

# CHLORINATED PARAFFINS INDUSTRY ASSOCIATION

---

---

1250 Connecticut Avenue, NW • Suite 700 • Washington, DC 20036 • Phone: 202-419-1500

March 23, 2016

Maria Doa  
Office of Pollution Prevention and Toxics (OPPT)  
Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460 - 0001

**RE: EPA Risk Assessments on Medium-Chain Chlorinated Paraffin and Long-Chain Chlorinated Paraffin; EPA-HQ-OPPT-2015-0789**

Dear Dr. Doa:

The Chlorinated Paraffins Industry Association (CPIA)<sup>1</sup>, is pleased to provide these comments in response to the Environmental Protection Agency's (EPA) request<sup>2</sup> for comments and information on risk assessments ("Risk Assessments") for several medium-chain chlorinated paraffins (MCCPs) and long-chain chlorinated paraffins (LCCPs). CPIA members include the companies that submitted the premanufacture notices (PMNs) related to these substances. In addition to these comments, CPIA also fully supports the comments submitted by the coalition of impacted trade associations ("Coalition"), in which CPIA is a participant. CPIA and the Coalition have identified significant concerns with EPA's assessment of these chemicals and also with the process under which EPA is attempting to review and regulate these substances. These concerns are especially significant given EPA's statement that U.S. manufacture and import of these chemicals should cease.

CPIA has previously provided comments and input to EPA in its review of chlorinated paraffins (CPs), including those substances that are the subject of this notice. These submissions are the following, which are included as attachments to these comments:

- January 2015: Letter to EPA on the Draft MCCP and LCCP Risk Assessments (Attachment A)
- March 2015: Existing Evaluations of LCCP/vLCCP Category Assessments for U.S. EPA Review of PMN Submissions Review of LCCP (Attachment B)
- May 2015: Evaluation of Environmental Release and Environmental Assessment of Medium Chain Chlorinated Paraffins (C<sub>14</sub>-C<sub>17</sub>) and Long Chain Chlorinated Paraffins (C<sub>18</sub>-C<sub>20</sub>) (Attachment C)

---

<sup>1</sup> CPIA is a nonprofit corporation whose purposes includes the sponsoring and conducting of programs to expand the knowledge of health, safety and environmental data regarding the manufacture, processing, distribution, use and disposal of chlorinated paraffins. CPIA members include Dover Chemical, Inovyn, and Qualice LLC.

<sup>2</sup> 80 Fed. Reg. 79886 (Dec. 23, 2015).

While these current Risk Assessments have been conducted under the PMN program, fundamentally these are not new chemicals. MCCPs and LCCPs have been used for decades and have well established practices for their use with regard to controlling exposures and releases as discussed in both the Coalition comments and those submitted by various associations that represent downstream users. Given the important roles that these chemicals have in commerce as detailed in these numerous submissions, CPIA continues to believe that its previous request (Attachment A) that EPA conduct a full assessment under the TSCA Work Plan Chemicals program with public comment and peer review is absolutely essential for appropriate regulation of these chemicals. Further, as detailed below, there are clearly aspects of both the exposure and risk assessments that would benefit from additional review and revisions.

Given the long-term and continuous use of these materials EPA does not need to rely solely upon models to predict levels in the environment; there are extensive measured data that allow for the assessment of the levels of these chemicals in the environment. CPIA previously submitted an expert review of the environmental monitoring data on MCCP in water and sediment (Attachment C) that showed levels are generally under EPA's concentrations of concern (COCs). In this submission, CPIA is providing additional data recently obtained from Environment Canada that includes an extensive review of MCCP levels in top predator fish in the Great Lakes. These data are of particular relevance to the Risk Assessments as they demonstrate that levels of MCCP in the top of the food-chain are quite low and appear to be decreasing over time even as MCCP manufacture and use continues. Further, these data provide an updated resource for evaluating the potential for MCCP exposure via the consumption of fish.

CPIA and its members have a long commitment to product stewardship on these chemical substances. The predecessor of CPIA, the CP Consortium, conducted significant toxicology, ecotoxicology and environmental fate testing on a range of CPs under a voluntary testing program<sup>3</sup> for EPA in the 1980's. These data were utilized in both EPA's RM1/RM2 reviews in the 1980's and 1990's and in these recent PMN reviews. In addition, some CPIA members have conducted extensive additional environmental fate research in Europe under the auspices of EuroChor. In total the industry has conducted more than 100 health and environmental studies over the past 30+ years at a cost of millions of dollars. CPIA supports the development of new data in order to address any remaining uncertainties in EPA's assessments of MCCPs and LCCPs though, as discussed below, we have concerns with key aspects of the testing program proposed by EPA. Alternatively, targeted environmental monitoring data could generate real world environmental data on MCCPs and LCCPs that could more directly address any lingering uncertainties in EPA's Risk Assessments.

An overlooked aspect in these assessments is the value that MCCPs and LCCPs provide to U.S. manufacturing, worker and consumer safety, and even to the environment in terms of greenhouse gas emissions reductions. These chemicals are essential to a wide array of industries as documented in the various submissions by the Adhesive and Sealants Council, American Chemistry Council, the American Wire Producers Association, the Independent Lubricant

---

<sup>3</sup> Chlorinated Paraffins; Response to the Interagency Testing Committee. 47 Federal Register 1017; January 8, 1982.

CPIA Submission to  
EPA-HQ-OPPT-2015-0789  
March 23, 2015  
Page 3

Manufacturers Association, the Industrial Fasteners Institute, and the Vinyl Institute, among others. Certainly the extensive interest in EPA's assessment and regulation of these chemicals by the Coalition, numerous manufacturing representatives, and even the Department of Defense, demonstrates the importance of the chemicals and the need for the Agency to develop a regulatory approach that considers all relevant data.

EPA has regulatory options for managing these substances beyond seeking to prohibit the manufacture and import under the PMN review process. These options, which are covered in detail in the Coalition comments, are legitimate and workable alternatives to EPA's current process.

These above points are expanded in our comments below. Should you have any questions or require clarification of these comments, please contact me at [ajagues@regnet.com](mailto:ajagues@regnet.com) or (202) 419-1504.

Best Regards,

A handwritten signature in black ink that reads "Andrew M. Jaques". The signature is written in a cursive, flowing style.

Andrew M. Jaques,  
CPIA Executive Director

**Chlorinated Paraffins Industry Association**  
**Submission to Environmental Protection Agency on the Review of Medium-Chain**  
**Chlorinated Paraffins (MCCP) and Long-Chain Chlorinated Paraffins (LCCP):**  
**EPA-HQ-OPPT-2015-0789**  
**March 23, 2016**

The Chlorinated Paraffins Industry Association (CPIA) is making this submission to provide additional information and comments on the Environmental Protection Agency's (EPA) review of seven premanufacture notices (PMNs) for medium-chain chlorinated paraffins (MCCPs) and long-chain chlorinated paraffins (LCCPs) as follows:

MCCPs:

P-12-0282	Alkanes, C <sub>14-16</sub> , chloro
P-12-0283	Tetradecane, chloro [C <sub>14</sub> ]
P-12-0453	Alkanes, C <sub>14-17</sub> , chloro (40-60 weight % chlorine)
P-14-0683	Tetradecane, chloro [C <sub>14</sub> ]
P-14-0684	Alkanes, C <sub>14-16</sub> , chloro

LCCPs:

P-12-0284	Octadecane, chloro [C <sub>18</sub> ]
P-12-0433	Alkanes, C <sub>18-20</sub> , chloro (40-55 weight % chlorine)

EPA's review of these PMN substances have been presented in a series of three closely related Risk Assessments ("Risk Assessments") and supplemental materials to the Risk Assessments. Information and comments provided in this submission are generally equally applicable to all of these Risk Assessments. Beyond these PMNs, the Risk Assessments may also impact other chlorinated paraffin (CP) PMNs still under review including those that contain C<sub>18-20</sub> as minor constituents in a predominantly C<sub>>20</sub> chlorinated paraffin substance.

