Industry comments to TermaNord 2008:520 Hexabromocyclododecane as a possible global POP

10 July 2009

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	4.	**Information on Hexabromocyclododecane in relation to the POP screening criteria**	
24	4.1. Persistence *4.1.1. Test results*	"…no mass balance could be made and the recovery was generally bad…"	The statement that recovery was generally bad is an oversimplification – see note below. ***<u>The response below is focusing on the soil study as an example:</u>*** The *Recovery Factors* reported in the HBCD soil study report (Davis *et al*. 2003b) reflect several aspects of the sample processing including; 1) extraction of the HBCD from the soil matrix, 2) chemical drying of the soil, 3) extraction solvent evaporation/concentration, 4) hydration/solvent exchange and, 5) injection/detection/ ionization in the HPLC-mass spectrometer. Correspondingly, recovery of HBCD is expected to be a result by the entire sampling process and not to be influenced solely by adsorption to soil. Although some irreversible sorption of HBCD to the soil may have occurred it is important to note that the degradation kinetics reported in Study #1were based solely on the disappearance of the *available HBCD fraction* in the **Viable Mixtures** as compared to the *available HBCD fraction* in the **Abiotic Controls**. In the aerobic-abiotic soil controls this "*available HBCD fraction*" remained constant over time where the HBCD concentrations were 18 ng/g on Day 0 and 17.4 ng/g on Day 119. Similar trends were seen in the anaerobic soil microcosm where the HBCD concentrations remained constant in the abiotic controls during the active degradation phase of the study.

European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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Anaerobic soil microcosms	Viable HBCD (ng/g)	Abiotic Control HBCD (ng/g)
Day		
0	11	17.2
21	0.9	19.1

The following section of the report from the first soil study (Study #1, Davis *et al.* 2003) describes the extensive steps taken to ensure the accuracy of the reported HBCD concentrations used to calculate degradation rates for HBCD.

Quote from Env. Science and Technology 2006, 40, 5395-5401:

> *Calibration curves were generated at the beginning and end of each sample set to confirm proper operation of the instrumentation and linearity of detector response. To compensate for any change in response of the HPLC-MS, a reference standard was repeatedly analyzed throughout the sample set (e.g., every fourth or fifth analysis). Response factors were determined for the reference standard and an average response factor was used to calculate HBCD concentrations for samples bracketed by the reference standards.* ***Measured HBCD concentrations were corrected for recovery based on matrix spikes prepared for each sample set.***

Matrix spikes were prepared at each sampling time point which paralleled the analyses of the test microcosms (Viable and Abiotic Control). These matrix spikes consisted of soil microcosms (*e.g.*, Blank microcosms-without HBCD) which had been prepared on Day 0 and incubated with the test microcosms. At each sampling time point the Blank soil microcosms were removed from the

European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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			incubator, spiked with HBCD at nominal concentrations of 25 ng/g, and extracted with hexanes. A *Recovery Factor* was determined based upon the recovery of HBCD from the Blank microcosms. The *Recovery Factor* was used to correct the final HBCD concentrations reported for the Viable and Abiotic microcosms. Thus the variability noted in the extraction efficiency (Recovery Factor) did not adversely impact the final HBCD values reported in Study # 1. Again this point is illustrated by the consistent HBCD values (*i.e.*, concentrations) reported for the soil Abiotic controls (see above).
28	4.1. Persistence *4.1.1. Test results*	"Half-lives which should be understood as disappearance half-lives (not degradation half-lives)…"	If it is meant that disappearance stands for the possibility that HBCD might have been eliminated by irreversible adsorption to organic matrices we do not agree: there is no evidence that the chosen extraction procedures of the different simulation studies were not sufficiently effective as was evidenced by corresponding spiking experiments. (See comments made on p. 25)
28	4.1. Persistence *4.1.1. Test results*	"…1,5,9-cyclododcatriene (product III) is the raw material for the production of HBCDD."	It is important to specify that product III has been identified as the **all trans** (t,t,t-1,5,9-cyclododecatriene) and does not correspond to the raw material of the HBCD synthesis which is the cis, trans, trans isomer.
30	4.1. Persistence *4.2.1 Evidence from measured levels in the environment*	Fig. 4.2: "Relative concentrations of HBCDD (as % of initial conc.) in two hypotethical and one measured sediment core."	It is generally very difficult to predict sediment concentrations of deeper sediment layers because of confounding factors such as sediment re-suspension, difficulties to quantify in-put levels, absence of microbiological activity in deeper sediment layers. It is therefore not possible to directly compare measured values with calculated ones.
30	4.1. Persistence *4.2.3 Summary and conclusions*	"The temperature corrected values at 12°C were…"	It has been agreed at a recent SETAC Pellston conference that temperature corrections e.g. from higher to lower temperature using the Arrhenius plot are not applicable to environmental conditions because of the presence of different microbial populations at different environmental temperatures as a consequence of adaptation: "In general it is not sound scientific practice to use the Arrhenius equation (Q10 rule) to quantitatively correct biodegradation data to a common environmental temperature (e.g. 10 °C). This is due to the fact that microbial populations are generally adapted to

