# Annex E Questionnaire (one per chemical)

## Chemical name (as used by the POPS Review Committee (POPRC))

Short-chained chlorinated parrafins (SCCPs): chlorinated derivatives of n-alkanes ”that have a carbon chain length of between 10 and 13 carbon atoms and the degree of chlorination more than 48% by weight”.[1] See UNEP/POPS/POPRC.3/INF/22 for more detailed information on the chemical identity of SCCPs

## Introductory information

### Name of the submitting Party/observer

NGO Observer: National Toxics Network on behalf of the International POPs Elimination Network (IPEN)

### Contact details (name, telephone, e-mail) of the submitting Party/observer)

Mariann Lloyd-Smith PhD
National Toxics Network
+ 612 66815340
biomap at oztoxics.org

### Date of submission

5 February 2008

## Additional Annex E Comments

At the Third Meeting of the POPs Review Committee (POPRC3) the SCCP Draft Risk Profile (Annex E) was to be evaluated to decide whether to pass it to the Risk Management Evaluation stage (Annex F). In the discussions, an industry association and several countries claimed that SCCPs did not meet Annex E criteria of toxicity and long-range environmental transport and should be dropped from further consideration. Other countries declared that the criteria were met and wanted the substance to proceed to the Annex F stage. Some of the countries that advocated dropping the substance did not fault the Risk Profile, but instead focused on the wide use of SCCPs. This was clearly inappropriate at the Annex E stage of assessment.

The Committee was obligated to evaluate the SCCPs Draft Risk Profile in a scientific manner using the criteria outlined in Annex E but unfortunately this did not happen. Instead, a political discussion took place that revealed the difficulties of prohibiting a currently used substance such as SCCPs. As a result, SCCPs did not pass to Annex F evaluation. Ironically, the socio-economic elements that underlined much of the concerns are precisely the elements, which Annex F takes up.

As observers to the POPRC representing the public interest and many organisations from civil society, IPEN would like to provide the following comments that explain why SCCPs meet the Annex E criteria.

[1] Risk profile on short-chained chlorinated parrafins UNEP/POPS/POPRC.3/16/Rev.1

## The purpose of an Annex E evaluation of SCCPs

The Stockholm Convention describes the purpose of the Annex E review as to evaluate whether the chemical is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and/or environmental effects, such that global action is warranted. Annex E does not weight the socio-economic importance of the substance, the difficulty of finding suitable alternatives, or the implications of various control measures.

IPEN considers that the SCCPs Draft Risk Profile provides sufficient data to demonstrate that SCCPs exhibit long-range environmental transport, and that their persistence, bioaccumulation and toxicity are serious enough to warrant global action.

IPEN acknowledges the current use of SCCPs in a range of industrial processes including the manufacture of goods used by the general public. We also acknowledge that production and use has decreased significantly in developed countries but stress that production, use and emission volumes are not known for many regions, including China. Hence, the assessment that emissions and therefore the risks are already decreasing is not a statement that is supported by available information.

A precautionary response to the SCCPs, which are persistent, bioaccumulative and intergenerational, is therefore required.

## Persistence

Sediment core data from the 1940s indicates the presence SCCPs.[2] This has been used to determine a half life of greater than one year. The UK Environment Agency estimated a half life for $C_{10\text{-}13}$ of 1630 days in freshwater sediments and 450 days in marine sediments under aerobic conditions.[3] Other information indicates persistence in air.[4] The Committee agreed during Annex D evaluation (POPRC2) and discussions of the Draft Risk Profile (POPRC3) that SCCPs meet Stockholm Convention criteria for persistence.[5]

## Bioaccumulation

The Draft Risk Profile indicates that laboratory-derived BCFs range from 1900 – 138,000 depending on species and congener.[6] Model- and field-derived BAFs were above 5000. [7] The Committee agreed during

[2] Tomy, G.T., G.A. Stern, W.L. Lockhart and D.C.G. Muir. 1999. Occurrence of $C_{10}$–$C_{13}$ polychlorinated n-alkanes in Canadian mid-latitude and Arctic lake sediments. *Environ. Sci. Technol*. 33: 2858–2863.

[3] Thompson R. S. and Noble H. (2007). Short-chain chlorinated paraffins (C10-13, 65% chlorinated): Aerobic and anaerobic transformation in marine and freshwater sediment systems. Draft Report No BL8405/B. Brixham Environmental Laboratory, AstraZeneca UK Limited.

