

Brief report from the 17th PBT EG meeting (Helsinki, 2-3 November 2017)

In total 26 external participants were present in the meeting representing 15 member states and 5 stakeholder organisations. Eight substances were on the meeting agenda, of which two were discussed in closed session and six in open session. Furthermore, two generic topics were discussed in open session.

Substance highlights of the meeting were:

- The experts discussed the bioaccumulation assessment of D6 and asked for few minor refinements. Overall the MS experts which participated in the discussion (most of the MS experts of the group) supported UK's proposal on a vB -conclusion.
- Two phenolic benzotriazoles (ES, SE), related to substances already included in the Candidate List (UV-320, UV-327, UV-328 and UV-350). The Expert Group supported the read-across approach for P-assessment proposed for both the ES and SE cases. Subsequently, the substances would seem to fulfil the vP criterion. Furthermore, ES, SE, DE and ECHA, aim to carry out a group approach on phenolic benzotriazoles, which in total make a large group of substances.

For several substances on the agenda, the Expert Group considered it necessary to assess their potential to bioaccumulate in air-breathing organisms. However, there are several challenges to be tackled before that can be done in a systematic manner. E.g., clarification is necessary as to whether human biomonitoring data can be requested. Further, approaches for use of toxicokinetic metrics in the B-assessment and for interpretation of in vitro metabolism and molecular docking tests and models in the B-assessment need to be developed.

ECHA provided an overview of the comments received on ECHA's document on "Speeding up the PBT/vPvB assessment". The suggestions received will be used to help speed up the assessment and identification of suspected PBT substances. For example, requesting all data relevant to clarify a PBT/vPvB concern in one decision (where possible) under Substance Evaluation, re-consideration of the appropriate deadlines for sequential testing strategies, annual tracking of the status of suspected PBT cases.

ECHA also provided an overview of the learnings from annulment actions/appeals against ECHA Decisions (to the General Court of the European Court of Justice and/or to ECHA's Board of Appeal) in relation to PBT/vPvB assessments. Some of the main learnings have been:

- i. ECHA is not bound by law or previous practice to require testing on constituents of the substance only if the mass fraction of a constituent exceeds 0.1% w/w (cf: MCCPs SEv case). It is rather for the Agency to identify the appropriate method for identification of PBT/vPvB properties.
- ii. The persistence criteria set out in Annex XIII refer to the intrinsic hazardous properties of a substance and not to the risk(s) arising from the actual use(s).
- iii. There is nothing in the REACH Regulation requiring further or different persistence testing depending on the use. Additionally, persistence testing can be required in all compartments where the substance is potentially present (i.e. not only for the compartments covered by the CSA of the registration).

ECHA also provided an overview on the status of the project on harmonisation of the use of weigh-of-evidence approaches and uncertainty analysis in the context of the ECHA processes. The background document and the reporting template will be published on the ECHA website soon. ECHA asked the members to consider and comment whether they would deem for the purpose of PBT assessment more specifically tailored templates necessary. Discussion on this could be scheduled for the Expert Group meeting in spring. For the B-assessment such development is already on-going as a CEFIC-LRI funded project on "Bioaccumulation assessment tool (BAT)", which the PBT EG had commented in written procedure in September 2017.

Substances discussed in the 17th PBT EG meeting:

EC number	Substance Name	Authority
208-762-8	Dodecamethylcyclohexasiloxane (D6)	United Kingdom
222-020-0	Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate (or TOTM)	Austria
251-118-6	N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide)	Norway
264-120-7	quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides	Italy
400-830-7	A mixture of: α -3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl- ω -hydroxypoly(oxyethylene); α -3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl- ω -3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyloxypoly(oxyethylene) (UV-1130)	Sweden
407-000-3	A mixture of branched and linear C7-C9 alkyl 3-[3-(2H-benzotriazol-2-yl)-5-(1,1-dimethylethyl)-4-hydroxyphenyl]propionates	Spain
430-050-2	A mixture of: N,N'-ethane-1,2-diylbis(decanamide); 12-hydroxy-N-[2-[1-oxydecyl]amino]ethyl]octadecanamide; N,N'-ethane-1,2-diylbis(12-hydroxyoctadecanamide)	Spain
447-780-2	Shale Oil Bitumen	Estonia