CPIA has provided previous submissions to EPA on various CP substances and these are included as Attachments A to C. We have not restated all of this information below, though CPIA would like to emphasize that this information should also be considered as EPA reviews the current submissions from CPIA and other commenters, including the Coalition of impacted trade associations.

Concerns with Assessment of Environmental Exposure, Fate, and Toxicity

CPIA will not restate all of the extensive comments provided in the Coalition comments on EPA's assessment of the environmental fate and toxicity of MCCPs and LCCPs, though we do believe it is important to emphasize the following:

- The Risk Assessments present a wide range of results for environmental fate endpoints. The current presentation of the information in the Risk Assessments makes it impossible to ascertain which data are used to support EPA's conclusions on persistence and bioaccumulation.

- It is not possible to determine where EPA believes there are data gaps and uncertainties in the Risk Assessments and how the proposed testing program will address those data gaps and uncertainties.
- Recent data and reviews, including sources cited in the Risk Assessments, establish that:
  - MCCPs under 50% chlorination are readily biodegradable based on test data;
  - MCCPs up to 51% chlorination are inherently biodegradable based on test data;
  - MCCP field biomagnification and trophic magnification data show a clear pattern of MCCPs not bioaccumulating in the environmental food web;
  - LCCPs are not toxic to aquatic organisms at or below their upper water solubility limit;
  - LCCPs are not predicted to be bioaccumulative using EPA models;
  - LCCPs were determined to be “unlikely to meet the B or vB (very bioaccumulative) criteria” by the U.K. Environment Agency in a 2009 report cited extensively in the Risk Assessments.
- Existing environmental monitoring data indicate levels of MCCPs in the environment are low, below the Concentrations of Concern (COCs), in U.S. and Canada even after decades of continuous manufacture and use.

### Environmental Monitoring Data

Environmental monitoring data present an opportunity for the assessment of MCCPs and LCCPs in the environment that is not typically possible with PMN assessments. Observing actual levels of these chemicals in the environment, which captures all current and past sources of release for a given location or organism, provides a data source that cannot be duplicated by modeling. In addition, environmental monitoring data can provide an important source of comparison and validation to modeled environmental levels. The vast majority of existing CP environmental monitoring data is on short-chain chlorinated paraffins (SCCPs) and MCCPs, though given recent improvements in analytical techniques it appears collecting environmental monitoring data on LCCPs is feasible.

CPIA has previously provided EPA with a detailed review of the monitoring data on water and sediment (Attachment C), which is also presented in the Coalition comments. The key conclusion from this review is that exceedances of the EPA COCs for surface water or sediment do not appear to be occurring in the U.S. and, while there are limits in geographical and temporal coverage of the samples, EPA’s conclusion of frequent or likely exceedances of the COCs is not supported by the available data.

### Additional Sediment Monitoring Data

CPIA has recently identified an additional sediment monitoring study not previously considered by EPA in the Risk Assessments. This study by Gewurtz et al. (2007) evaluated 34 sediment sampling locations in the St. Clair Lake, between Michigan and Ontario (see Figure 1 below).

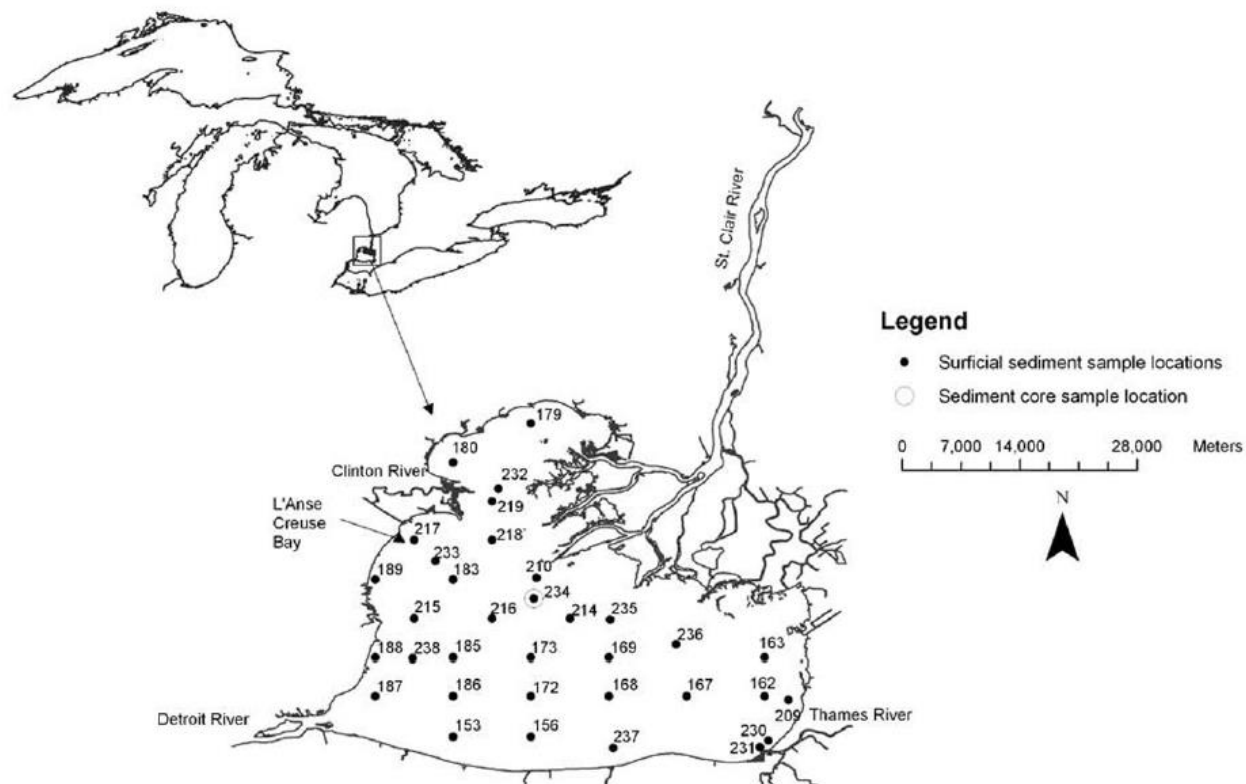


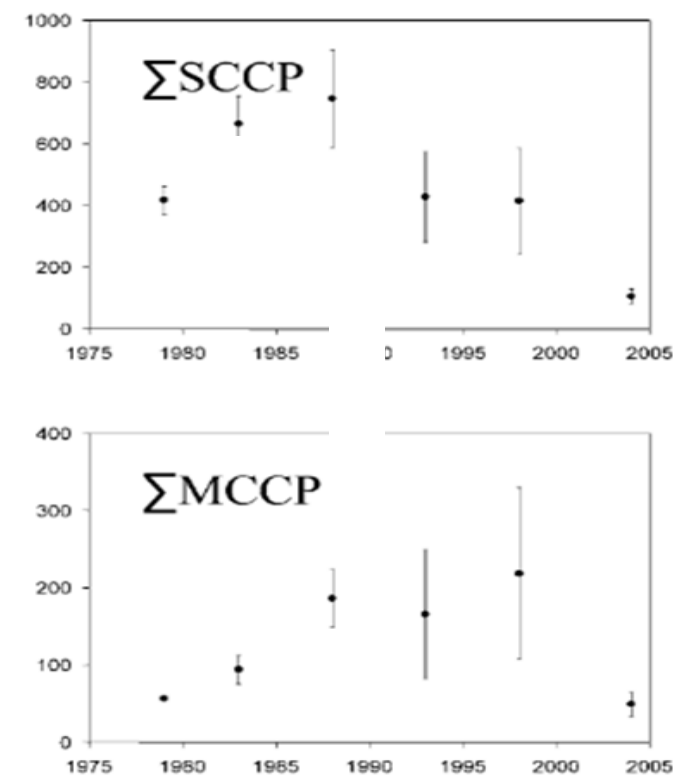
Figure 1: St. Clair Lake 2001 Sediment Sampling Locations from Gewurtz et al. (2007).

