPs are listed amongst the 16 initial substances of very high concern under REACH. The European Union restricted the concentration of SCPPs in metal working and leather fat liquoring preparations to <1% in 2004 (ECHA 2008a, cited in <https://ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=D048964A-1>).

Identification of Gaps in Management and/or Science Activities:

(1) Are environmental levels below applicable benchmarks and are there any discernable environmental trends?

Data from Lake Ontario lake trout 2001 – 2011 suggest that recent concentrations of SCCPs are showing a decreasing trend and that concentrations of MCCPs may also be showing slight decreasing trend, although not significant. Data were generally not available for the other Great Lakes. A review of concentrations in fish from Lake Michigan and Isle Royale show some potential exceedances of what is still a draft Canadian Federal Environmental Quality Guideline. New data from the Minnesota Pollution Control Agency should be available shortly and is expected to indicate exceedances of relevant benchmarks in Lake Superior, but was not available at time of decision making.

The limited data available suggest that concentrations of SCCPs and MCCPs in sediment from Lake Ontario have not yet begun to show similar declines. Furthermore, there is data available to suggest that US tributaries could be a significant source of contaminated sediment due to ongoing industrial uses.

There is extremely limited data available for LCCPs, with nothing specific to the Great Lakes identified. Uncertainties in evaluating the status of CPs in the Great Lakes are compounded by major difficulties with their reliable measurement, which is particularly true for the LCCPs. Further, our understanding of their toxicity is somewhat limited.

(2) Is the GLB-relevant human health exposure being adequately addressed?

No human biomonitoring data was reviewed and fish consumption restrictions due to CPs were not identified.

(3) Are applicable/available objectives for the substances being met?

It is reasonable to expect that Canada's mandated federal goal for CPs of Virtual Elimination, as per CEPA 1999, has not yet been achieved, as presently MCCPs and LCCPs are not risk managed. Furthermore, the compliance with / performance of the Canadian prohibition of SCCPs has yet to be assessed.

In the US, work is progressing towards implementing the 2012 TSCA Workplan, along with related risk management actions.

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

There is some evidence to indicate that progress has recently been made towards reducing the levels of SCCPs and MCCPs in some media of the Great Lakes environment. More data is needed to confirm long-term trends and confirm whether some of the recent observed declines will continue over the long term, especially when considering the present lack of risk management actions for SCCPs in the US and for MCCPs and LCCPs in both Canada and the US.

DRAFT DOCUMENT OF THE IDENTIFICATION TASK TEAM

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

While there is some very limited evidence to indicate that progress is being made for SCCPs and MCCPs (described in previous question) there are forthcoming federal actions anticipated (as described in Section 4) for SCCPs MCCPs and LCCPs which could further reduce emissions to and levels within the Great Lakes basin.

(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:

Noting that actions and regulations to address CPs are forthcoming in Canada and the US, as described previously in this document, these actions remain to be implemented and until such a time that they enter into force, this should be considered a gap in risk management.

Furthermore, research should be considered which evaluates whether existing and forthcoming activities sufficiently address the issue posed by CPs in imported products, given rapid growth in production observed in the international market.

There is a need to continue targeted monitoring in fish species (including top-predator species as well as others with a significant benthic component in their diet) across the Great Lakes, including in the nearshore environment, in order to confirm if recent trends continue to show decreases for SCCPs and definitely establish whether a downward trend exists for MCCPs.

Targeted sediment monitoring should be continued to establish trends and evaluate loadings of these chemicals to the lakes, including in the near shore environment and tributaries,. This monitoring work will provide some of the information necessary to evaluate the performance of existing and forthcoming risk management and control activities.

Given that recent evidence suggests that SCCPs are subject to atmospheric transport and deposition, air concentrations should be measured in the Great Lakes in order to assess atmospheric loadings from in basin and out of basin sources.

Finally, research should be supported to improve methods of measurement for LCCPs, such that the availability and reliability of monitoring and surveillance data is improved.

5. Final Recommendation:

With respect to CPs, including SCCPs (C10-C13), MCCPs (C14-C17) and LCCPs (\geq C18), the ITT has concluded that there is insufficient data and/or information available to effectively apply the *Binational Considerations*. Therefore, **the ITT has recommended that CPs be identified as insufficient information on which to base a determination.** With respect to SCCPs and MCCPs, the decision was by 2/3 majority and with respect to LCCPs, the decision was unanimous.

While consensus was reached for SCCPs and MCCPs, there were minor dissenting views. Given the information available and considering existing and forthcoming management actions:

- Some members felt that SCCPs should be designated as a Chemical of Mutual Concern, while others felt that they should be designated as Not a Chemical of Mutual Concern;
- Some members felt that MCCPs should be designated as a Chemical of Mutual Concern.

