TO: UNEP Secretariat and POPs Review Committee Chair

Dear Madam, Sir,

On 19 June 2008, Norway nominated the flame retardant HBCD¹ as a possible Persistent Organic Pollutant (POP) under the UNEP² Stockholm Convention on Persistent Organic Pollutants.

The POP Review Committee (POP RC) has decided to begin examination of the proposal at its next meeting. This initial assessment of the POP properties, according to the screening criteria set out in Annex D of the Convention, will start at POP RC 5 in October 2009.

In the context of this initial assessment, the European HBCD Industry Working Group³ wishes to submit its views on the HBCD nomination dossier to the POP Review Committee members. The detailed comments are tabulated in an attached document.

Our comments also take into consideration an in-depth evaluation of HBCD for POP properties and for the potential to cause adverse effects in the environment, conducted by leading independent scientists specialized in the field (Arnot et al., 2009). The full report is also attached to this letter.

The following are the points which we consider to be vital for a thorough scientific evaluation of the POP properties of HBCD according to the criteria listed in Annex D.

Criterion 1(b): Persistence

1. Need to use relevant studies

Corresponding to the industry comments on the HBCD EU Risk Assessment Report, we urge the use of the fully valid biodegradation simulation studies performed with <u>low</u> and environmentally relevant HBCD concentrations (around 25 μ g/l) for the calculations of more realistic half-life times.

At the same time, studies performed with higher HBCD levels, which were specifically designed for the characterization of biodegradation pathways, should not be misused to calculate biodegradation kinetics since at higher HBCD concentrations important steps such as transfer of HBCD into the microbial cell might become rate-limiting.

2. Half life values are below POP thresholds

The experimentally determined half-life time values for sediment and soil, which were determined in the above mentioned valid studies, are below the POP threshold values of 180 days. For sediment and soil these values are

- Sediment 1.1 1.5 / 11 32 days (anaerobic / aerobic)
- Soil 6.9 / 63 days (anaerobic / aerobic)

In addition, it should be noted that corrections of experimentally determined half life values to a lower ambient temperature of 12 °C, as summarized in the TemaNord document, are not recommended for microbial catalyzed processes by experts in the field (SETAC Pellston Workshop 2008).

³ The HBCD Industry Working Group gathers HBCD producers and users in the polystyrene insulation foam sector, the major application of HBCD. The HBCD producers are represented by EBFRIP (European Brominated Flame Retardant Industry Panel) and the HBCD users in the polystyrene insulation industry are members of PlasticsEurope (for expandable polystyrene) and Exiba (for extruded polystyrene).



European HBCD Industry Working Group

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¹ Hexabromocyclododecane, CAS N° 25637-99-4 & CAS N°3194-55-6

² UNEP: United Nations Environment Programme

Criterion 1(e): Adverse effects

The available aquatic toxicity data were critically reviewed in the above mentioned report by Arnot et al. (2009). It was observed that these studies which were conducted according to standard OECD Guidelines have methodological problems, especially because of the use of co-solvents. The addition of co-solvents in aquatic toxicity tests is expected to increase the bioavailability of the tested compound thus rendering a final interpretation of the data difficult. Therefore, based on the questionable reliability of the aquatic toxicity studies, no scientifically sound conclusion can be made on evidence for adverse effects to the environment.

To assess this criterion, residue-based and Total Daily Intake (TDI)-based risk assessments were performed by Arnot et al. 2009. In the first approach, effect data based on experimental exposure are put into perspective by using critical body burden or tissue residue concentrations, which can be associated with no adverse effects, and comparing them with monitoring data of biota from remote areas such as the Arctic. In the second approach, a TDI is calculated, corresponding to the highest measured concentration found in a marine mammal in a remote region. This estimated TDI is compared to the experimentally determined TDI No Observed Adverse Effect Level (NOAEL) derived from a chronic rat study.

Using the residue-based risk assessment approach it can be concluded that if the available information on critical body burden is compared with corresponding biota concentrations in remote areas, **no adverse effects** on marine fish, birds and mammals have to be anticipated. A similar conclusion can be drawn if the TDI approach is used. The calculated TDI required to obtain the highest measured concentration in marine mammals in a remote region is 5 orders of magnitude below the NOAEL.

We would like to stress the importance of taking the above conclusions into consideration to ensure a scientifically sound assessment of the POP properties of HBCD; given that the present submission dossier does not supply enough information on the comparative toxicity or ecotoxicity data, as required by Paragraph 2 of Annex D.

It is finally considered to be of key importance to point out that although a number of screening level hazard criteria are met for HBCD such as those on long-range transport and bioaccumulation, a more in-depth evaluation in the sense of a risk assessment is required to be able to make a scientifically sound assessment of the POP properties of HBCD.

We would be grateful if our comments could be shared with the POP Review Committee members in advance of the fifth meeting scheduled on 12-16 October 2009.

We would also like to request the opportunity of being involved in the technical discussions during the Review Committee meeting and giving a short presentation at this meeting on this new information on the POP properties of HBCD. We will register to attend.

We are fully committed to cooperating with the UNEP POP Review Committee and participating in the technical review process, in order to ensure a thorough science-based assessment of HBCD's nomination dossier.

Yours sincerely,

Dr Smadar Admon Chair of the European HBCD Industry Working Group

Annexes:

1. Industry Comments on HBCD nomination dossier

2. Arnot J., McCarty L., Armitage J., Toose-Reid L., Wania F., Cousins I (2009). An evaluation of Hexabromocyclododecane (HBCD) forPersistent Organic Pollutant (POP) properties and the potential for adverse effects in the environment.



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