Gewurtz et al. (2007) found a mean sediment concentration level for MCCPs of 64 ng/g dry weight (0.064 mg/kg) with a median concentration of 14 ng/g dw (0.014 mg/kg) and the highest measured concentration of 760 ng/g dw (0.76 mg/kg). All of these values are well below EPA's sediment COC of 18.7 mg/kg dw for MCCPs.

### Fish Monitoring Data

In addition to monitoring data on CPs in water and sediment, CPIA has become aware of several recent studies on levels of MCCPs in top predator fish in the U.S./Canada Great Lakes and other freshwater bodies in Canada. This work was conducted by Environment Canada (EC) and reviewed by EPA and several state agencies that are participating in the Identification Task Team (ITT) on Chemicals of Mutual Concern in the Great Lakes (ITT 2015). None of these data were considered in the Risk Assessments and CPIA believes they should be included, particularly for use in determining human fish ingestion exposure as presented below.

Ismail et al. (2009) analyzed archived samples of lake trout from Lake Ontario collected from 1979 to 2004 for concentrations of SCCP and MCCP. They found an increasing but non-significant trend from 1979 to 1988 followed by a significant decrease until 2004 (Figure 2), with the 2004 samples being several factors lower than all previous samples. Ismail et al. (2009) states, “The MCCP concentrations increased significantly from 1979 until 1998 (p 0.05), then decreased in 2004 to less than the 1979 levels.” This decrease may be attributable to improved handling and disposal methods as MCCP production and use in the U.S. and Canada was continuous during this period.



**Figure 2:** SCCP and MCCP (ng/g wet lipid) measured in archived samples of Lake Trout from Lake Ontario. Source: Ismail et al. (2009).

The recently published paper by Sarborido-Basconcillo et al. (2015) details the assessment of SCCPs and MCCPs concentrations in fish from nine water bodies across the Canada.<sup>4</sup> These fish samples were collected in 2010-2011 and are provided in Table 1 from this paper (see below).

<sup>4</sup> Much of the data from water bodies shared by the U.S. and Canada including the Great Lakes and the Columbia River.

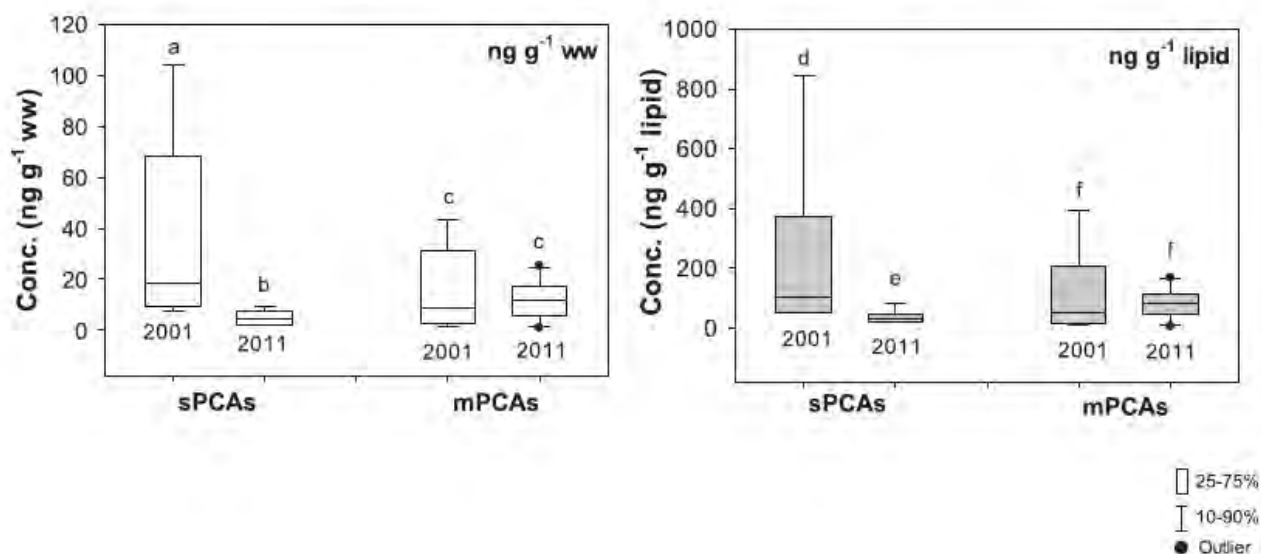
**Table 1**  
Concentrations of sPCAs and mPCAs in fish in Canada.

Waterbody	Species	Collection year	n	$\Sigma$ sPCAs (mean $\pm$ SD)		$\Sigma$ mPCAs (mean $\pm$ SD)	
				ng g <sup>-1</sup> ww	ng g <sup>-1</sup> lipid	ng g <sup>-1</sup> ww	ng g <sup>-1</sup> lipid
Kusawa L.	L. trout	2011	10	2 $\pm$ 3	22 $\pm$ 18	1 $\pm$ 1	13 $\pm$ 11
Columbia R.	Walleye	2011	9	5 $\pm$ 4	110 $\pm$ 115	1 $\pm$ 1	28 $\pm$ 22
L. Athabasca	L. trout	2011	10	9 $\pm$ 11	93 $\pm$ 144	5 $\pm$ 3	45 $\pm$ 17
L. Superior	L. trout	2011	9	3 $\pm$ 3	22 $\pm$ 19	4 $\pm$ 1	36 $\pm$ 28
L. Huron	L. trout	2011	9	3 $\pm$ 2	26 $\pm$ 24	12 $\pm$ 15	100 $\pm$ 119
L. Erie	L. trout	2011	8	3 $\pm$ 2	12 $\pm$ 7	11 $\pm$ 8	57 $\pm$ 39
L. Ontario	L. trout	2011	10	5 $\pm$ 3	37 $\pm$ 21	12 $\pm$ 7	83 $\pm$ 48
St. Lawrence R.	Walleye	2010	9	5 $\pm$ 2	84 $\pm$ 51	6 $\pm$ 6	88 $\pm$ 79
Kejimikujik L.	Brook trout	2010	10	10 $\pm$ 8	288 $\pm$ 301	5 $\pm$ 5	130 $\pm$ 161

The Sarborido-Basconcillo (2015) study analyzed a total of 84 top predatory fish from nine locations consisting of 55 lake trout, 10 brook trout and 10 river Walleye fish. A high resolution mass spectrometer was used for the quantitative analyses. Mean MCCP concentrations in fish tissue ranged from 1 to 12 ng/g ww at the nine locations in this study. The highest mean concentration of 12 ng/g ww in trout was associated with Lake Huron. Sarborido-Basconcillo et al. (2015) also compared their results for fish from Lake Ontario to those samples collected in 2001 by Houde et al. (2008). See Figure 3 below. The results indicated that concentrations of SCCPs in lake trout in Lake Ontario were significantly lower in 2011 than 2001. Likewise concentrations of MCCPs were also lower in 2011 than 2001, though the differences were not as significant. The ITT concluded that these downward trends in fish are consistent with those reported by Ismail et al. (2009). Further it is worth noting that Environment Canada recently proposed a draft Environmental Quality Guideline for MCCP in fish of 760 ng/g lipid (0.76  $\mu$ g/g lipid) and that all of the reported values from Sarborido-Basconcillo (2015) are well below this concentration. This same conclusion of a low concern for CP levels in the environment was also reached in a recent publication by Hull et al. (2015) which found that, “chlorinated paraffins... were not monitored at concentrations approaching water or sediment toxicity benchmarks” in the Great Lakes.