[4] See UNEP/POPS/POPRC.3/INF/22, Section 2.3.1.1 Persistence in Air for more detailed information on the persistence of SCCPs in air

[5] Decision POPRC-2/8: Short-chained chlorinated paraffins

[6] See Madeley, J.R. and B.G. Maddock. 1983b. Toxicity of a chlorinated paraffin to rainbow trout over 60 days. Imperial Chemical Industries PLC, Devon, U.K. (Brixham Report No. BL/B/2203); Madeley, J.R. and R.S. Thompson. 1983. Toxicity of chlorinated paraffin to mussels (Mytilus edulis) over 60 days. (iv) Chlorinated paraffin – 58% chlorination of short chain length n-paraffins.

Annex D evaluation (POPRC2) and discussions of the Draft Risk Profile (POPRC3) that SCCPs meet Stockholm Convention criteria for bioaccumulation.[8]

**Long-range environmental transport**

The data in the Draft Risk Profile meet two important Convention criteria for long-range environmental transport [9]:

1) Monitoring data showing that long-range environmental transport of the chemical, with the potential for transfer to a receiving environment, may have occurred via air, water or migratory species; or

2) Environmental fate properties and/or model results that demonstrate that the chemical has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For a chemical that migrates significantly through the air, its half-life in air should be greater than two days;

The SCCPs Draft Risk Profile cites studies that satisfy the first criterion:

- measurement of SCCPs in Arctic air and sediment;[10]
- measurement of SCCPs in Arctic animals including ringed seal, beluga whales, walrus, char, and seabirds; [11] and
- the presence of SCCPs in the breast milk of Inuits.[12]

The SCCPs Draft Risk Profile also cites studies that satisfy the second criterion; that is, calculation of atmospheric half-lives varying from 1.2 – 15.7 days noting that estimates varied according to the hydroxyl radical concentration used in the calculation. Major SCCP homologues[13] were found to have half-lives greater than two days, exceeding the Convention criterion.

---

Imperial Chemical Industries PLC, Devon, U.K. (Brixham Report No. BL/B/2291); Renberg, L., M. Tarkpea and G. Sundström. 1986. The use of the bivalve Mytilus edulis as a test organism for bioconcentration studies. *Ecotoxicol. Environ. Saf*. 11: 361–372.

[7] UNEP/POPS/POPRC.3/16/Rev.1 Bioaccumulation Summary, pp13

[8] Decision POPRC-2/8: Short-chained chlorinated paraffins

[9] Annex D para 1 (d)

[10] See Borgen, A.R., M. Schlabach and H. Gundersen. 2000. Polychlorinated alkanes in Arctic air. *Organohalogen Compd*. 47: 272–274; Tomy (1997), Bidleman, T.F., M. Alaee and G.A. Stern. 2001. New persistent chemicals in the Arctic environment. In: S. Kalhok (ed.), Synopsis of research conducted under the 1999–2000 Northern Contaminants Program. Department of Indian Affairs and Northern Development, Ottawa, Ontario. pp. 93–104; Tomy, G.T., G.A. Stern, W.L. Lockhart and D.C.G. Muir. 1999. Occurrence of $C_{10}$–$C_{13}$ polychlorinated n-alkanes in Canadian mid-latitude and Arctic lake sediments. *Environ. Sci. Technol*. 33: 2858–2863; Stern, G.A. and M. Evans. 2003. Persistent organic pollutants in marine and lake sediments. In: Canadian Arctic Contaminants Assessment Report II. Sources, occurrence, trends and pathways in the physical environment. Northern Contaminants Program, Department of Indian Affairs and Northern Development, Ottawa, Ontario. pp. 100–115.

[11] See Tomy, G.T., D.C.G. Muir, G.A. Stern and J.B. Westmore. 2000. Levels of $C_{10}$–$C_{13}$ polychloro-n-alkanes in marine mammals from the Arctic and the St. Lawrence River estuary. *Environ. Sci. Technol*. 34: 1615–1619; Reth, M., Ciric, A., Christensen, G.N., Heimstad, E.S., and M. Oehme. 2006. Short- and medium-chain chlorinated paraffins in biota from the European Arctic- differences in homologue group patterns. *Sci. Tot. Environ*. 367: 252-260.

