

SUMMARY REPORT OF THE 23RD PBT EXPERT GROUP MEETING

The 23rd meeting of the PBT Expert Group (PBT EG) was hosted by ECHA on 29-30 October 2019. The meeting was attended by 25 participants representing 15 Member States, the European Commission, Switzerland and 3 accredited stakeholder organisations (ECETOC, CEFIC and Concawe). The group discussed ten substances in closed and open sessions, three of which were discussed as a group of pigments. All ten substances were REACH substances and are currently under substance evaluation (SEv). Additionally, a number of PBT approach development topics were discussed.

Main outcomes of the substance discussions

Closed session

- BCPS (4,4'-Dichlorodiphenyl sulfone)(CoRAP 2019, assessed by AT): There was agreement by a majority of the PBT EG that this substance can be considered vPvB based on the available data. There are various lines of evidence pointing to biomagnification in terrestrial food-chains and to high bioaccumulation in the environment.
- DBT m cresol (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol)(CoRAP 2019, assessed by FR):. The substance may be borderline vB, however more detailed information on available studies was requested from FR to enable conclusions on the B- and T properties. The PBT EG agreed that degradation simulation testing will be needed to clarify the P concern if this substance fulfils the B/vB criteria. The OECD 309 was recommended as the preferred study if technically feasible Case discussion will be continued in written procedure.
- Octocrylene (2-propenoic acid, 2-cyano-3,3-diphenyl-, 2-ethylhexyl ester)(CoRAP 2012, assessed by FR): Discussion was mainly focused on the bioaccumulation potential. The dietary OECD 305 study was seen as valid and in line with other presented evidence, it points towards the substance not meeting the B-criteria.

Open session

- Group of Nitrophenyl azo dyes (Yellow pigments); PY 74 (2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide), PY 65 (2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide) and PY 3 (2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide)(CoRAP 2019, assessed by IT): The PBT EG agreed that more testing will be needed on P, B and T to clarify the PBT properties. There was clear support for requesting simulation testing in sediment or soil, but also testing in surface water was considered potentially feasible.
- Hexamethyldisiloxane (L2) (CoRAP 2013, assessed by UK): UK PBT experts were not able to attend the meeting due to Brexit, but the case was presented by NO. UK sought advice on the interpretation of the OECD 308 simulation study and on the vP conclusion they proposed based on derived half-life in sediment. The PBT-EG considered that it should be further explored whether a credible mass-balance can be established for the test system in order to conclude on the P property.
- Bis(2-ethylhexyl)amine (CoRAP 2019, assessed by PT): PBT EG discussed whether there was enough data from screening level biodegradation tests to conclude on P. BCF estimations were also discussed. The group noted that the substance is ionising with surface activity and that this needs to be taken into account in the assessment. PT suggested to share additional information on ready biodegradability tests and the group agreed to provide written comments once this information is available.

- Trigonox 301 (Methylethylketone peroxide trimer) (CoRAP 2019, assessed by NL): The PBT EG supported the proposed testing strategy, starting by requesting further information on persistency. There was no clear conclusion on the most appropriate simulation test method but the options preferred were first either OECD 309 with the modifications or OECD 307.
- Decalin (Decahydronaphthalene) (CoRAP 2012, assessed by FI): The validity of the simulation study in surface water (OECD 309) was discussed as there had been significant modifications to the test because of the volatile nature of the substance. The test item had been dosed by means of silicone oil as a carrier. Other data on primary biodegradation of the substance was also discussed. It was agreed that the members would provide further written comments on the questions brought forward by Finland.

General PBT-related approach development topics

ECHA and Germany reported on their findings and views with regard to the applicability of the BAT tool (Bioaccumulation assessment tool), developed by Arnot Research and Consulting as a Cefic-LRI project in order to facilitate transparent weight of evidence based bioaccumulation assessments.

Establishment of a working group in the context of the approach development topic "Use of Toxicokinetic Data in B-assessment for terrestrial organisms" was agreed. Several members from MSCAs and Stakeholder organisations confirmed their participation. Following-up discussion of the topic at the previous PBTEG meeting, it was agreed that a first deliverable of the WG should be a scoping and planning paper for development of a screening approach which would allow to deprioritise substances from the suspicion to accumulate in air-breathing organisms. Potential time frame 1st or 2nd PBTEG meeting 2020.

The discussion on the suitability of the hydrocarbon block method (HCBM) for PBT assessment of petroleum and coal stream UVCBs continued with presentation of NL's toxicity assessment for the group of 3-ring PAHs and their alkylated derivatives (C14-18). Written commenting of the assessment report was agreed and discussion will continue once NL has taken comments received into account.

Short status updates were presented on (i) current ECETOC projects, (ii) the ECHA led project "Expectations and limitations of chemical analysis in environmental fate testing for REACH" and (iii) progress with assessment of non-CoRAP substances. For the latter point (iii) some members expressed interest in performing assessments of not yet assigned non-CoRAP substances.

Substances discussed at the 23rd PBT EG meeting:

EC number	Substance Name	Submitted by
201-247-9	BCPS (4,4'-Dichlorodiphenyl sulfone)	Austria
201-618-5	DBT m cresol (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol)	France
228-250-8	Octocrylene (2-propenoic acid,2-cyano-3,3-diphenyl-, 2-ethylhexyl ester)	France

228-768-4	PY74 (2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide)	Italy
229-419-9	PY65 (2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide)	
229-355-1	PY3 (2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide)	
203-492-7	Hexamethyldisiloxane	UK (NO)
203-372-4	Bis(2-ethylhexyl)amine	Portugal
429-320-2	Methylethylketone peroxide trimer (Trigonox 301)	the Netherlands
202-046-9	Decahydronaphthalene (Decalin)	Finland