*L. Saborido Basconcillo et al./Chemosphere 127 (2015) 93–100*



**Figure 3:** Concentrations of SCCPs (sPCAs) and MCCPs (mPCAs) in lake trout from Lake Ontario in  $\text{ng/g}$  wet weight (left) and  $\text{ng/g}$  lipid (right). Source: Saborido Basconcillo et al. (2015)

In the supplemental information to Sarborido-Basconcillo (2015) provided by Environment Canada (Attachment D) a detailed congener analysis for  $C_{14}$ - $C_{16}$  is presented. See Figure 4 below. This comparison shows the relative abundance of each congener group in this range and, while the absolute levels are very low, it shows that  $C_{14}$  and  $C_{15}$  congeners in the 50-60% chlorination by weight range are the most common. These results are influenced by the standards used in this analysis, which for MCCP were 52% and 57% Cl by weight, and thus may tend to under report lower chlorinated congener groups. Still, the data appear to be consistent with information on the composition of typical commercial MCCP products. More importantly, however, these data indicate that there are few to zero highly chlorinated MCCP congeners present in these fish indicating that such highly chlorinated congeners are not present in the environment of these fish. As discussed elsewhere, there are data that shows that MCCP congeners in this chlorination range have the ability to biodegrade, which is supported by the overall downward trends in this study and the prior study by Ismail et al. (2009). Moreover, predictive models (e.g. EPISUITE) suggest that lower chlorinated congener groups are more likely to bioaccumulate than higher chlorinated congeners, though these lower chlorinated congeners are not present. These data along with other field data support the conclusion that MCCPs are not bioaccumulating in the environment as the overall levels have been going down, not up, even while MCCP has been in continuous use in the region. Again, it is important to note that the total sum of all of these congener groups is in the low  $\text{ng/g}$  (ppb) range.

Finally, there is a new paper by D. McGoldrick of Environment Canada (EC) and E. Murphy of EPA (McGoldrick and Murphy (2015, in press)) that summarizes EC and EPA lake trout and Walleye fish concentration measurements on a wide range of chemicals of concern, including SCCPs and MCCPs. The data were collected between 2008 and 2012 in the Great Lakes. The data from this publication for SCCPs and MCCPs are the same as reported in Sarborido-

Basconcillo (2015), so there is no need to summarize them again. However, CPIA would like to note that Figure 3 below (take from Figure 6 in the publication) demonstrates just how small the levels of both SCCP and MCCP (combined) are in comparison to other chemicals in this analysis. Further, this analysis helps illustrate the stark differences between CPs and other chlorinated chemicals such as PCBs. During the time of this sampling both SCCPs and MCCPs were on the market and had been in continuous manufacture and use for decades whereas PCBs have been banned in both the U.S. and Canada for more than three decades, yet SCCPs and MCCPs combined are a minor fraction compared PCBs. While CPIA has no opinion about the levels of non-CP chemicals reported in this study, we do believe that this analysis is sufficient reason for EPA to rethink its proposed prohibition on the manufacture and import of MCCPs in the U.S.

In total, these monitoring data consistently demonstrate that levels of CPs in the environment are below conservative benchmarks, indicating that there is no reason to pursue a prohibition on the manufacture and import of MCCPs and LCCPs. CPIA believes that the development of a reasonable risk management program, focusing on minimizing releases to the environment, is the appropriate approach to managing these chemicals. CPIA and the Coalition support the development of additional monitoring data, as deemed necessary, to address any unresolved issues in the Risk Assessments as a practical and efficient approach to assessing these chemicals in the environment.

Figure 4: Relative Abundance of MCCP Congeners in Great Lakes Fish Samples 2010-2011 from Supplement to Saborido-Basconcillo et al. (2015), Chemosphere 127 (2015) 93–100

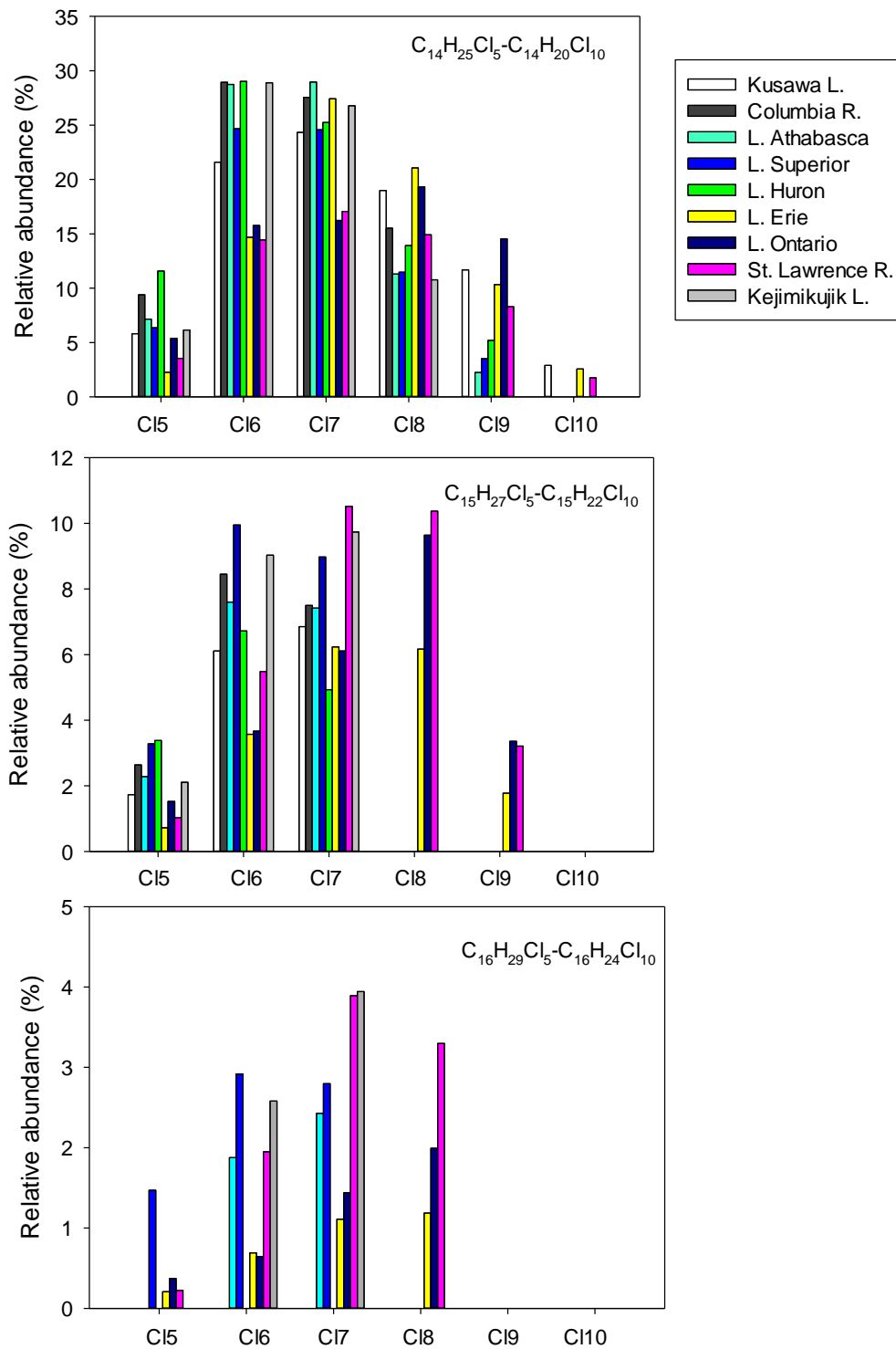
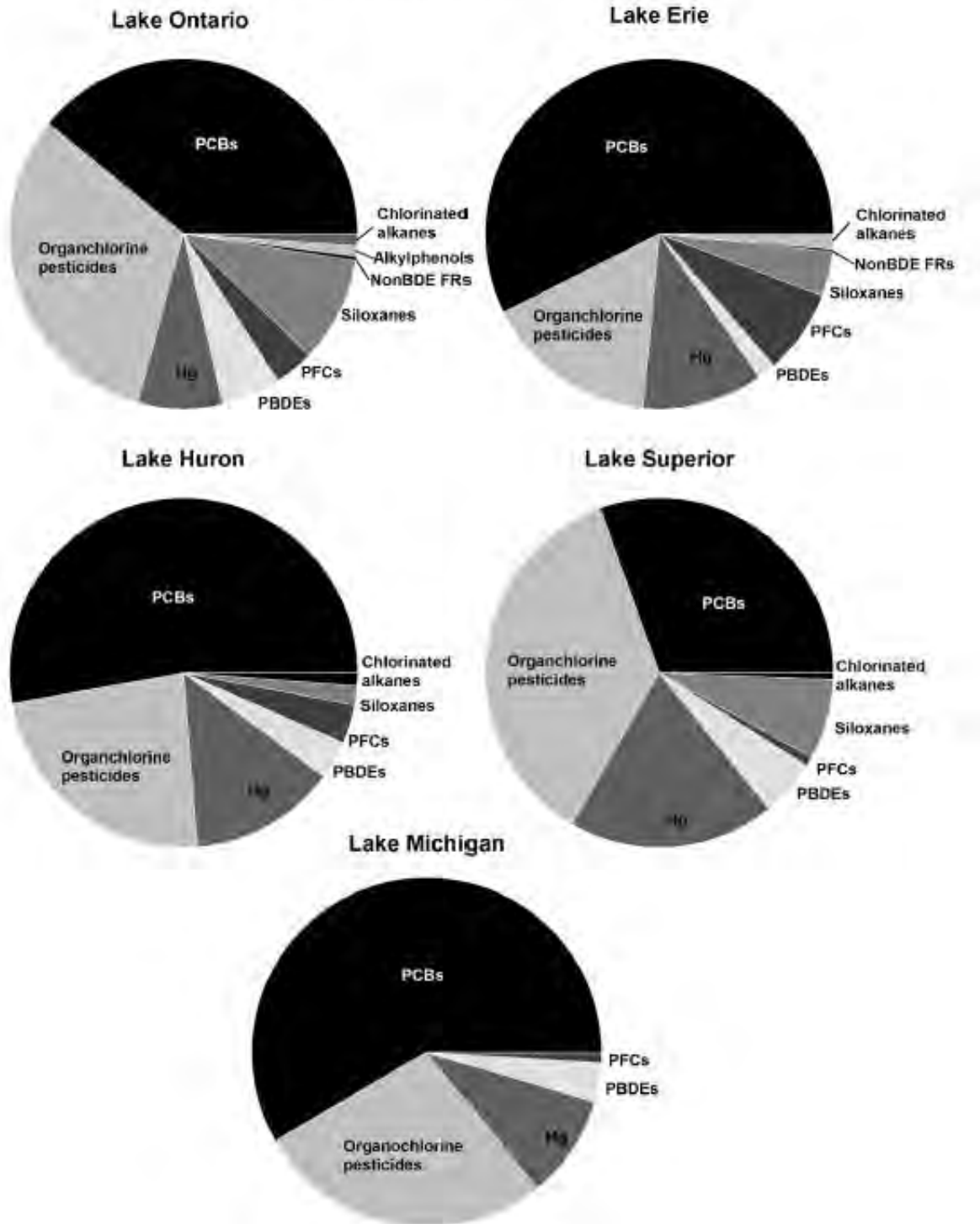


