SUMMARY REPORT OF THE 34th PBT EXPERT GROUP MEETING

The 34th PBT Expert Group (PBT EG) meeting was hosted by ECHA on 26-27 September in Helsinki. PBT EG members provided advice on the assessment of three CoRAP substances. The outcomes of the substance discussions are listed in the table below. It includes also the three written procedures, for which the outcome was reported at the meeting. In addition to the substance discussions, the status of grouping and assessment of regulatory needs (ARN) of PBT/vPvB and PMT/vPvM substances and a summary of the learnings from PBT related appeals were presented by ECHA.

ECHA recognised comments provided by the PBT EG members on the draft CLP Guidance for new PBT/vPvB and PMT/vPvM hazard classes in June 2023 and provided a summary of how these comments were considered. The revised draft guidance was submitted to the Partner Expert Group (PEG) consultation in September 2023.

30 participants representing 14 Member States, Norway, Switzerland and 4 accredited stakeholder organisations (CEFIC, Concawe, ECETOC and EEB) participated.

Two ad-hoc meetings organised between the 33rd and 34th plenary meetings are also listed in the table below.

Main outcomes of the substance discussions

Closed session

- EC 939-505-4; tert-butylphenyldiphenyl phosphate (CoRAP 2023; assessed by FR): This multiconstituent substance is under Substance Evaluation (SEv) for endocrine disruptive (ED) properties of the potential degradation products. Formation of p-tert-butyl phenol and tri-phenyl phosphate was observed in a sediment microcosm study but not quantified. p-tert-butyl phenol is identified as a substance of very high concern with endocrine disrupting properties (Article 57(f) of Regulation (EC) 1907/2006 (REACH). CATALOGIC and EAWAG BBD pathway prediction model predicted likely formation of p-tert-butyl phenol. Thus formation of ED degradation products with ED properties was considered plausible. Based on the available information, also PBT properties of the substance was considered relevant to be studied further by first clarifying persistence of the constituents of the substance.

- EC 248-948-6; ditolyl ether (CoRAP 2014, assessed by NL): Results from OECD TG 309, 305 and 319A studies were discussed. For the 2,2’ isomer, a degradation half-life > 40 days was determined in the surface water simulation biodegradation study, which had a relatively high suspended matter content. Extensive fish growth and lipid increase over the course of the aqueous exposure bioaccumulation study required recalculation of the BCF to consider this significant deviation from the requirements for a standard TG 305 study. A qualitative *in vitro* study with trout hepatocytes focused on metabolite formation rather than clearance rate. Rapid disappearance of parent as seen in the *in vitro* study could not be observed in the *in vivo* fish bioaccumulation study. P and B conclusion was supported for the 2,2’-isomer, and next tier testing (algae toxicity) is therefore required.

Open session

EC 435-790-1; 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)-hexane (CoRAP 2018, assessed by ES): The PBT EG supported

the vPvB conclusion. Bioaccumulation was discussed already at 19th PBT EG meeting. Dissipation half-life was > 180 days in the OECD TG 308 study (under both, aerobic and anaerobic conditions) with some deviations from the TG (e.g. shaking as aeration method and lower water sediment ratio).
P, M, and B properties of similar hydrofluoroethers (HFEs) (EC 484-450-7 and EC 422-270-2) were also discussed. Weight-of-evidence including screening tests, predictions and potential read-across from structurally similar EC 435-790-1 was considered to support the vP conclusion. Further assessment including potential for protein binding would be needed for B assessment. Also it was noted that M assessment and possibility to apply arrowhead approach will have to be further scrutinised.

General PBT assessment related guidance and approach development topics

The need for further guidance for biodegradation testing of difficult to test substances was acknowledged based on consideration presented by Phillip Mayer and Heidi Birch from Technical University of Denmark (DTU).

ECHA provided an overview of the recent Board of Appeal and Court cases (T-636/19 (under appeal in C-293/22 P), A-005-2021, A-012-2021, T-121/23, T-226/18 and T-519/18 (under appeal in C-558 and 559/21 P), A-001-2022 and A-009-2023) and their potential impact on the PBT EG work.

Project presentations by CEFIC supporting experts:

- LRI-ECO54: Developing a tiered modelling framework in support of risk assessment of chemical substances associated with mobility concerns" by Li Li, University of Nevada, US
- LRI-ECO55: Assessing the impact of sample collection on microbial population and validity criteria in the OECD 309 surface water mineralisation test by Sigrid Hakvåg, SINTEF Ocean, Department of Climate and Environment, Norway

Substances discussed at the 34th PBT EG meeting:

MS	EC number	Substance Name	Outcome	Session	CoRAP year
NL	248-948-6	ditolyl ether	PB Testing needed (T)	Closed	2014
ES	435-790-1	3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)-hexane	vPvB	Open	2018
FR	939-505-4	tert-butylphenyldiphenyl phosphate	Testing needed	Closed	2023

Written procedures and ad-hoc meetings between 33rd and 34th meeting

MS	EC number	Substance Name	Session	Notes
PT	203-372-4	bis(2-ethylhexyl)amine	closed	WP
ES	403-080-9	Sodium 3-(2H-benzotriazol-2-yl)-5-sec-butyl-4-hydroxybenzenesulfonate	closed	WP

ECHA	n/a	Ad-hoc meeting on CLP draft guidance	open	Ad-hoc meeting 16-17 May 2023
ECHA	n/a	Ad-hoc meeting on monitoring project updates: - Life Apex- Systematic use of contaminant data from apex predators and their prey in chemicals management; demonstration of available tools (UBA/Environmental Institute (SK) - Cefic/Silicones Europe sector group: Investigation on the Occurrence of Cyclic Volatile Methylsiloxanes (cVMS) in Air, Soil, Vegetation and Aquatic Biota in the Antarctica (Cefic)	open	Ad-hoc meeting 13 June 2023