

Brief report from the 21st PBT EG meeting (Helsinki, 14-15 May 2019)

In total 26 external participants were present at the meeting, representing 17 member states and 4 stakeholder organisations. The meeting agenda comprised discussion on five substance cases and some PBT-guidance and approach development related issues. Four substance cases were discussed in closed session. At the 21st meeting the 200th substance was discussed by the PBT EG since the start of the group in 2012.

Substance discussion main outcomes:

- Trigonox 29 (Di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide): Although results from studies are pointing towards vPvB properties of the substance, this CoRAP follow up case could not be concluded because the P assessment needs further refinement. The group discussed how to address the significant rate of volatilisation observed during the sediment simulation test and how to calculate the results.
- 1,4-Dioxane: Point for discussion was the P assessment. There is no direct PBT concern for the substance, however, 1,4-dioxane raises concerns given that the substance is carcinogenic and found in drinking and river water. Advice was given to refine the P assessment, including consideration of the need for further testing. Information relevant for risk management should also be considered and reported.
- Disperse Violet 057 and Solvent Blue 122: These two related phenyl amino anthraquinone dye substances are being assessed as a group and read-across is envisaged and will be further explored. The experts considered further testing necessary and as a first step simulation testing for P and identification of degradation products.
- DCBS: Studies supporting the vPvB status of DCBS (N,N-dicyclohexylbenzothiazole-2-sulphenamide) were discussed as a preparatory step for submission of an Annex XV dossier to identify the substance as SVHC.

ECHA presented its management approach for groups of substances, which is a central part of ECHA's new regulatory strategy. Once a strategic plan for a substance group or some group members is drawn up, PBT assessment can be one of the next steps of the regulatory work to be carried out. Two options for ways of working with the PBT EG were introduced to the group for further consideration. Existing methods developed and applied in the PBT EG for working with groups of substances, such as the arrow head approach were highlighted, as well as some examples where substances have been assessed as groups.

With respect to approach development, the focus at this meeting was on using toxicokinetic (TK) data for B-assessment. After reflection on learnings gained so far from the various activities on this topic, the Expert Group felt that it should be possible to establish a relationship between BMF and elimination half-life in mammals and from this to potentially derive half-life cut-off value(s) suitable for benchmarking in B-assessment.

Additionally, short status updates on several of the on-going approach development topics and on current ECETOC projects were presented. Learnings from different testing strategies in the SEV process, e.g. parallel versus tiered testing, were also discussed.

Substances discussed in the 21st PBT EG meeting:

EC number	Substance Name	Submitted by
229-782-3	Di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide (Trigonox 29)	Germany
204-661-8	1,4 Dioxane	Germany
216-475-4	1-hydroxy-4-[[4-[(methylsulphonyl)oxy]phenyl]amino]anthraquin (Disperse Violet 057)	Belgium
267-636-0	N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo 1-anthryl)amino]phenyl]acetamide (Solvent Blue 122)	Belgium
225-625-8	N,N-dicyclohexylbenzothiazole-2-sulphenamide (DCBS)	Germany