European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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			prevailing environmental conditions, and the transformations that they perform cannot be scaled directly with temperature as is the case for abiotic reactions" (SETAC, 2008) In other words, the corrections of experimentally determined half-lives to a lower ambient temperature of 12 °C as summarized in the TemaNord document must be considered as unrealistic assumptions not representing real environmental conditions.
31	4.1. Persistence *4.2.3 Summary and conclusions*	"The main biodegradation product, 1,5,9-cyclododecatriene,…"	It should be specified (see corresponding comment for page 28) that the product of complete de-bromination of HBCD has been characterized as **all-trans** (t,t,t)-1,5,9-cylclododecatriene.
31	4.1. Persistence *4.2.3 Summary and conclusions*	"In addition the concentrations measured in the sediment core samples…provide an indication of that HBCDD is degraded in sediment more slowly than predicted by the simulation tests"	As already indicated above (comment for page 29) it is difficult if not impossible to directly link sediment concentrations to degradation kinetics:
31	4.1. Persistence *4.2.3 Summary and conclusions* (Box)	"The available measured environmental data from sediment indicate, that the actual sediment half-lives in the environment can be longer than what would be expected based on the experimental half-lives."	It is very difficult to link levels found in the environment, especially those found in sediment, to biodegradation half-life time values since the corresponding input levels (initial concentrations) are unknown. Levels in sediment cores represent sinks where suspended particulate matter of former years was deposited. In deeper sediment layers no biodegradation (also no anaerobic biodegradation) is expected to occur since these layers are lacking biologically active microorganisms. The fact that HBCD can be detected in sediment samples at variable levels can, therefore, not be considered as a direct indication for the lack or low level of HBCD biodegradation under environmental conditions. These levels, partially linked to historical high emissions, have to be seen as a result of complex environmental distribution mechanisms, which at the end are characterized by sedimentation of organic matter to which HBCD is adsorbed.

European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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31	4.1. Persistence *4.2.3 Summary and conclusions* (Box)	"The abundance of HBCD in biota and abiotic samples…provides solid evidence of the persistency…"	The fact that HBCD is not only found close to emissions sources but also at low concentrations in remote areas is a result of complex interactions of which especially transport mechanisms are not yet well understood. The mere presence in biota of remote areas cannot not be regarded as sufficient proof for persistency, especially in the absence of consideration of important aspects such as emission volumes. Decreasing concentrations of HBCD in biota (Law et al, 2008) suggests a relatively quick response of the food chain to changes in HBCD emissions – See also comments further below on overall temporal trends made by Arnot et al. (2009) (comments on page 61 (Ch. 6.3.1 Environmental Exposure) on the TemaNord document. Furthermore, it is worth mentioning that the steady state models used by Arnot et al. (2009) arrived at predicted environmental concentrations close to the measured ones. This can be seen as an indirect justification that the used default half-live times (air – 1.3 days; water – 85 days; sediment – 35 days; soil – 85 days) reasonably well characterize the overall degradation behaviour of HBCD. –Note that especially for the relevant compartments, sediment and soil, these half-life times are below the trigger values for persistence according to the criteria set in Annex D of the Stockholm convention on POPs.
36	4.2 Bioaccumulation *4.2.2Evidence from measured levels in the environment*	"The ratio between harbour porpoise and its diet in UK was subsequently estimated to be 254".	It should be noted that Leonard (2008) estimated a BMF of 0.3 for harbour seals, indicating metabolism. Similar results were also reported by Sormo at al (2006), where no biomagnification of HBCD from ringed seals to polar bears was found.
38-39	4.3 Potential for long range transport *4.3.1 Test results and model predictions*		Results of long range transport models need to be interpreted very carefully. The calculated Characteristic Travel Distance for HBCD can vary considerably depending on the models and the input parameters used. In fact the Characteristic Travel Distance calculated by Wania and Dugani for HBCD is significantly lower than the ones calculated for Pentabromodiphenyl ether and other identified POPs. Without a properly conducted sensitivity analysis, with the aim to quantify the model uncertainties resulting from uncertainty ranges of the input values, it is not appropriate

