Risk Assessment of PBDEs in the European Union – Process and Update

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Introduction:
The EU Risk Assessment process under the existing substances legislation Regulation 793/93 will be described and an update of the conclusions of finalized and *draft* Risk Assessment Reports on various polybrominated diphenyl ether (PBDE) mixtures and products will be provided. Of special interest will be the re-assessment of the DecaBDE product due to the generation of new information.

Background on EU Risk Assessment Process:
The risk assessment carried out under Regulation 793/93 in the EU is conducted following the principles of the Regulation 1488/94 and the detailed methodology laid down in the Technical Guidance Document on Risk Assessment for New and Existing Substances (TGD). To assist Member States (MS) to implement the TGD and carry out risk assessments of individual priority substances, the European System for the Evaluation of Substances (EUSIS) was developed as a user friendly computer based system. The TGD and EUSIS together were developed by the European Commission directly with work groups from the EU MS, Industry and NGOs. The TGD was issued in four parts in 1996 with a strategy to continually update in accordance with available science and methodologies. The TGD was last revised in 2003.

Scope:
The scope of the RA covers emissions and consequent environmental impact and human exposures at each stage of the life-cycle of a priority substance from production, through processing, formulation, use and disposal. Protection goals are established for the environmental compartments - atmosphere, aquatic organisms, sediment and soil dwelling organisms, microorganisms in WWTPs, and mammals and birds exposed via accumulation in the food chain. Exposure of humans from all relevant sources is considered including exposure from consumer products and through air, food, and drinking water and the workplace. Each exposure scenario is assessed individually, and where appropriate, an overall combined exposure is also estimated.

Risk Assessment Paradigm:
The purpose of the RA is to determine the risk posed by a chemical or a chemical product, and the assessment of the risk is addressed by four steps 1) hazard identification, 2) dose-response assessment, 3) exposure assessment and 4) risk characterization. Hazard identification provides an indication of the adverse effect which a chemical has an inherent capacity to cause. A dose-response assessment is an estimation of the relationship between dose or level of exposure to the substance and the severity of an effect where appropriate. Exposure assessment is an estimation of the concentration/dose to which populations (workers, consumers, man) exposed indirectly through the environment or environmental compartments are or may be exposed. The estimation entails the determination of the sources, emission routes and degradation pathways of the chemical. Risk characterization is the estimation of the incidence and severity of the effects likely to occur in a human population of environmental compartment due to actual or predicted exposure to a chemical, and may include "risk estimation".

Exposure Assessment:
The exposure assessment methodology is designed to take a cautious reasonable worst case estimate of exposure where measured data are lacking, but there exists a scope to obtain such information. An extension of the environmental modeling also predicts the levels to which humans are exposed via air, drinking water and food thus providing an estimate of daily exposure of the effected human populations locally and regionally. Exposure data are frequently lacking so exposure models are often applied. Applying the EUSIS modeling framework, predicted environmental concentrations (PEC) locally and regionally in all environmental compartments are estimated.

Effects Assessment:
Industry is obliged to provide a minimum data set (depending on production levels) on which to identify hazards but other tests may be required if there is reason for concern. A human health effects assessment is conducted for several toxicological endpoints including acute toxicity, irritation, corrosivity, sensitization, repeated dose toxicity, mutagenicty, carcinogenicity, and reproductive toxicity. For each endpoint a no observed adverse effect level – NOAEL – is estimated; for environmental effects assessment, predicted no effect concentration - PNEC is estimated using acute and chronic data (and perhaps an assessment factor).

Risk Characterization:
The goal is to carry out quantitative risk characterization by identifying or extrapolating from the (eco)toxicity data, to give concentrations at which no effects are expected and comparing to this level with the estimated exposure level. For human population, risk characterization is expressed as the no observed adverse effects level divided by the exposure which provides then a Margin of Safety. For the environmental concern, the risk characterization is expressed as a predicted environmental concentrations divided by the predicted no effect concentration where if the ratio is > 1, then there is considered to be a risk. Risk management measures are taken up for those chemicals which yield either or both an environmental risk or human health risk.

EU Risk Assessment Reports:
EU RA Reports are drafted by a Member State rapporteur, the science is intensely examined by the Technical Committee on New and Existing Substances, and the reports revised according to discussions and then approved. Following a scientific opinion of the final result by DG SANCO's Scientific Committee for human and environmental risk (SCHENIR), the RA may be revised and approved by the EU Member States. The EU Risk Assessment Reports are published on the European Commission's European Chemicals Bureau (ECB) webpage -

- **DecaBDE** (Bis(pentabromophenyl) ether; CAS Nr. 1163-19-5; EC Nr. 214-604-9):

The completed DecaBDE RAR did not show formal Conclusions (iii), but there are still significant gaps in knowledge, expressed by Conclusions (i) in the EU Risk Assessment Report (RAR) of 2002.