Figure 5. Comparison of Contaminants in Fish in the Great Lakes as presented in McGoldrick and Murphy (2015, in press)

*D.J. McGoldrick, E.W. Murphy / Environmental Pollution xxx (2015) 1–12*



## Evaluation of Higher Fish Diet on Human Health Risk Assessment

One use these new fish monitoring studies could be used to address the recent submission of the National Tribal Toxics Council (NTTC) on the potential for unique exposures to MCCPs and LCCPs by tribal populations. While the CPIA believes that EPA’s human health risk assessment in the Risk Assessments is inherently conservative, and thus implicitly considers sensitive subpopulations, CPIA is providing additional analysis on this issue for EPA and NTTC to consider. Of particular interest to NTTC appears to be the potential for greater fish ingestion levels in Native American populations compared to that of the general public. This concern can be evaluated by considering data on levels of these chemicals in fish and comparing them to dietary information already collected by EPA.

In order to translate these fish concentrations into human dietary exposure, the E-FAST model assumes a general population daily mean fish ingestion rate of 6 g/day wet weight based on the freshwater fish recommendation of the 1997 edition of the Exposure Factors Handbook (EFH) (EPA, 1997; Table 10-81). The 2011 edition of the EFH does not present a specific recommendation for Native American Populations, but it does refer the reader to a table summarizing fish ingestion data from several Native American studies (EPA, 2011; Table 10-6). Table 2 below presents mean fish ingestion rates for the tribe data summarized in the EFH. As shown in this table, mean fish consumption rates in tribal populations are greater than in the general population, ranging from 29 to 201 g/day. These greater values for fish consumption were used to evaluate the potential for an increased risk to tribal populations.

To characterize the risks of oral exposure, including from dietary fish consumption, EPA derives a human equivalent dose (HED) for oral exposure to the general population -  $HED_{oral-genpop}$ . This HED is then used to calculate margins of exposure (MOEs) for fish consumption and other consumption by dividing the HED by the exposure level. CPIA used an MCCP  $HED_{oral-genpop}$  of 5.6 mg/kg-day based on the equation provided in the Risk Assessments. CPIA notes that the Risk Assessments did not specifically list a value for  $HED_{oral-genpop}$ . In the next section we discuss the derivation of this value and concerns regarding an apparent error in how EPA derived this value for the Risk Assessments.

**Table 2:** Summary of Exposures and MOEs for tribal populations summarized in the EPA (2011) Exposure Factors Handbook based on the highest mean measured MCCPs concentration of 12 ng/g ww in fish from Sarborido-Basconcillo et al. (2015)

Location/Tribe	Mean Fish Ingestion Rate (g/day) <sup>a</sup>	Dose (mg/kg-day) <sup>a,b</sup>	MOE <sub>HED</sub> <sup>c,d</sup>
94 Alaska Communities (median; all respondents)	81	1.35E-05	4.1E+05
Chippewa Indians (Wisconsin; all adult respondents)	39	6.52E-06	8.6E+05
4 Columbia River Tribes (Oregon; consumer adults)	63	1.05E-05	5.3E+05
Florida (consumers)	57	9.60E-06	5.8E+05

Minnesota (consumers)	201	3.36E-05	1.7E+05
Mohawk Tribe (New York and Canada; adult consumers)	29	4.85E-06	1.2E+06
North Dakota (consumers)	29	4.80E-06	1.2E+06
Tulalip Tribe (Washington; adult consumers)	72	1.20E-05	4.7E+05
Squaxin Island Tribe (Washington; adult consumers)	72	1.20E-05	4.7E+05
Suquamish Tribe (Washington; adult consumers)	194	3.24E-05	1.7E+05

<sup>a</sup>Default E-FAST body weight of 71.8 kg assumed when fish ingestion expressed as g/kg-day.

<sup>b</sup>Example calculation for first row: Dose = 81 g/day x 12 ng/g x 10<sup>-6</sup> mg/ng / 71.8 kg = 1.35 x 10<sup>-5</sup> mg/kg-day.

<sup>c</sup>The human equivalent dose (HED) = 5.59 mg/kg-day (see discussion below).