European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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			to conclude that "long range transport potential for HBCD is also comparable and inside the range of estimated characteristic travel distances of POPs already included in the treaty". In the HBCD POP assessment report performed by Arnot et al (2009) a more elaborated comparison of the long-range transport potential of HBCD using different models has been conducted. It has been concluded that "…HBCD shows some potential for long-range transport ….however other non-POP chemicals also show these properties."
41	4.3 Potential for long range transport *4.3.2 Evidence from measured levels in the environment*	"Knudsen et al. (2005) found a statistically significant, increasing temporal trend of HBCDD concentrations in eggs of marine bird populations of the Norwegian Arctic…"	Most publications dealing with monitoring data, which show trends of increasing HBCD concentrations in environmental compartments and biota, were performed before 2003. It has to be emphasized that only after 2003 industry-wide efforts to significantly reduce HBCD emissions for the production and use of HBCD in Europe were undertaken. Recent published studies provide indications for reversed trends of environmental HBCD levels over time: Roosens et al showed decreasing total HBCD concentrations in eel caught in the W. Scheldt by comparing samples collected in 2000 and 2006 (Roosens et al 2008). Law et al. (2008) reported on decreasing concentrations of HBCD in harbour porpoise blubber for those specimens caught after 2003. The Arctic Monitoring and Assessment Program (AMAP) report on "Arctic Pollution 2009", which evaluates multiple sources of information, concludes "Environmental levels of PBDEs and HBCDs have followed the production and use of BFRs with increasing levels up until the early 2000s, which are now starting to level off or decline, at least in some areas." See also comments further below on overall temporal trends made by Arnot et al. (2009) (comments on page 61 (Ch. 6.3.1 Environmental Exposure) of the TemaNord document and a more detailed discussion in the study of Arnot et al (2009).

European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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44	4.3 Potential for long range transport *4.3.3 Summary and conclusions*	"…HBCD would be roughly similar as the long-range transport potential of middle sized PCBs and PBDEs."	A more detailed benchmarking exercise has been performed by Arnot et al. (2009) using different types of models. In the report it is acknowledged that "The benchmark comparisons do not provide clear evidence for assigning HBCD as a "POP" or a "non-POP" largely because of the uncertainties in the half-life data and the wide range of LRT and Pov* values for POPs and non-POPs." * *Pov = overall persistence*
46-47	4.4 Adverse effects *4.4.2 Toxicity*		This section of the document cites various studies on mammalian toxicity of HBCD, such as Zeller and Kirsch 1969, Chengelis 2001, van der Ven 2006 and Kurokawa 1984. These studies have been performed in different decades of this and the last century, according to very different quality criteria, and have in part not been reported in sufficient detail. The mere citation of selected details of the studies without any assessment of the reliability and relevance of the results does not suffice nowadays criteria for a regulatory document. The proposing party should provide the evaluation of each study assessed for and cited in the document with regard to reliability and relevance criteria, and conclude on the weight of evidence provided from different studies concerning the cited results.
47	4.4 Adverse effects *4.4.2 Toxicity*	"Although the indices have been observed at very high exposure levels, considering the very high bioaccumulation potential of HBCDD and the ability to be transferred to milk (…), multigeneration studies with mammals should be conducted."	This statement is outdated, as a 2-generation study and a 1-generation study in rats have been published in 2008 (Ema et al 2008)..
48	4.4 Adverse effects *4.4.3 Summary*	"Based on HBCDDs high	The current OECD (2000) guidance document on testing of difficult substances and mixtures specifically advises against the use of co-solvents, unless the effects are quantified. This can increase the water solubility/bioavailability of HBCD in the water

