9 February 2007

Secretariat of the Stockholm Convention
Att: POPs Review Committee
United Nations Environment Programme
11-13 chemin des Anemones
CH-1219, Chatelaine, Geneva, Switzerland
Fax: (+41 22) 797 34 60
E-mail: ssc@pops.int

Via E-Mail

On behalf of the International Council of Chemical Associations (ICCA) and the World Chlorine Council (WCC) we appreciate the opportunity to provide information relevant to the development of risk profiles under the Stockholm Convention on Persistent Organic Pollutants (POPs). This information includes:

1. General comments and considerations for the development of risk profiles under the Convention.
2. Specific Annex E information to be considered in the development of the risk profile for pentachlorobenzene (PeCB). [*Please note that while this information is specific to PeCB, the approaches and case-studies outlined for PeCB may be helpful in the development of risk profiles for other chemicals.*]

The risk profile is a critical step in the review of candidate chemicals under the Stockholm Convention. Therefore, it is imperative that these documents accurately assess "whether a chemical is likely, as a result of long-range environmental transport, to cause significant adverse effects on human health and/or the environment, such that global action is warranted". We offer the attached information to assist the work of the POPs Review Committee (POPRC).

ICCA and WCC were significantly engaged in the negotiations of the Stockholm Convention, and we remain committed to its rational implementation. If you have any questions or would like any additional information regarding these comments, please contact Allan Jones at allan.g.jones@sympatico.ca, Robert Simon at robert_simon@americanchemistry.com or Dolf Van Wijk at dvw@cefic.be.

I. The risk profiles developed for candidate chemicals and the POPRC's decisions regarding those risk profiles must assess the actual risk of a chemical.

The listing process for new chemicals under the Convention is inherently a risk-based process, driven by scientifically grounded evidence, as reflected in several key elements of the agreement. These are core elements in the treaty that cannot be ignored or circumvented.

Article 8 paragraph 7 requires the POPRC to determine, on the basis of the risk profile conducted in accordance with Annex E, that a candidate 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*." Unfortunately some of the initial risk profiles have failed to provide an adequate synthesis of the risk-related information upon which the POPRC can make such a determination.

To make that determination, the POPRC will necessarily have to reach several discrete conclusions: it will need to conclude that there is (i) a *likelihood* of (ii) *significant adverse effects* that are (iii) due to the chemical's *long-range transport*, (iv) such that *global action is warranted*.

- **Likelihood** refers to a *probable* outcome. It does not require certainty, but the outcome must by definition be more likely than not. To satisfy this standard the POPRC must have sufficient evidence (and, where relevant, have considered the weight of evidence where conflicting information exists) to allow it to conclude both that the chemical will, more likely than not, produce **significant adverse effects**, and that those effects are, more likely than not, linked to the chemical's long-range environmental transport. With respect to the "significance" element, this is largely a policy judgment that will have to be made on a case-by-case basis. However, it is clear that the term must be given some operational weight in screening out low-level or *de minimis* effects.
- This standard is clearly one that is different from and higher than the minimum screening threshold established in Annex D. Therefore, it cannot be sufficient simply to conclude that adverse effects are likely merely because the chemical has passed the screening criteria. Such an approach would render the Annex E standard null without operational effect, and it is therefore a *per se* an invalid interpretation of the standard. Instead, this determination effectively requires an evaluation of the chemical's risk. And that evaluation in turn must flow from a synthesis of the information collected pursuant to Annexes D and E -- a synthesis that integrates the information relating to hazard, exposure and dose responses. The draft guidance that had been prepared at POPRC 1 goes some way toward setting out the factors that should be addressed in developing this synthesis.
- The risks being evaluated must also be linked to **long-range transport**. Adverse effects due to local or regional sources are beyond the scope of the Convention, which focuses by its express terms on effects that flow from a chemical's long-range transport. It is therefore incumbent upon the Committee to take care in evaluating the information in the risk profile to focus only on effects that can be linked to long-range transport.
- The last component -- **whether global action is warranted** -- is largely a policy judgment to be made based on the information established by the first three components. It is possible that the POPRC might find that no global action is warranted even where the other elements are well-established. That might be the case, for example, for a chemical that has long been phased out and for which there is no realistic chance of re-introduction. It is also worth noting that the "significance" and "global action" elements are in this sense linked: the Committee must consider

whether the adverse effects are significant enough to warrant action at the legislative and regulatory level *across the globe*.