<sup>d</sup>MOE = HED / Estimated Exposure; example calculation for first row: MOE = (5.59 mg/kg-day) / (1.35x10<sup>-5</sup> mg/kg-day) = 4.1x10<sup>5</sup>

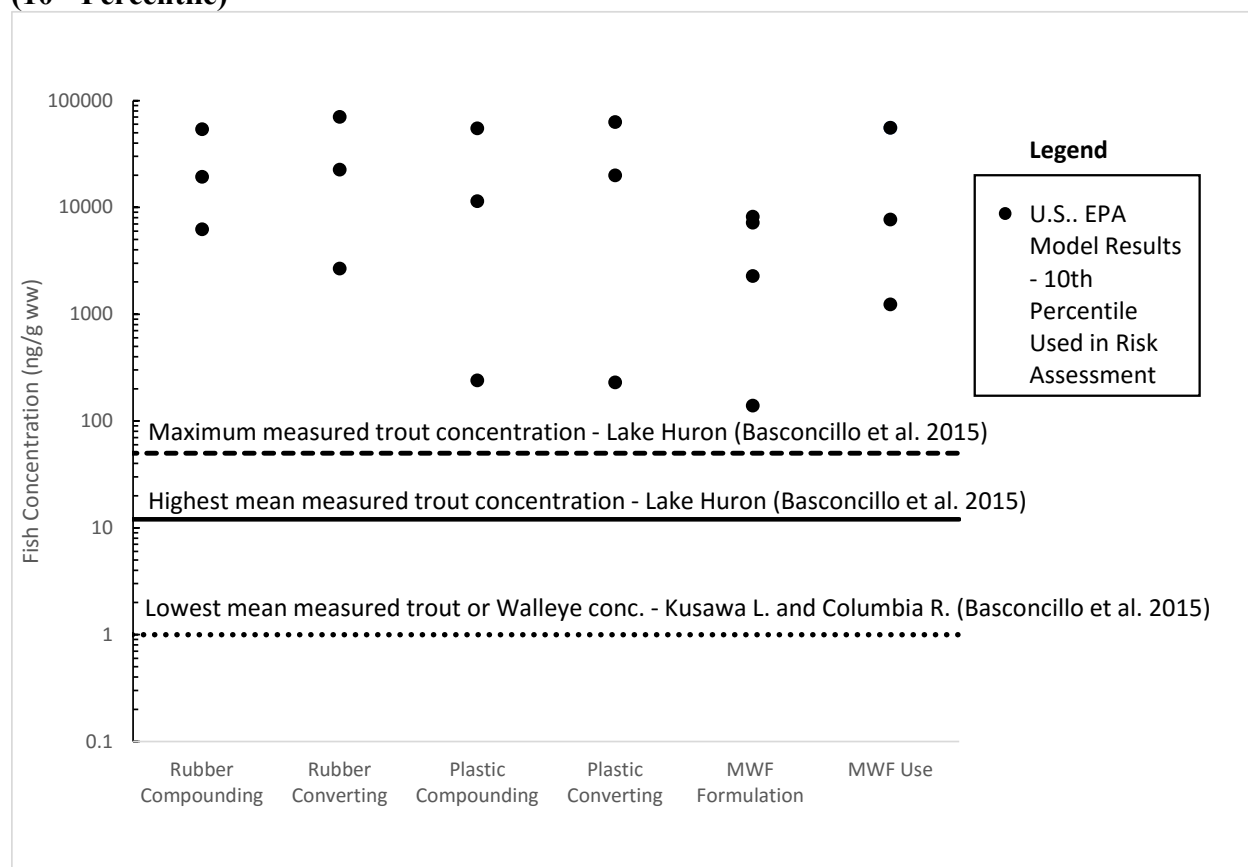
In general, EPA considers MOEs greater than 1000 to indicate a “low risk finding.” As shown in Table 2, estimated tribal population MOEs range from 1.7x10<sup>5</sup> to 1.2x10<sup>6</sup> when the highest mean concentration of 12 ng/g ww from the Sarborido-Basconcillo et al. (2015) study is used to represent MCCP levels in fish. These MOEs are orders of magnitude above 1000, indicating no concern for human health for this pathway even at elevated fish consumption rates. It is also important to note that even if the maximum historical U.S. measured fish concentration of 904 ng/g from the Risk Assessments had been used in the above assessment, the MOEs would still have exceeded 1000, ranging from 2,200 to 15,000. Again, this suggests a very low risk even to communities with much higher fish consumption rates than that of the general population.

The NTTC comments also raise concerns about the possibility of dermal exposure. The dermal absorption rates for MCCPs and LCCPs are exceptionally low. As such, dermal exposure is unlikely to be a meaningful pathway for systemic exposure to MCCPs and LCCPs. Scott (1989) conducted a 52% CI (wt.) MCCP product using an *in vitro* human skin cell method and found no absorption of the MCCP product after 54 hours of exposure using 5 different receptor fluids. Yang et al. (1987) tested two <sup>14</sup>C-labelled chlorinated paraffins, C<sub>18</sub>, 50-53% CI (CP-LH) and C<sub>28</sub>, 47% CI (CP-LL) for dermal absorption in rats (5-7 animals of each sex) at a concentration of 66 mg/cm<sup>2</sup>, approximately equivalent to 2000 mg/kg body weight. Only 0.7% (males) and 0.6% (females) of the C<sub>18</sub> dose was absorbed after 96 hours. Only 0.02% of the C<sub>28</sub> dose was absorbed in males whereas in females the level was not detectable. This indicates that increasing chain length leads to decreased permeability. Scott (1989) noted the Yang (1987) results as being consistent with his since there is evidence that animal skin is more permeable than human skin (Scott and Ramsey 1987, Scott et al. 1987). Overall, these data indicated that absorption of MCCPs and LCCPs is likely to be less than the 1% dermal absorption amount EPA used in the Risk Assessment. This adds further confidence to the above conclusions that MCCPs and LCCPs will not present a risk to human health.

It should be noted that while EPA has identified high MOEs for fish ingestion, ranging from approximately 16,000 to 3,000,000, it appears that EPA has greatly overestimated fish tissue concentration based on unrealistic default releases to water used in the modeling. In the Risk Assessments, EPA’s E-FAST modeling predicted a maximum fish tissue concentration of approximately 70,000 ng/g ww (70 mg/kg ww) for MCCPs, which exceeds the maximum detected amount of 50 ng/g of MCCPs in the recent study by Sarborido-Basconcillo et al. (2015)

by a factor of 1400. Even the minimum E-FAST predicted concentration of approximately 140 ng/g ww (0.14 mg/kg ww) exceeds this maximum measured concentration by almost three-fold. Figure 1 shows that the vast majority of predicted model concentrations exceed the value reported in Sarborido-Basconcillo et al. (2015) by a significant margin. As explained in CPIA’s previous submission (Attachment C), EPA’s use of unrealistic default releases to water has resulted in model predictions that exceed measured environmental data by a very wide margin. The comparison of these estimated fish concentrations to actually measured data is just another illustration of the impact of these water release assumptions on EPA’s modeling.

**Figure 1: Comparison of MCCP modeled results used in risk assessment to measured data (10<sup>th</sup> Percentile)**



### Evaluation of Derivation of Human Equivalent Dose for Oral General Population Exposure

As presented in the previous discussion, the  $HED_{oral-genpop}$  is used in the Risk Assessments to calculate MOEs, as follows:  $MOE = HED_{oral-genpop} / \text{Exposure Level}$ . In order to make these MOE calculations for consumption of MCCPs via fish, CPIA used EPA’s equation in the Risk Assessment:

$$MCCPs\ HED_{oral-genpop} = NOAEL_{oral} \times (ABS_{oral-rat} \div ABS_{oral-human}) \times (BW_{rat} \div BW_{human})^{1/4}$$

where,

$NOAEL_{oral} = 23 \text{ mg/kg-bw/day}$

$ABS_{oral-rat} = \text{percent absorption by the oral route in rats} = 50 \%$

$ABS_{oral-human} = \text{percent absorption by the oral route in humans} = 50 \%$

$BW_{rat} = \text{rat bodyweight} = 0.250 \text{ kg}$

$BW_{human} = \text{human bodyweight} = 71.8 \text{ kg}$

$MCCP \text{ HED}_{oral-genpop} = 23 \text{ mg/kg} \times (50\%/50\%) \times (0.25 / 71.8)^{1/4} = 5.6 \text{ mg/kg-day}$

As mention above, the Risk Assessments did not report a specific  $MCCP \text{ HED}_{oral-genpop}$  in the text. However, in reviewing the MOEs for oral general population in the Risk Assessments we noted that in several places it appears that EPA used an incorrect value for  $\text{HED}_{oral-genpop}$  in calculating the MOEs.