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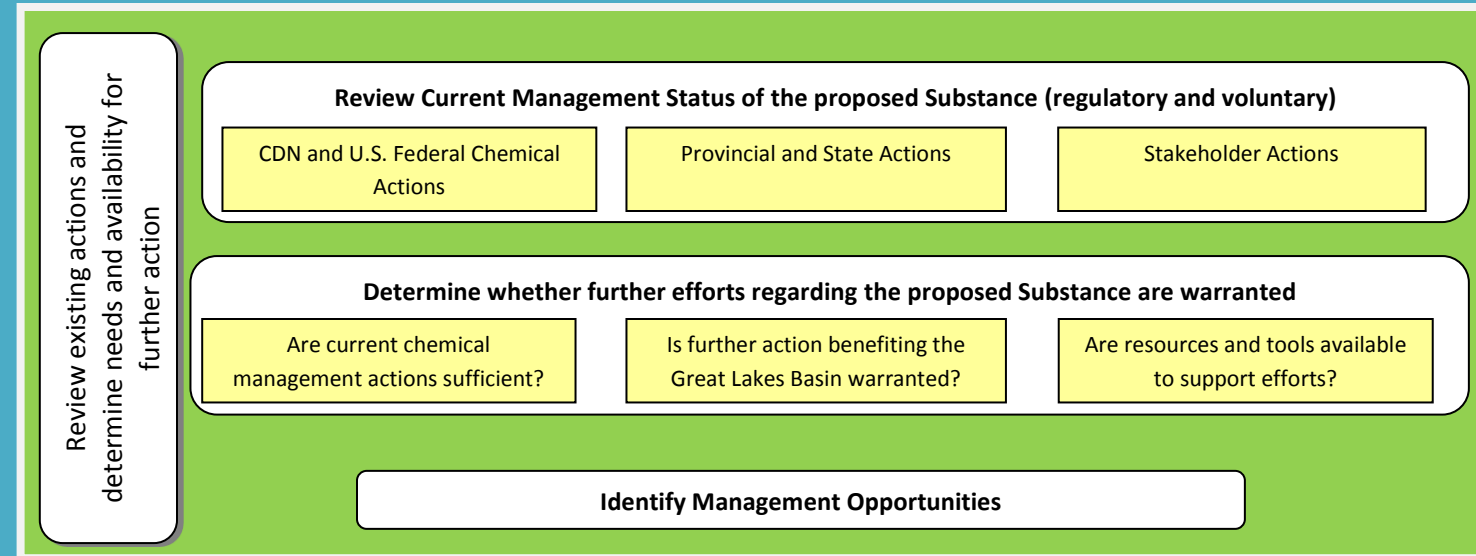
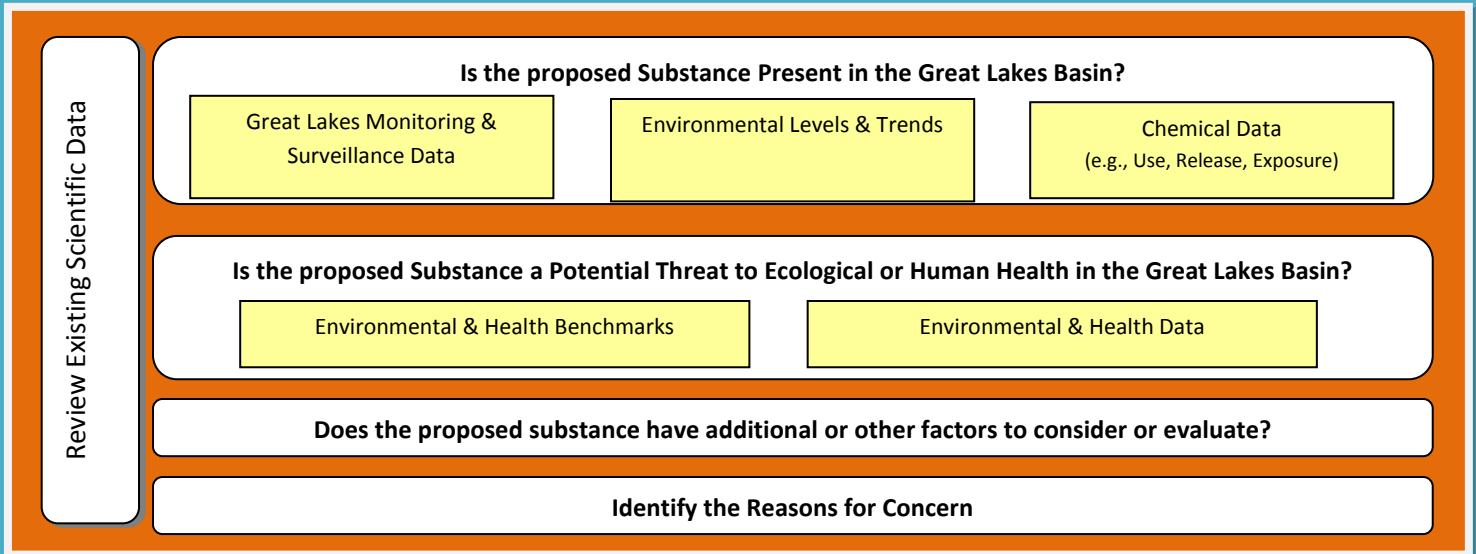
Appendix A:
Binational Considerations When Evaluating Candidate
Chemicals of Mutual Concern

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Proposed
Canadian and
U.S. Chemicals

BINATIONAL CONSIDERATIONS FOR IDENTIFYING CANDIDATE CHEMICALS OF MUTUAL CONCERN IN THE GREAT LAKES BASIN (Box 4. from the *Annual Process for Recommending CMCs* Flowchart)



Recommended as a Candidate Chemical of Mutual Concern

Not Recommended as a Candidate Chemical of Mutual Concern

Insufficient Information on which to base a Determination

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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