II. The evaluation of whether a chemical is "*likely to have significant adverse effects as a result of long-range environmental transport, such that global action is warranted*" should consider:

- Annex D, paragraph 2 of the Convention, which states "w*here possible, a comparison of toxicity or ecotoxicity data with detected or predicted levels of a chemical resulting or anticipated from its long-range environmental transport".* In other words, there should be evidence that a substance is likely to have significant adverse effects based on actual exposure, that is, presence in the environment (including in biota) at or approaching levels sufficient to cause such adverse effects. The determination of "likely to have significant adverse effects" should not be based simply on the measurement of a substance in the environment at any level. The ability to measure a substance in the environment is primarily a function of the analytical technology and is not in itself an indicator of risk.
- The Risk Profile Outline adopted at POPRC-1, which specifically states that the risk profile should be "in the form of a risk characterization". The Risk Profile Outline also provides specific information and factors that can be used, including, among others:
  - the comparison of toxicity and ecotoxicity data with detected or predicted levels of the chemical resulting or anticipated from its long-range environmental transport,
  - evidence of effects on human health or the environment in remote areas, or
  - concern about potential effects on humans or the environment (particularly on the higher levels of the trophic chain) based on the assessment of the reported trends in environmental concentrations or potential for significant increases in production or use at the worldwide level.
- Other relevant factors, including but not limited to:
  - trends in environmental levels – specifically are levels in remote areas increasing, decreasing or constant
  - whether levels in the environment in remote areas exceed established government "levels of concern" which include concentrations shown to cause adverse effects in organisms based on a scientific consideration of all relevant studies and regulatory or other standards established by responsible governments as representing a level requiring attention (e.g. EU Predicted No Effect Concentrations)
  - verification that levels in remote areas are a result of long-range transport rather than local or regional sources.
- The information outlined above should be analyzed to determine:
  - If levels in remote areas are due to long-range atmospheric transport, are increasing or constant, and exceed or are approaching established government "levels of concern" then the POPRC might determine that a substance is likely to cause significant adverse effects such that global action is warranted.
  - If levels in remote areas are only due to local or regional sources then the POPRC might state this and recommend national or regional action outside of the Stockholm process.
  - If levels in remote areas are due to long-range atmospheric transport, are decreasing and are below established government "levels of concern" then the POPRC might determine that a substance is unlikely to cause significant adverse effects and does not warrant global action.
  - if sufficient information is not available to make a determination of "significant adverse effects" then the POPRC could recommend additional monitoring of the substance and request additional information from countries and stakeholders.

III. In evaluating data and studies for this assessment of candidate chemicals, the following general principles should be applied:

- Studies should be critically evaluated with respect to their validity and acceptability. Where ever possible, existing internationally recognized approaches for assessing the validity of studies should be applied (e.g., approaches outlined in the EU Technical Guidance Document, the Klimish scoring approach, etc.).
- Decisions should be based on studies conducted using VALIDATED experimental guidelines (EPA, OECD, ASTM, ISO, etc), and preferably under Good Laboratory Practices.
- Decisions should consider the "data hierarchy" of available studies and information (e.g., valid experimental/field data should take precedence over QSAR/modeled predictions, etc.).
- Emphasis should be placed on a "weight of the evidence" approach.

IV. Pentachlorobenzene (PeCB) does not meet the criterion for significant adverse effects as a result of long-range transport based on an analysis of the PeCB nomination, existing scientific literature, and available evidence (both trend information and the evaluation of levels in the environment/tissues).