For example, in the analysis for P-12-0282, PROC1 for fish ingestion presents the following:

Table 9, PROC 1, fish ingestion dose = 4.6E-3 mg/kg-day

Table 20, PROC 2, fish ingestion MOE = 20,000

Based on these values, EPA would have had to use an  $\text{HED}_{oral-genpop}$  of over 90 mg/kg- day. This can be determined by using an inversion of the MOE equation:

$\text{HED}_{oral-genpop} = \text{MOE} \times \text{Exposure (fish ingestion dose)}$

or

$\text{HED}_{oral-genpop} = 2000 * 4.6\text{E-}3 \text{ mg/kg-day} = 92 \text{ mg/kg-day}$

Given the equation that EPA provide for this HED value in the Risk Assessments, it appears that one likely possibility may have been that EPA accidentally flipped animal and human body weights so that the HED was incorrectly calculated as:

$\text{HED}_{oral-genpop} = 23 \text{ mg/kg-day} \times (50\%/50\%) \times (71.8 \text{ kg}/0.25 \text{ kg})^{1/4} = 94.6 \text{ mg/kg}$ .

CPIA strongly urges EPA to re-evaluate this portion of the Risk Assessments, to determine whether an error is present. Assuming EPA should have used the lower  $\text{HED}_{oral-genpop}$  of 5.6 mg/kg-day, CPIA still believe that the MOEs for general population human exposure are very high (indicating very low risk) given the available measure values.

In addition, CPIA would like to note that the Department of Defense (DOD) has also noted concerns regarding the derivation of  $\text{HED}_{DermWorker}$  and  $\text{HED}_{DermConsumer}$ . While CPIA does not believe that corrections to these HED values will have a significant impact on the risk conclusions for human health given the very high margins of exposure, and the limited dermal absorption of MCCPs and LCCPs, it is important that these issues be addressed and revised Risk Assessments provided before further restrictive action is proposed for these chemicals. As discussed in the Coalition comments, scientific peer review is essential given the highly



influential scientific assessment nature of the Risk Assessments. There are clearly aspects of the Risk Assessments that would benefit from such peer-review.

### Future Environmental Fate Testing

EPA has proposed a testing plan to address environmental fate issues of sorption, persistence and bioaccumulation of MCCPs and LCCPs and the toxicity of transformation products to sediment organism. This testing plan includes running a series of laboratory tests on 9 test materials, which are C<sub>14</sub>, C<sub>16</sub>, and C<sub>18</sub> each chlorinated to 30, 56, and >70% by weight.

CPIA can appreciate that EPA feels additional data may be needed to address uncertainties in the risk assessment. However, it is not clear how these studies, which CPIA estimates could cost several million dollars or more, address EPA's uncertainties and data gaps, which are not clearly stated in the Risk Assessments. Moreover, EPA has proposed that this testing be done while these products are prohibited from manufacture and import in the U.S. which would create an enormous upset to U.S. manufacturing and is an unreasonable and seemingly unprecedented action for chemicals that have been in continuous manufacture and use.

Furthermore, it is unclear why EPA has chosen some of the test materials in this testing plan given that:

- There are already test data on C<sub>14</sub> test materials that show these products are readily biodegradable up to 50% chlorination by weight.
- The commercial MCCPs are mostly in the range of 40- 60% chlorination by weight, and LCCPs, C<sub>18-20</sub>, are mostly in the range of 40-55% chlorination by weight suggesting that there is little value to testing materials at 30% and >70% chlorination by weight for these classes of CPs.

Additionally, CPIA is aware of scientific concerns over the appropriateness of some of the test methods proposed, in particular the OECD 308 test guideline.

The OECD Guideline 308 was originally designed for substances with far greater water solubility than MCCPs or LCCPs and it has not been ring-tested to validate the method for chemicals like MCCPs and LCCPs. The test system represents a simultaneous combination of various test conditions, which makes it very difficult to draw meaningful conclusions from the test results.

For hydrophobic substances like MCCPs and LCCPs, bioavailability plays a major role in the degradation process. These chemicals will have little opportunity for biodegradation in this test system as they will be directly added to the sediment phase which will greatly limit access to the microorganisms in the test system. In this regard, these tests are likely to simply confirm that MCCPs and LCCPs greatly partition to the organic phase rather than the aqueous phase, a fact that is well documented for substances with high octanol-water coefficients like these chemicals. Further, prior work by Knaebel et al. (1994 and 1996) shows that test media can have a profound impact on the biodegradation rates in test systems and some media produce slow biodegradation results even for chemicals that are well recognized as being readily biodegradable.

Finally, the OECD Guideline 308 test system does not allow for real-life processes, such as bioturbation, which are expected to be important for biodegradation of CPs.

A recent project evaluating the OECD Guideline 308 was conducted by an independent panel of experts lead by Dr. Kathrin Fenner of Eawag (the Swiss Federal Institute of Aquatic Science and Technology), Dübendorf, Switzerland. Attachment E contains an opinion Dr. Fenner provided to ECHA Board of Appeal regarding the use of the OECD Guideline 308 for MCCP. Dr. Fenner concludes that OECD Guideline 308 will not generate reliable information regarding the half-lives of MCCP components in sediment because it is not well suited to assess persistence for compounds such as MCCPs given the static nature of the test system and the high hydrophobicity of MCCPs. Bioavailability of highly hydrophobic compounds such as MCCPs and LCCPs will be low in OECD Guideline 308 studies which will result in artificially low biodegradation results.

Other expert reviews and assessments have also raised significant concerns with the OECD Guideline 308. A review by Ericson et al. (2014) of 31 studies performed using the OECD Guideline 308 noted serious problems with non-extractable residues in the sediment phases, meaning that many substances experience sorption problems with the OECD Guideline 308 test system. In 2012, the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) held an expert workshop on assessing environmental persistence of chemicals. The report from the workshop notes specific concerns with the appropriateness of the OECD Guideline 308 study for complex substances and concludes that the OECD Guideline 308 was developed for single (mono-constituent) substances and not for complex substances (ECETOC 2013).

Given these expert opinions on the deficiencies of the OECD Guideline 308, CPIA believes this test guideline is inappropriate for evaluating MCCPs and LCCPs.

Once EPA has fully considered the additional information provided in this and other submissions on the MCCP and LCCP Risk Assessments, EPA should identify those specific areas where there are remaining uncertainties or information needs. If EPA believes additional information is still needed to evaluate the environmental risk of these chemicals, EPA should consider alternative sources of information, such as additional environmental monitoring, rather than conducting more laboratory studies that are unlikely to represent the actual environmental fate of MCCPs and LCCPs.

### **Benefits of Chlorinated Paraffins**

As indicated by their presence on the market for decades, there are established benefits to the use of MCCPs and LCCPs. CPIA is aware that one of its members, Inovyn (formerly INEOS Chlorvinyls), provided EPA with a thorough overview of these benefits in a previous submission. CPIA is also aware of the numerous submissions from various downstream user organizations that explain the importance of MCCPs and LCCPs to their products and operations.

Inovyn hired Manchester University to conduct an independent ‘cradle-to-grave’ life cycle assessment (LCA) of its facility in Runcorn, England following ISO 14040/14044 methodology. Considering just one aspect of this assessment, greenhouse gas (GHG) emissions, the March 2014 report from the University of Manchester found that the GHG emissions for the manufacture of MCCPs and LCCPs were considerably lower compared to other common plasticizers and flame retardants. For example, the report found that Inovyn’s manufacture of MCCPs has a global warming potential of about 0.8 kg CO<sub>2</sub> eq./kg of MCCPs, whereas another popular phthalate plasticizer, DINP (di-iso nonyl phthalate) has a global warming potential of about 2.3 kg CO<sub>2</sub> eq./kg of DINP. The American Chemistry Council’s Center for the Polyurethanes Industry also mention the importance of one-component spray foams, which use MCCPs and LCCPs to creating more energy efficient buildings. In this way, MCCPs and LCCPs can help to reduce GHG emissions both in terms of their manufacture and in the products that they help create.