European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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	and conclusion	aquatic toxicity, it is concluded, that HBCDD clearly fulfils the toxicity screening criteria set for POPs."	phase, thereby overestimating the toxic effect of HBCDD at reported test concentrations. Results from these studies might therefore not be predictive for the aquatic environment. The reliability of the aquatic toxicity tests listed in table 4.11 as valid studies must therefore be questioned as in most of the fish, Daphnia and algae tests, co-solvents have been used. A similar conclusion was drawn in the report of Arnot et al. (2009) according to which a scientifically stringent conclusion cannot be made based on the exposure-based aquatic toxicity tests: "…the aquatic exposure based results….are considered to be uncertain….". Based on the questionable reliability of the aquatic toxicity studies, no scientifically sound conclusion of the "T" properties of HBCD can be made. As alternative approaches, a tissue/organ residue and total daily intake (TDI) based assessments of the effects data are proposed which are specifically suitable for bioaccumulative substances. As it is explained in greater detail in the Arnot et al. (2009) report, tissue based Predicted No-Effect Concentrations (PNECs) of HBCD were calculated for two different scenarios. In the first scenario, a PNEC based on a narcotic mode of action (MOA) of HBCD was determined. Five different long-term studies were used for which HBCD tissue residue concentrations were determined which could be associated with no adverse effects. Considering these data on freshwater and marine fish as well as on earthworms, a narcotic MOA seems to best characterize the HBCD effect data. As a worst case, also a more specific hypothetical MOA was taken into account at 100-times lower PNEC using a recent rodent study as a basis. Both tissue based PNECs were compared with arctic biota monitoring data. For both scenarios there is no indication of potential adverse effects. Similarly, calculated upper trophic level TDI estimates were compared with the experimentally determined TDI NOAEL derived from a chronic rat study. The estimated TDI to obtain the steady state concentration, corresponding to the highest HBCD level found in a marine mammal from a remote region, was 5 orders of magnitude below the TDI NOAEL indicating that also using this risk assessment

European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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			based procedure no adverse effects have to be expected based on the HBCD concentrations found in remote regions. In other words, using three different risk assessment approaches, it can be concluded that no adverse effects have to be expected due to the presence of HBCD in remote areas. These conclusions are also relevant to answer Annex D / Paragraph 2 of the Stockholm Convention (Comparison of toxicity or ecotoxicity data with detected levels of a chemical resulting from its long-range environmental transport).
	5.	**Statement for the reasons of concern and need for global action**	
49	5. Statement for the reasons of concern and need for global action		According to Annex D of the Stockholm Convention on information requirements and screening criteria, paragraph 2, "The proposing Party shall provide a statement of the reasons for concern including, where 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, …" This comparison of toxicity with levels in the environment has not been provided by the proposing Party although without doubt it would be possible to do so. As this comparison is crucial for the ability to determine whether the environmental levels present a risk, the section 5 fails to describe a main aspect of the Stockholm Convention information requirements. The same conclusion has also been made by Arnot et al. (2009). As opposed to the TemaNord document, in the latter report a risk assessment has been performed using different methodologies (based on biota tissue / organ residues as well as based on total daily intake via food) arriving in all cases at the conclusion that the concentrations found in Arctic biota as a result of long-range transport cannot be linked to adverse effects (see above comments made on Ch. 4.4. Adverse Effects).
49	5. Statement for the reasons of concern and need for global action	"Furthermore, HBCD is degraded slowly in the aquatic environment and soil."	The generalization of slow degradation in both aquatic environment and soil is not correct. It could be shown that HBCD can efficiently be debrominated in anaerobic water / sediment systems. This latter observation is of importance specifically because the sediment compartment can be seen as the key sink for HBCD.

