SUMMARY REPORT OF THE 26th PBT EXPERT GROUP MEETING

The PBT Expert Group (PBT EG) meeting was virtually hosted by ECHA on 27-28 October 2020. ECHA presented an update on GMT work focusing on interaction possibilities with the EG, the state of play of the Non-CoRAP and NONS cases on the PBT EG list and learnings from appeal cases. Advice was provided on the assessment of **six substances** in closed and open sessions. All substances were REACH substances of which four currently under substance evaluation (SEv), one SVHC and one non-CoRAP substance. Three of the substances were concluded potentially not PBT/vPvB pending the possibility to refine the assessment. To reach the conclusion on PBT properties further testing would be required on two of the discussed substances. One substance was considered to meet the criteria for P/vP, and T being as well very mobile. The outcome of **two written procedures** (WP), including one POP substance, was reported. The discussion on approach developments focused on review of the ECHA guidance update needs and related priority setting.

38 participants representing 17 Member States, Norway, Switzerland and 4 accredited stakeholder organisations (CEFIC, Concawe, ECETOC and EEB) attended the meeting. The feedback from the participants at the end of the meeting was positive, especially regarding the use of the added functionalities of the virtual meeting tool to increase interaction amongst the meeting participants.

Main outcomes of the substance discussions

Closed session

- EC 926-564-6; 2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether (CORAP 2016 assessed by DE): New information on dietary bioaccumulation study (OECD TG 305) for this UVCB substance was discussed. No uptake was observed while the used analytical method was lacking adequate sensitivity. Refinement of the assessment including e.g. total bromine concentration, potential uptake in mammals, and molecular size may allow concluding on the B potential.

- EC 260-830-6; Tetraphenyl m-phenylene bis (phosphate) (CORAP 2020, assessed by FR): This UVCB substance is also under ED assessment. Based on contradicting screening studies on degradation, WoE on bioaccumulation and aquatic toxicity studies on tree trophic levels, the PBT EG considered that the substance would likely not biodegrade fast and is likely not bioaccumulative or toxic.

- EC 420-470-4; A reaction mass of: dicalcium (bis(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)dihydroxide; tri-calcium (tris(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)tri-hydroxide; poly[calcium ((2-hydroxy-5-tetrapropenyl-phenylmethyl)methylamine)hydroxide] (NONS, assessed by ES): This is a complex UVCB with constituents as main fractions being monomers, dimers, trimers and tetramers. The main fractions screen potentially P/vP with the monomers and dimers screening potentially B/vB. The PBT EG advised ES to clarify first the substance ID, including the concentrations of unreacted alkyphenols which pose an ED concern.

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Open session

- EC 204-661-8; 1,4-Dioxane (SVHC proposal by DE): Revised assessment including new information on persistency (OECD TG 309) was presented. Studies supporting the P/vP status as well as mobility of the substance were discussed as a preparatory step for submission of an SVHC proposal. DE will propose the substance as SVHC based on Art 57 (f). PBT EG advised to consider also identification based on Art 57 (a) following the adoption of the RAC opinion on Carc. 1B classification.

- EC 273-066-3; Phenol, isopropylated, phosphate (3:1) (CoRAP 2020 assessed by NL): The PBT EG was consulted on the testing strategy for the UVCB substance to assess persistency. The group discussed the selection of constituents and the proposal to test first in enhanced ready tests rather than to go directly to biodegradation simulation testing, with the expectation that the substance may degrade if the bioavailability is increased.

- EC 403-030-6; A mixture of: O,O-di(1-methylethyl)trithio-bis-thioformate; O,O-di(1-methylethyl)tetrathio-bis-thioformate; O,O-di(1-methylethyl)pentathio-bis-thioformate (CoRAP assessed by BE): Simulation test in surface water (OECD TG 309) showed mineralisation to a relevant extent and rapid primary degradation. Unidentified degradation product was considered potentially P/vP. Refinement of the assessment including prediction of the potential degradation products and their fate may allow concluding the substances as not PBT/vPvB.

Grouping of substances

ECHA presented an update on managing groups of substances with Group Management Teams (GMTs). ECHA suggested possibilities for interaction with the PBT EG for specific, difficult cases, with the aim to increase efficiency. The PBT EG members welcomed the presentation; there was interest in the GMT process and the resulting reports.

NONS/non-CoRAP

ECHA presented the state of play of the Non-CoRAP and NONS cases, requested feedback on the pending hazard assessment outcome documents to conclude the cases that have been assessed and made a call for volunteers to assess the few NONS that are still on the PBT list.

Legal update

ECHA presented learnings from appeal cases highlighting main pleas related to the PBT assessment such as testing fraction of UVCB substance, identification and assessment of PBT/vPvB properties of degradation products, definition of relevant conditions, relevant test compartments and non-extractable residues.

General PBT-related approach development topics

The following approach development related projects were presented:

- The following three projects were presented by CEFIC:
  - LRI ECO37 –Development of a bioaccumulation assessment strategy for surfactants by Steven Droge, University of Amsterdam
  - LRI ECO41 – Improved characterization of partitioning and biotransformation for screening organic compounds for the potential to bioaccumulate in air-breathing species by Frank Wania, University of Toronto Scarborough

- LRI ECO40 – Investigations on the bioconcentrations of xenobiotics in the freshwater amphipod *Hyalella azteca* and inter-laboratory comparison of a new BCF test protocol by Björn Hidding on behalf of Christian Schlechtriem, Fraunhofer IME
- LRI ECO53 – A chemical categorization approach for Long-Range Transport Potential (LRTP) assessment by Knut Breivik, NILU

ECHA presented the result of the review of the ECHA PBT assessment guidance update needs. The review consisted of contribution from the EG members and outcome of the approach development topics. Priorities of the guidance update and communication needs will be further discussed.

Substances discussed at the 26th PBT EG meeting:

EC number	Substance name	Submitted by
260-830-6	Tetraphenyl m-phenylene bis (phosphate)	France
403-030-6	A mixture of: O,O-di(1-methylethyl)trithio-bis-thioformate; O,O-di(1-methylethyl)tetrathio-bis-thioformate; O,O-di(1-methylethyl)pentathio-bis-thioformate	Belgium
273-066-3	Phenol, isopropylated, phosphate (3:1)	Netherlands
420-470-4	A mixture of: dicalcium (bis(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)dihydroxide; tri-calcium (tris(2-hydroxy-5-tetra-propenylphenylmethyl)methylamine)tri-hydroxide; poly[calcium ((2-hydroxy-5-tetrapropenyl-phenylmethyl)methylamine)hydroxide]	Spain
926-564-6	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether	Germany
204-661-8	1,4-Dioxane	Germany