The Environment section of the RAR concluded that further information was required in relation to the PBT (Persistent, Bioaccumulative, Toxic) assessment. DecaBDE is likely to be very persistent (vP), according to the criteria presented in the Technical Guidance Document (European Commission, 2003). The substance has some similarities in its behaviour to a vPvB (very Persistent, very Bioaccumulative) substance and its breakdown to substances with PBT or vPvB properties could occur in the environment (for example by metabolism in fish).

Additional testing is needed also with respect to secondary poisoning. Furthermore there are uncertainties regarding possible neurotoxic effects by mammals in laboratory studies; and possible formation of more toxic and accumulative products such as lower BDE congeners and brominated dibenzofurans in the environment.

This means that the available assessment methodology might not be applicable to this substance, and in general also not to other BFR's. There is a continued need to monitor environmental contamination for both the substance and its more toxic and bioaccumulative degradation products. This uncertainty surrounding DecaBDE is expected to be clarified through further testing and long term biomonitoring. In the meantime a voluntary program of reducing & controlling emissions to the environment has been put in place. On 18th March 2005, the Scientific Committee on Health and Environmental Risks (SCHER) gave its opinion on the environment risk assessment, and they considered that risk reduction measures should be investigated (SCHER, 2005).

DecaBDE is exempted from the overall EU ban via the RoR Directive because of the positive conclusion of the 2003 RA Report and the assertions by industry of lack of safe and appropriate substitutes. New scientific information leading to a revison of the 2003 RAR and the wide application

of non-brominated substitutes as flame retardants by the electronic industry has led to further discussion about the appropriateness of the exemption.

- **TBBA**: 2;2',6,6'-tetrabromo-4,4'-isopropylidene diphenol (CAS Nr. 79-94-7; EC Nr. 201-236-9): the *draft* Environment RAR indicates concerns for water and terrestrial compartments and the need for risk reduction measures has already been identified for some uses.

  This conclusion applies to the use of TBBPA as an additive flame retardant in ABS from compounding and conversion sites. Many uncertainties remain regarding the risk assessment, in particular about the emission estimates and the biodegradation rates in the environment. The substance has been shown to break down in marine sediments to another substance (bisphenol-A) that is known to be toxic and shows effects on the endocrine system. For aquatic systems (e.g. fish and amphibians), TBBPA can cause effects on thyroid-hormone mediated processes. Of possible additional environmental concern is the release of brominated dibenzo-p-dioxins and dibenzofurans from incineration or fires of plastics/articles containing TBBPA (see Appendix A of the 2007 Draft RAR).

No health effects of concern have been identified by the TBBP-A Human Health RAR[17], but the impact on the endocrine system is currently scrutinised (e.g. under the EU FIRE project).

- **PentaBDE: Pentabromodiphenyl ether (CAS Nr. 32534-81-9; EC Nr. 251—94-2):** The RAR was finalized in 2001. PentaBDE is a flame retardant used mainly in the polyurethane foam industry. Local releases may occur in manufacture, from articles produced, and in disposal in landfills. There is a need for additional data generation especially in toxicity to WWTP organisms and in long term accumulations in all accumulative compartments as a result of long-term releases. There is a need for limiting the risks, especially applied to increases in local sediment and terrestrial concentrations due to releases. Once released to the environment from both point and diffuse sources, PentaBDE is transported widely and accumulates in the food chain. On the human health side, there is a large stated need for more information on dermal exposure, movement of product from breast milk into infants, toxicity to liver. The risk reduction measures proposed a restriction on the marketing and use of the product, but to not specify needed data requirements with a view to reducing the use of animals in testing.

- **HBCDD: Hexabromocyclodecane (CAS Nr. 25637-99-4; EC Nr. 247-148-4**): the RAR is not yet finalised. However its Environmental part suggests concerns for aquatic and terrestrial compartments (for local site-specific and generic scenarios), together with effects on the food chain (secondary poisoning). The PBT assessment is still ongoing, but HBCDD fulfils the vB and T-criteria. Thus it is sufficiently persistent to behave like a PBT/vPvB substance, i.e. it accumulates in predators even in remote areas. On the Human Health side, there is a need for further information and/or testing in order to address the uncertainties relating to potential for bioaccumulation, potential excretion of HBCDD to breast milk, and indications of developmental neurotoxicity.