European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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49	5. Statement for the reasons of concern and need for global action	"Due to harmful POP properties and risks related to its widespread production and use, international action is warranted to control this substance."	The document provided by the proposing party does not include a comparison of environmental levels with hazard levels, i.e. a risk assessment (see also comment made above and a detailed discussion in Arnot et al 2009). The claim of "risks related to its widespread production…" is therefore not supported by this document. Also, in the case of HBCD, only few production sites exist globally, so that one can hardly speak of "widespread production".
	6.	**Additional information on hexabromocyclododecane**	
57	6.3 Exposure *6.3.1 Environmental exposure*	" The only reported concentrations from seawater (suspended solids) are 74 µg/kg dw and 472 µg/kg dw in Western Scheldt and Tern canal (NL, Terneuzen), respectively, in the vicinity of a production plant (Bouma, et al. 2000)."	Many publications reported in this section dealing with monitoring data, show trends for increasing concentrations of HBCD in environmental compartments and biota, were performed before 2003. It has to be re-emphasized that only after 2003 industry wide efforts to significantly reduce HBCD emissions for the production and use of HBCD in Europe were undertaken. A manufacturing site in the UK (Aycliffe) known to have emitted quantities of HBCD ceased production in 2003. This is considered to account for raised levels in the UK and around the North Sea. The sole remaining European plant manufacturing HBCD has made significant efforts to reduce its emissions (now down to 2 kg/yr).
58	6.3 Exposure *6.3.1 Environmental exposure*	For estuarine, brackishwater and marine sediments of Norway, the Netherlands and Ireland a mean concentration of 174 µg HBCDD/kg dw and a range of 0.25-8 024 µg HBCDD/kg dw have been reported by European Commission (2007a).	It should be noted that the Standard deviation (SD) for this mean is 174 µg ±1100 for the mean concentration leading to a big spread and possible uncertainty in the value.
60	6.3 Exposure *6.3.1*	"The corresponding median concentration is 5.5 µg	Again the SD should be included showing the variation in the data. The data should read 321 µg ±1130.

European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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	Environmental exposure	HBCDD/kg ww and arithmetic mean 321 µg HBCDD/ww."	
60	6.3 Exposure *6.3.1 Environmental exposure*	"The values included contain a range of < LOD to 9432 µg HBCDD/kg ww."	It should be reminded that the 9432 µg HBCDD/kg ww is the value recorded near the point source of the UK manufacturing site which has been closed down. It is misleading to include this data point as it is not usual to include closed facilities in risk characterization.
60	6.3 Exposure *6.3.1 Environmental exposure*	"Levels in marine and brackish water fish muscle (n= 102) range from < LOD to 49 µg HBCDD/kg ww with a mean of 2.6 µg HBCDD/kg ww(European Commission, 2007a)."	Again the SD for the mean is more than the mean itself, and should be adjusted to 2.6 µg ±7.9 HBCDD/kg ww.
61	6.3 Exposure *6.3.1 Environmental exposure*	"HBCDD was measured by Law RJ et al. (2006) in blubber of 85 harbour porpoises stranded or dying in the U.K. during 1994-2003. The mean concentration in the mid 1990s was 100 µg/kg lw and increased to 9 400 µg/kg lw in the samples from the year 2003."	Correction to the text: The sentence should state the **median** concentration was 100 µg/kg lw and increased to 9 400 µg/kg lw in the samples from the year 2003. It should also be noted that recent published studies provide indications for reversed trends referring to decreasing concentrations over time: Rossens et al showed decreasing total HBCD concentrations in eel caught in the W. Scheldt by comparing samples collected in 2000 and 2006 (Rossens et al 2008). Law et al. (2008) reported on significant decreases in concentrations of HBCD in harbour porpoise blubber for those specimen caught after 2003. Furthermore, the report of Arnot et al. (2009) concluded that overall “temporal trends show no uniform pattern. In some species, concentrations of HBCD may have stabilized over the past decade or even begun to decrease whereas there are indications from other studies that concentrations are still increasing in other species, including humans.” This conclusion is illustrated by findings from remote regions: Concentrations found in Herring gull, Atlantic Puffin and Kittiwake are increasing between 1980 and 2005 whereas those reported for peregrine falcon eggs decrease

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Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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			over the same time period. The interpretation of these findings seems to be complicated by the observation that for different locations different exposure sources have to be considered.
62	6.3 Exposure *6.3.1 Environmental exposure*	"The longest temporal series of concentrations measured in biota has been reported by Sellström et al. (2003) for the years 1969 to 2001 for guillemot (*Uria aalge*) eggs (see Figure 6.4) collected from the Baltic Sea."	Sellström (quoted in EC2007a) considered that the increase leveled out since that time. This should be added.

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European HBCD Industry Working Group

Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be

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Avenue E. van Nieuwenhuyse 4 B - 1160 Brussels Belgium

Tel: +32 2 676 72 05 Fax: +32 2 676 7432 Email pdt@cefic.be