Finally, some user organizations have presented information about the time and expense related to reformulation. CPIA agrees this is an important consideration, but also notes that there is the issue of the safety, environmental impact and reliability of alternatives that should be considered as well.

## **Conclusions**

Overall, CPIA finds that the Risk Assessments and supporting documents do not provide an adequate basis to support EPA’s key conclusion that MCCPs and LCCPs present an unacceptable risk to the environment. There are significant and extensive data, both in this submission and in prior submissions from CPIA and the Coalition, that show levels in North America to be below EPA’s COCs even after decades of continuous manufacture and use. Further, information provided by manufacturers and users of these chemicals indicates that releases of MCCPs and LCCPs to the environment, particularly to water, are not occurring to the extent EPA indicates in the Risk Assessments. This information, indicating little to no release to the environment from the manufacture and use of MCCPs and LCCPs, is consistent with the measured data and does not support the modeled values presented by EPA in the Risk Assessments.

Regarding concerns about the persistence and bioaccumulation of MCCPs, there are significant laboratory and environmental data that demonstrate both the biodegradation potential and lack of bioaccumulation of these chemicals. There are a series of well conducted biodegradation studies that demonstrate that MCCPs up to 51% chlorination are either readily or inherently biodegradable and therefore not persistent. Further, environmental monitoring in predator species, field biomagnification and trophic magnification data show a clear pattern of MCCPs not bioaccumulating in the environmental food web. This conclusion of low bioaccumulation potential for MCCPs is also supported by recent analyses of several bioaccumulation experts as presented in the Coalition comments.

As for LCCPs, EPA’s own Risk Assessment did not make a determination that these substances are toxic to aquatic organisms at or below their upper water solubility limit. Rather the Risk Assessments read across to the results of MCCP tests for all key data and conclusions, noting limitations in the LCCP dataset, and indicating that this is “a very conservative approach in the

absence of data for the LCCP materials themselves and therefore may not inherently characterize toxicity to LCCPs directly.” In fact there are dozens of aquatic toxicity studies on LCCPs substances that contain C<sub>18-20</sub> constituents that could have been used in the assessment of LCCPs. Additionally, EPA could have called for the development of sediment toxicity data on LCCPs to develop a COC for LCCPs on this endpoint rather than read across to MCCPs though such a test is not mentioned in the testing plan. By contrast, there are limited environmental monitoring data on LCCPs, and this is an area where the development of new monitoring data would allow for the direct assessment LCCPs rather than drawing analogies to MCCPs. Finally, as discussed in the Coalition comments and Attachment B, LCCPs are not predicted to be bioaccumulative using EPA models and were also concluded not to be bioaccumulative by environmental agencies in the United Kingdom and the European Union.

In proposing to prohibit the manufacture and importation of MCCPs and LCCPs, EPA has chosen the most expensive and disruptive regulatory option for these chemicals. Environmental monitoring data indicate that these substances are being effectively managed and thus suggest that future regulation and management of these chemicals can occur without the need to seek a complete prohibition on the manufacture and import in the U.S.

List of Attachments

- A. CPIA January 2015: Letter to EPA on the Draft MCCP and LCCP Risk Assessments
- B. CPIA March 2015: Existing Evaluations of LCCP/vLCCP Category Assessments for U.S. EPA Review of PMN Submissions Review of LCCP
- C. CPIA May 2015: Evaluation of Environmental Release and Environmental Assessment of Medium Chain Chlorinated Paraffins (C14-C17) and Long Chain Chlorinated Paraffins (C18-C20)
- D. Supplemental Information from Sarborido-Basconcillo, L. S.; S.M. Backus, D.J. McGoldrick, D. Zaruk, E. Sverko, D.C.G. Muir. 2015. Current status of short- and medium chain polychlorinated n-alkanes in top predatory fish across Canada. Chemosphere 127: 93-100.
- E. Opinion from Dr. Kathrin Fenner to ECHA Board of Appeal regarding the use of the OECD Guideline 308 for MCCPs.

## References

European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). 2013. Assessing Environmental Persistence: 6-7 November 2012, Paris. Workshop Report No. 24. December 2013. Brussels. ISSN-2078-7200-24.

Ericson, JF, Murray Smith R, Roberts G, Hannah B, Hoeger B, Ryan J. 2014. Experiences with the OECD 308 transformation test: A human pharmaceutical perspective. *Integr Environ Assess Manag* 10(1):114-124.

EPA. 1997. Exposure Factors Handbook 1997 Edition (Final). U.S. Environmental Protection Agency. Washington, DC. EPA/600/P-95/002F a-c.

EPA. 2011. Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency. Washington, DC. EPA/600/R-09/052F.

Gewurtz SB, Helm PA, Waltho J, Stern GA, Reiner EJ, Painter S, Marvin CH. 2007. Spatial distributions and temporal trends in sediment contamination in Lake St. Clair. *Journal of Great Lakes Research*. 2007 Sep;33(3):668-85.

Houde, M., D. C. Muir, G. T. Tomy, D. M. Whittle, C. Teixeira, and S. Moore. 2008. Bioaccumulation and Trophic Magnification of Short- and Medium-Chain Chlorinated Paraffins in Food Webs from Lake Ontario and Lake Michigan. *Environmental Science & Technology*, 42(10), 3893-3899.

Hull, R.N. , S. Kleywegt, J. Schroeder. 2015. Risk-based screening of selected contaminants in the Great Lakes Basin. *Journal of Great Lakes Research* 41 (2015) 238–245.

Identification Task Team (ITT) for Chemicals of Mutual Concern (CMCs) in the Great Lakes. 2015. Binational Summary Report: Chlorinated Paraffins.

Ismail, N., S.B. Gewurtz, K. Pleskach, † D.M. Whittle, P.A. Helm, C.H. Marvin, and G.T. Tomy. 2009. Brominated and Chlorinated Flame Retardants in Lake Ontario, Canada, Lake Trout (*Salvelinus namaycush*) Between 1979 and 2004 and Possible Influences on Food-Web Changes. *Environmental Toxicology and Chemistry*, Vol. 28, No. 5, pp. 910–920.

Knaebel, D.B., T.W. Federle, D.C. McAvoy, J.R. Vestal. 1994. Effect of Mineral and Organic Soil Constituents on Microbial Mineralization of Organic Compounds in a Natural Soil. *Applied and Environmental Microbiology*. Dec. 1994, p. 4500-4508.

McGoldrick, D.J., E.W. Murphy. 2015. Concentration and distribution of contaminants in lake trout and walleye from the Laurentian Great Lakes (2008-2012). *Environmental Pollution* 2015: 12.019.

Sarborido-Basconcillo, L. S.; S.M. Backus, D.J. McGoldrick, D. Zaruk, E. Sverko, D.C.G. Muir. 2015. Current status of short- and medium chain polychlorinated n-alkanes in top predatory fish across Canada. *Chemosphere* 127: 93-100

Scott, Robert. 1989. In vitro absorption of some chlorinated paraffins through human skin. *Archives of Toxicology*. 63: 425-426.

van Mourik, L.M. P.E.G. Leonards, C.G, Jacob de Boer. 2015. Recent developments in capabilities for analysing chlorinated paraffins in environmental matrices: A review. *Chemosphere*: 136 (2015) 259–272.

Yang, J.J., T.A. Roy, W. Neil, A.J. Krueger, C.R. Mackerer. 1987. Percutaneous and Oral Absorption of Chlorinated Paraffins in the Rat. *Toxicology and Industrial Health*. Vol. 3 No. 3 405-412.