Levels of PeCB in the environment are decreasing and are significantly below levels likely to cause significant adverse effects. Specifically:

- **Trends in environmental levels are decreasing**:
  - 90% decline in PeCB levels in Great Lake herring gull eggs over the last 30 years. (Canadian Wildlife Service)
  - 90% decline in PeCB concentrations in Niagara River sediments since 1960's.
  - Extremely low PeCB concentrations measured in remote places.
- **Current levels in the environment (including wildlife) are below regulatory guidance levels**.
  - Levels in sediments are below Environment Canada's estimated no effect value ($ENEV_{sed}$),
  - Consumption of Greenland avian, mammalian, and fish species result in exposure below the RfD for PeCB.
  - Available data for total chlorobenzenes in Arctic polar bears are well below US EPA and Health Canada regulatory guidance levels for PeCB alone. (Verreault et. al., 2005)

Attachment 1 to these comments provides technical information and references that support this conclusion. As requested this information is provided in a format consistent with the questionnaire developed by the Stockholm POPs Review Committee and circulated by the Stockholm POPs Secretariat. [*Please note that while this information is specific to PeCB, the approaches and case-studies outlined for PeCB in Section (e) may be helpful in the development of risk profiles for other chemicals.*]

Format for submitting information pursuant to Article 8 of the Stockholm Convention as specified in Annex E of the Convention

Attachment 1 – WCC Submission Regarding Pentachlorobenzene (PeCB)

As requested this information is provided in a format consistent with the questionnaire developed by the Stockholm POPs Review Committee and circulated by the Stockholm POPs Secretariat. While this information is specific to PeCB, the approaches and case-studies outlined for PeCB in Section (e) may also be helpful in the development of risk profiles for other chemicals.

Introductory information	
Name of the submitting Party/observer	**World Chlorine Council**
Contact details (name, telephone, e-mail) of the submitting Party/observer	**World Chlorine Council Secretariat** **Avenue E Van Nieuwenhuyse 4, box 2** **B-1160 Brussels,** **Belgium** **Tel + 32 2 676 7211** **Fax + 32 2 676 7241** **c/o: Dolf Van Wijk at dvw@cefic.be or Robert Simon at robert_simon@americanchemistry.com**
Chemical name (as used by the POPS Review Committee (POPRC))	**Pentachlorobenzene (PeCB)**
Date of submission	**9 February 2007**

(a) Sources, including as appropriate (provide summary information and relevant references) Note: The summarised information provided below has been extracted from the text in **Annex Section (a)** of these comments. **Annex Section (a)** contains the full references to the sources of information outlined below.	
(i) Production data: **Quantity** **Location**	PeCB is not known to have any commercial uses at present (Beck 1986; Environment Canada 1993) and therefore no commercial production is expected.
Other	
(ii) Uses	PeCB is not known to have any commercial uses at present (Beck 1986; Environment Canada 1993).
(iii) Releases: **Discharges** **Losses** **Emissions** **Other**	The estimated global emissions of PeCB around the year 2000 from all known sources are 85,000 kg/y. This information is summarized in Table 3.3 of WCC's Annex Section (a) submission. There is considerable uncertainty about the size of the estimated PeCB emissions, potentially an order of magnitude. The global emissions are clearly dominated by combustion sources. Of all sources, combustion of biomass (43,900 kg/y), combustion of solid waste (32,740 kg/y) and combustion of coal (6,113 kg/y) represent the three largest emissions. Industrial sources of unintentional by-products are relatively minor due to improvements in industrial practices.

(b) Hazard assessment for endpoints of concern, including consideration of toxicological interactions involving multiple chemicals (provide summary information and relevant references)

(c) Environmental fate (provide summary information and relevant references) Note: The summarised information provided below has been extracted from the text in **Annex Section (c)** of these comments. **Annex Section (c)** contains the full references to the sources of information outlined below.	
Chemical/physical properties	
Persistence	
How are chemical/physical properties and persistence linked to environmental transport, transfer within and between environmental compartments, degradation and transformation to other chemicals?	
Bio-concentration or bio-accumulation factor, based on measured values (unless monitoring data are judged to meet this need)	Pentachlorobenzene is bioconcentrated and bioaccumulated in aquatic organisms but there is little biomagnification in aquatic food webs. Bioconcentration factors for various fish species under different circumstances showed values between 4700 and 20000, with the higher values measured in experiments with chlorobenzene mixtures, including HCB. In another study reported in WCC Annex Section (c) submission, a geometric mean BCF of 5300 was reported. BCFs for scud ranged from 1175 to 1900. Field studies indicate a BAF for fish of 69000, but are difficult to interprete. A field study in an industrially polluted area showed BAFs of 6600-18700. A well controlled chronic laboratory study with fathead minnows gave a BCF of 8400 after 31 days.

