CHLORINATED PARAFFINS

INDUSTRY ASSOCIATION

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June 17, 2008

Robert Chénier, Ph.D. Manager, Assessment Section Existing Substances Division Environment Canada Tel.: 819-953-1680 Fax: 819-953-4936 Via E-mail: robert.chenier@ec.gc.ca

<u>Re:</u> Comments on Revised Risk Profile for Short-chain Chlorinated Paraffins (SCCPs)

Dear Robert:

The Chlorinated Paraffins Industry appreciates the opportunity to submit comments on the revised Risk Profile for short-chain chlorinated paraffins (SCCPs).

We have provided in the attached, using the Track Change and Comment feature of Microsoft Word, several comments throughout the document. In general, we find the document to be well written and to contain most of the relevant literature. At the same time, we are very disappointed with the biased approach taken in the "Synthesis of Information" section which appears intended to maximize the Risk Quotients (RQ) and thereby drive the conclusion that SCCPs should be listed as a POP under the Stockholm Convention.

At the last (third) POPRC meeting, SCCP was the only compound that members did not agree satisfied the criteria of paragraph 7 of Article 8 of the Stockholm Convention. As noted in the meeting report:

Several members in the latter group said that the risk profile for the chemical did not demonstrate either toxicity to humans or to higher predators or that the chemical was subject to long-range transport. Others questioned the environmental effects, saying for example that concentrations of the substance even near production facilities appeared to be very low.

As a result, it was agreed, to further consider SCCP at the next POPRC meeting. It had been our expectation that a more thorough review of the data would be undertaken to assess whether there is a basis for listing SCCP under the Stockholm Convention. While additional information and data have been included in the latest version of the Risk Robert Chénier, Ph.D. June 17, 2008 Page 2 of 3

Profile, none appear to significantly change the conclusions from the previous version. Instead, the revised Profile has incorporated a series of worst-case assumptions that appear to be without precedence or merit and reflect an intent to force a conclusion that SCCP warrant action.

The most significant concern with the draft assessment is the manner in which the Risk Quotients are derived in the concluding "Synthesis of Information" section, most notably Table 3-3. The Risk Quotient is supposed to reflect an objective comparison between the predicted environmental concentration (PEC) and the toxicity level that may cause adverse effects (Predicted No Effect Concentration).

In the case of the <u>Predicted Environmental Concentration</u>, the assessment relies on the highest environmental concentration reported at any point in time and at any location in the world, irrespective of whether germane to the Stockholm Convention evaluation. The draft Risk Profile describes various studies that have measured SCCPs in remote regions such as the Arctic. While there are issues associated with many of those measurements, in general the levels found in these remote regions are very low. Disappointingly, the RQs assessment does not use those environmental measurements and instead utilize "the maximum reported value" such as urban/industrial sewage treatment plants in Canada and the UK. The goal of the POPs program is to address chemicals that may pose a threat to the environment or to human health from its long range transport. From our perspective, there is simply no justification to rely on environmental measurements from an industrial area to assess whether there should be a concern regarding a suspect POP compound.

The conservative reliance on industrial/urban measurements for the PECs is further compounded by the approach used to derive the <u>Predicted No Effect</u> <u>Concentration</u> (PNECs). Unlike the previous draft of the Risk Profile, this version takes the Critical Toxicity Values (CTVs), which as noted in the assessment "typically represents the most sensitive chronic toxicity value," and divides them by an assessment factor (safety factor) of 1,000. The consequence of this is to lower the most sensitive toxicity determination by three orders of magnitude. No justification is offered to support the use of such a high assessment factor other than to assert that a conservative approach is needed for persistent compounds. Given that the PECs for this assessment are being compared directly to PNECs derived from the most sensitive species, we do not believe that a 1000 fold assessment factor is justified.

Consider one example described in Table 3-3 to demonstrate the extreme approach adopted in the risk assessment. The highest RQ reported is 3,329. This RQ is based on a PEC of 2.63 μ g/g which represents the highest measured value of SCCP found in carp. The CTV selected is from a bioconcentration study by Cooley *et al.*, which found effects in trout containing 0.79 μ g/g of a 12-carbon chlorinated alkane.

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The draft Risk Profile does not simply compare the highest PEC to the CTV. Instead, the Risk Profile contrasts the 2.63 ug/g PEC with the 0.79 μ g/g measured value, but only after dividing by 1,000 to derive a PNEC of 0.00079 μ g/g. Such an extrapolation is without technical justification. It is significant to note that the Cooley study itself shows that the same toxicological response was not observed at the next lowest dose level. In fact according to the Cooley et al. paper, none of the low dose exposures resulted in any toxicological response.

Similar concerns (although not as extreme) are relevant for the other RQ derivations for each one includes dividing the CTV by 1,000 and using the highest reported monitoring result for the particular medium being evaluated.

The CP industry believes that an objective evaluation should utilize environmental measurements from remote regions, particularly for SCCPs which have been in commerce for more than a half a century. Also, an objective assessment would not take the most conservative CTV and then divide by 1,000. If one were to use more reasonable assumptions about the PEC and the PNEC, it would be clear that SCCPs do not warrant listing as a POP pursuant to the Stockholm Convention.

The CP industry urges the drafters and members of the POPRC to assess SCCPs based on an objective approach. To do otherwise, only serves to undermine the sanctity of the process and will impede the credibility of the Convention itself.

I would welcome the opportunity of clarifying or providing additional information.

Sincerely,

Robert J. Fensterheim Executive Director

cc: Aslam Yadallee, <u>yadaas@intnet.mu</u> Kei Isobe, <u>kisobe@pops.int</u>