[12] Tomy, G.T. 1997. The mass spectrometric characterization of polychlorinated n-alkanes and the methodology for their analysis in the environment. Thesis, University of Manitoba, Winnipeg, Manitoba [cited in Tomy et al. 1998a, 1999].

[13] $C_{10}H_{17}Cl_5$, $C_{10}H_{16}Cl_6$, $C_{10}H_{15}Cl_7$, $C_{11}H_{18}Cl_6$, $C_{11}H_{17}Cl_7$, $C_{12}H_{20}Cl_6$, $C_{12}H_{19}Cl_7$

Despite apparent disagreement over this issue at POPRC3, IPEN believes that the data cited in the Draft Risk Profile demonstrate that SCCPs exhibit long-range environmental transport both through environmental fate data and monitoring data. In addition, the Draft Risk Profile also provides information on SCCPs in air, waste water effluents, surface waters, sediments, and biota.

## Assessment of Toxicity and Hazard

Much of the discussion at POPRC3 focused on the lack of evidence of the toxicity of SCCPs and their 'levels of concern'. The dismissal of human health concerns appeared to be based on the EU Risk Assessment Report carried out in 2000.[14] The Report acknowledged that there was very limited information on the toxicokinetics of short-chain chlorinated paraffins. No data, other than limited rat, mice and guinea pig studies are available

In 2000, the SIDS Assessment Profile agreed, noting that "very little toxicological information is available from studies in humans" and that the available animal data did not allow a direct comparison from every toxicological endpoint of the effects of SCCPs.[15]

In 2002, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE)[16] also found that while SCCPs can be transported over long distances and can be bioaccumulated, there was still a lack of information on levels in humans, and the data on effects was still rather scarce.

In a 2005 study,[17] SCCPs were detected in 14 out of 18 samples of breast milk in the UK with a median concentration of 180 ng/g fat (range of 49 to 820 ng/g fat).

The discussion at POPRC3 and to a degree the Draft Risk Profile, did not acknowledge either the limited nature of the toxicity data nor the uncertainty inherent in the use of such limited data.

The POPRC3 discussions and the Draft Risk Profile acknowledged that SCCP exposure in rodent studies showed dose related increases in adenomas and carcinomas in the liver, thyroid, and kidney.[18] However, these observations were dismissed as not likely to be relevant for human health.

In the EU Risk Assessment Report [19] there is a report of the technical discussion of the EU Specialised Experts. The report notes that they could not agree on the significance of these tumours nor on their

[14] EC (European Commission). 2000. European Union risk assessment report. 1st Priority List Vol. 4: alkanes, $C_{10–13}$, chloro-. European Chemicals Bureau, Luxembourg 166 pp. (EUR 19010; ISBN 92-828-8451-1).
[15] SIAM 10, 15-17 March 2000 UK: EU SIDS Initial Assessment Profile
[16] Scientific Committee On Toxicity, Ecotoxicity And The Environment (CSTEE) Opinion of the CSTEE on "Short-Chain Chlorinated Paraffins (SCCPs)"
Follow-up of Directive 2002/45/EC Opinion expressed at the 35th CSTEE plenary meeting
Brussels, 17 December 2002 Brussels,C2/VR/csteeop/SCCPs 17122002/D(02)
[17] Gareth O. Thomas, David Farrar, Eric Braekevelt, Gary Stern, Olga I. Kalantzi, Francis L. Martinb, Kevin C. Jones, (2005) Short and medium chain length chlorinated paraffins in UK human milk fat, *Environment International* 32 (2006) 34 – 40
[18] UNEP/POPS/POPRC.3/16/Rev.1Section 2.5 Hazard Assessment for Endpoints of Concern; Toxicity
[19] EC 2000, P113 Section 4.1.2.8.3

relevance to humans. The Commission Group of Specialised Experts in the fields of Carcinogenicity, Mutagenicity and Reprotoxicity met on 4th - 6th June 1997. The Specialised Experts considered the NTP cancer bioassays to be of poor quality. They agreed that of the tumours observed, only those in the liver, thyroid and kidney should be considered significant. The Specialised Experts considered that no plausible mechanism was suggested for the kidney tumours and considered that as there was still insufficient evidence to conclude a male rat specific event, the consequences for humans could not be ruled out.

The Scientific Committee On Toxicity, Ecotoxicity and the Environment Opinion on the Risk Assessment of Short Chain Length Chlorinated Paraffins [20] also found that the alveolar/bronchiolar carcinomas in male mice should not totally be discounted and that the finding of lung tumours in male mice may be of importance for humans.