(d) monitoring information Note: The summarised information provided below has been extracted from the text in **Annex Section (d)** of these comments. **Annex Section (d)** contains the full references to the sources of information outlined below.
Trends in Environmental Levels Measured PeCB concentrations in remote areas are extremely low. Moreover, when trends can be derived from available data, there is a clear, significant downward trend in concentration. PeCB concentrations, even in heavily contaminated areas, have declined. Additionally, environmental concentrations of chemicals that could degrade to PeCB, such as hexachlorobenzene and hexachlorocyclohexane, are declining as indicated by monitoring results. It is also important to note that PeCB is a trace byproduct of combustion, and as such, it cannot be eliminated completely.

An overview of concentrations and trends of PeCB in the environment is presented in **Annex Section D**, below is a summary of the main conclusions:

Presence in the environment

- PeCB has been observed at low concentrations essentially everywhere in the environment that has been carefully analyzed.
- Polar bear adipose tissue had the highest reported concentrations of PeCB+TeCB with an average concentration of 30 ng/g lipid weight.
- Among the highest reported PeCB concentrations in prey organisms for polar bears is about 5 ng/g wet weight in the blubber of Arctic seals.

Trends in environmental levels

- PeCB concentrations in herring gull eggs on the shore of Lake Superior, Canada have dropped by over 90% since the 1970s.
- Concentrations of PeCB have dropped by over 90% since the 1960s in sediments near the industrially impacted Niagara Falls area of the US and Canada.
- PeCB concentrations in sediments from remote lakes in northern Canada averaged 0.20 ng/g compared to about 8 ng/g off the mouth of the Niagara River in Lake Ontario.

(e) exposure information

Note: The summarised information provided below has been extracted from the text in **Annex Section (e)** of these comments. **Annex Section (e)** contains the full references to the sources of information outlined below.

Assessment of Exposure and Effects

The attached information outlines several approaches for evaluating the 'significant adverse effect' criterion for PeCB. Based upon the available evidence, each of the three approaches suggests that the existing data for PeCB do not meet the 'significant adverse effect' criterion. This is based on the following key conclusions from the various approaches:

- Approach 1: Studies of Canadian lake sediments in both rural and remote sites show typical PeCB organic carbon concentrations are *at least three orders of magnitude lower* than Environment Canada's "estimated no effect value" ($ENEV_{sed}$) for freshwater benthic organisms.

- Approach 2: PeCB concentrations in various animal species represent particular dose levels to predator organisms. For example, a piscivorous mammal, i.e., mink, consuming 15% of its own body weight in food each day (a consumption rate based on data from Vorkamp, 2004), and ingesting food with an average PeCB level of 1 ng/g wet weight (based on gull egg data), would be exposed to only a small fraction of the US EPA Integrated Risk Information System's reference dose. (A reference dose is an estimate of a daily oral exposure to humans, including sensitive subgroups, likely to be without appreciable risk of deleterious effects over a lifetime).

- Approach 3: Biomonitoring studies of polar bears indicate PeCB levels are much lower than concentrations necessary to produce adverse health effects. Reported values of PeCB levels in polar bears represent a margin of exposure of *at least* 460. (A margin of exposure is a ratio of a no-observed adverse-effect-level to an estimated exposure dose.)

(f) National and international risk evaluations, assessments or profiles and labelling information and hazard classifications, as available (provide summary information and relevant references)

See information provided above in Section e that includes information on national and international risk evaluations. U.S. EPA, Health Canada, and Environment Canada have derived non cancer regulatory guidance values for PeCB (see WCC Annex Section (e) submission).

(g) Status of the chemical under international conventions