SUMMARY REPORT OF THE 24th PBT EXPERT GROUP MEETING

This first virtual PBT Expert Group (PBT EG) meeting was hosted by ECHA on 13-14 May 2020. Despite the different set-up, participants actively contributed to discussions, gave their expert opinion on the interpretation of data and testing strategies and reported on the progress of various approach development topics. Broad agreement was reached on **the PBT-properties of the three-ring PAHs and their alkylated derivatives (C14-18)** after a final discussion of the toxicity of this block as an example case for the applicability of the **hydrocarbon block method (HCBM) for PBT assessment of petroleum and coal stream UVCBs**. Furthermore, the group gave advice on the assessment of **four substances** in closed and open sessions. Three substances were REACH substances and are currently under substance evaluation (SEv), one substance to be proposed as POP was discussed. Outcome of **nine written procedures** (WP) was reported with indication of further actions. For three cases, Members States consider to propose the substance as SVHC. 44 participants representing 18 Member States, the European Commission, Switzerland and 4 accredited stakeholder organisations (ECETOC, EEB, CEFIC and Concawe), attended the meeting.

Main outcomes of the substance discussions

Closed session

- EC 237-695-7, bis(dibutyldithiocarbamato-S,S')copper (CoRAP 2020, assessed by FR): The interpretation of OECD 308 study regarding the impact of significant NER formation and a bi-phasic decline of the parent substance was discussed. Further information on study details and the identity of transformation products are needed in order to reach a conclusion on P.

- EC 700-992-1, Alkanes, C16–(branched), C20-(branched) and C24-(branched) (tetrabutan) (CoRAP 2014, assessed by NO): New information on bioaccumulation potential on heptamethylnonane, an analogue substance addressing C16 fraction of the registered substance, has become available after the request for OECD TG 309. While read-across was considered plausible, the bioaccumulation study was not considered adequate to conclude on B. Hence, the BCF estimation is still uncertain. There was no support to change the order of testing starting from P. Testing a representative structure within the substance due to the complexity of the substance was discussed.

Open session

- EC 220-864-4, Chlorpyrifos (POP proposal, DE for the EU). The substance is a pesticide, however, its use within the EU was not approved anymore by EFSA last year. The members of the PBT EG discussed a number of issues in relation to persistence, bioaccumulation, toxicity, long-range transport potential and interaction of these factors and made proposals how to further assess the POP properties of the substance.

- EC 473-390-7, reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl) (CoRAP 2016, assessed by BE): FC-770 is a very volatile perfluorinated substance which can be regarded as very persistent due to the carbon-fluorine bonds. The substance does not meet the T criterion for human health. A Pilot study based on modified OECD TG 305 protocol (aqueous exposure) was discussed. The PBT-EG acknowledged the technical difficulties due to the volatile nature of the substance and the uncertainties due to the test setup. The

discussion resulted in diverging views on the reliability of the study and on the possibility to conclude on vB. BE considered that due to the technical difficulties new OECD TG 305 (dietary) study would not benefit the assessment. BE was suggested to request further information on the fish lipid content and consider the role of regulation under the Montreal Protocol as the substance is a greenhouse gas. BE considers proposing the substance as SVHC due to vPvB properties.

General PBT-related approach development topics

Toxicity of three-ring PAHs and their alkylated derivatives (C14-18) is an example case for the application of the hydrocarbon block method (HCBM) for PBT assessment of petroleum and coal stream UVCBs - T assessment. NL experts responded to comments they had received from the PBT EG members since the previous PBT EG meeting. Especially the impact of phototoxicity was discussed at the current meeting. Overall, there was broad agreement by the members from MSCAs and the stakeholder organisation EEB to the assessment approach taken by NL and the conclusion that the constituents of the block can be considered to meet the T-criteria. Concawe experts disagreed since they question the relevance of the non-standard experimental data for C15-C16 and no experimental data are available for C17.

The following approach development related projects were presented:

- Life Apex –project: Systematic use of contaminant data from apex predators and their prey in chemicals management. The various project aims include the demonstration of which substances occur in top predators and that non-target and target-screening data can be used to prioritize substances for PBT-assessment. Further objectives are evaluation of the effectiveness and impact of substance risk mitigation measures, and provision of guidance and methods on how to use such information in regulatory context.

- LRI-ECO33: Strengthening the use and interpretation of dietary bioaccumulation tests for hydrophobic chemicals (ADME calculator): Frank Gobas presented the outcome of the project and advertised the Excel based spreadsheet to calculate BCF and BMF based on a refined toxicokinetic model framework for dietary bioaccumulation test.

- LRI-ECO 34: Rapid estimation of bioaccumulation by a tiered testing strategy of combined modelling (e.g PBTK models) and *in vitro* testing was presented. The *in-vitro* assays consider major sites of uptake of chemicals (gill, gut) as well of biotransformation (liver, and potentially gill and gut). Having multiple lines of evidence (from TK models and in vitro assays) help to reduce the uncertainty in the BCF prediction. One outcome of the project was that degradation of substances with logKow < 4 seem to be driven by gill and liver biotransformation, while degradation of substances with logKow >5.5 seem to be driven by liver and gut biotransformation.

- LRI-ECO 52: Expanding the conceptual principles and applicability domain of persistence screening and prioritization frameworks, including single constituents, polymers and UVCBs. This project kicked off in 2020 and aims to improve guidance on use of weight of evidence.

ECHA presented the plan for approach development topics to be addressed in 2020 and requested input for identification of Chapter R.11: PBT/vPvB assessment guidance update needs.

Substances discussed at the 24th PBT EG meeting:

EC number	Substance Name	Submitted by
237-695-7	bis(dibutyldithiocarbamato-S,S')copper	France
700-992-1	Alkanes, C16–(branched), C20-(branched) and C24-(branched) (tetrabutan)	Norway
220-864-4	Chlorpyrifos	Germany/ Commission
473-390-7	reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)	Belgium