In the 2000 SIDS Assessment Profile of SCCPs it was again confirmed that the EU Specialised Experts concluded that the consequences for humans could not be ruled out.

In 2004, the uncertainty in the interpretation of animal data continued in the considerations of SCCPs by the Commission Working Group of Specialised Experts in the fields of Carcinogenicity, Mutagenicity and Reprotoxicity.[21] Members noted that residual uncertainty remained about the relevance of these findings to human health.

**Impacts on Indigenous Communities**

In its preamble, the Stockholm Convention acknowledges that the Arctic ecosystems and indigenous communities are particularly at risk because of the biomagnification of persistent organic pollutants and that contamination of their traditional foods is a public health issue.

In the Technical Peer Reviews on Short Chained Chlorinated Paraffins (SCCPs) Dossier Submitted under the UNECE-LRTAP POPs Protocol, the authors [22] highlighted the relatively high concentrations of SCCPs (100-770 mg/kg wet wt.) in beluga and narwhal fat in Canada and Greenland. They stressed the relevance to exposure through traditional foods of Arctic communities. The dossier, points out that Aboriginal peoples living in the Arctic consume these animals as food, and therefore may be exposed to SCCPs at concentrations greater than the WHO health guideline of 11 µg/kg bw for neoplastic effects (tumor formation). In addition, as noted previously, the Draft Risk Profile notes that Inuit women have already been shown to have SCCPs in their breast milk.

There is clear evidence that SCCPs have contaminated the Arctic ecosystems and indigenous communities. Lack of full scientific certainty regarding the relevance of animal toxicity data should not prevent the SCCP proposal from proceeding. [23]

[20] Available at http://ec.europa.eu/health/ph_risk/committees/sct/docshtml/sct_out23_en.htm
[21] Extract from the DRAFT SUMMARY RECORD concerning SCCPs and MCCPs Commission Working Group of Specialised Experts in the fields of Carcinogenicity, Mutagenicity and Reprotoxicity
Ispra, January 22-23, 2004 (ECB1/08/04)
[22] Summary Of The Independent Track A Technical Peer Reviews On Short Chained Chlorinated Paraffins (SCCPs) Dossier Submitted Under The UNECE-LRTAP POPs Protocol, 16/1/08 Available at
http://www.unece.org/env/popsxg/2006/5th%20meeting/Final%20Summary%20Report%20SCCP%20May%201.doc.
[23] Article 8 Listing of chemicals in Annexes A, B and C Section 7a

## Environmental Toxicity

In POPRC3 discussions, it was acknowledged that the release of SCCPs into the environment can occur at almost all stages of the manufacture, transport, use and disposal of SCCPs and products containing SCCPs.

It was acknowledged that SCCPs are highly toxic to aquatic invertebrates and are also highly toxic to algae on which many species including fish depend. There was no information on which to assess toxicity to marine mammals and the marine food chain.

There was no consideration of the relevance of the liver, thyroid and kidney cancers found in rat and mouse studies to the long-term exposure of any of the 1500 other rodent wildlife species worldwide.

In the POPRC3 discussions on SCCPs toxicity, lack of data was presented as the rationale for no action. This clearly contrasts with the Committee's obligations for precautionary decision making as outlined in the Article 8, Section 7a.

## Levels of Concern

Much of the discussion at POPRC3 focused on levels of concern, yet based on the limited toxicity data which encompasses a very limited range of species, there is not adequate information on which to make informed decisions about levels of concern.

The persistent bioaccumulative nature of SCCPs mean that low concentrations build up in the food chain even in remote regions far from the source, providing ongoing sources of contamination to species.

The attempt to establish meaningful risk criteria, levels of concern or tolerable intakes in regards to POP chemicals simply ignores crucial questions relating to the timing and duration of the exposure, age, nutritional and reproductive status, enzyme function, as well as the additive or synergistic interactions with other substances in the environment.

The persistent bioaccumulative nature of SCCPs combined with the fact they are found in the body of humans and animals and in the environment with many other POPs of similar and differing modes of action, means that a precautionary approach is needed when assessing possible environmental and human health impacts.

### Conclusion

IPEN considers that SCCPs are, as a result of their long-range environmental transport, likely to lead to significant adverse human health and/or environmental effects, such that global action is warranted. SCCPs should now proceed to the next stage of assessment.