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**SUMMARY REPORT OF THE 33<sup>rd</sup> PBT EXPERT GROUP MEETING**

The 33<sup>rd</sup> PBT Expert Group (PBT EG) meeting was hosted by ECHA on 25-26 April remotely. PBT EG members provided advice on the assessment of three CoRAP substances and on five non-CoRAP substances. The discussion outcome and two written procedures, for which the outcome was reported at the meeting, are listed in the tables below.

The PBT EG was informed on the following upcoming ad-hoc meetings:

- PBT EG ad-hoc meeting on draft CLP Guidance for new hazard classes PBT/vPvB and PMT/vPvM (16-17 May 2023)
- PBT EG ad-hoc meeting presenting two monitoring projects (13 June 2023):
  - Life Apex- Systematic use of contaminant data from apex predators and their prey in chemicals management; demonstration of available tools. <https://lifeapex.eu/>
  - Cefic/Silicones Europe sector group: Investigation on the Occurrence of Cyclic Volatile Methylsiloxanes (cVMS) in Air, Soil, Vegetation and Aquatic Biota in the Antarctica

The PBT EG was also informed that cross check Partner Expert Group (PEG) consultation on the proposed revisions of the ECHA guidance IR&CSA, Chapter R.11 and relevant sections in Chapter R.7b and R.7c was launched on 11<sup>th</sup> of April and runs until 2<sup>nd</sup> May 2023.

39 participants representing 14 Member States, Norway, Switzerland and 5 accredited stakeholder organisations (CEFIC, Concawe, Croplife Europe, ECETOC and EEB) participated.

**Main outcomes of the substance discussions****Closed session**

- EC 241-867-3; 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane (M3T) and EC 217-496-1; 1,1,1,3,5,5,5-heptamethyltrisiloxane (H-L3) (assessed by NO; and group assessment approach by ECHA for linear/branched siloxanes):

ECHA presented a hypothesis for a group assessment of linear and branched siloxanes for persistence and bioaccumulation. The group of substances assessed consisted of L2, L3, Ethyl trisiloxane, H-L3, C6 trisiloxane, C8 trisiloxane, KF-56A, L4, M3T, PhM3T and L5. In the proposed grouping for P and B properties, it was hypothesised that the resistance to degradation increases with increasing number of Si atoms and molecular weight, and the bioaccumulation potential is driven by log K<sub>ow</sub> and chemical structure. The PBT EG supported the grouping approach in general with some recommendations. PBT EG proposed to further assess some of the bioaccumulation studies, to explain mechanism of biotransformation and biodegradation in more detail and to further clarify the role of some of the functional groups.

NO has submitted SVHC intention for six of these siloxanes (L2, L3, L4, L5, H-L3 and M3T) for SVHC identification (PBT/vPvB). NO presented more details on M3T and H-L3 assessments, including the assessment of OECD TG 308 study on M3T. Taking into account the information on the source substance (L3) and new OECD TG 308 study on M3T, there was general support for the vP conclusion for both M3T and H-L3. Overall, NO was advised to refine the assessment by addressing the uncertainties observed in the OECD TG 308 and to address the role of functional groups in more detail.

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- EC 251-020-3; [3R-(3 $\alpha$ ,3 $\beta$ ,7 $\beta$ ,8 $\alpha$ )]-1-(2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl)ethan-1-one (dossier evaluation, assessed by ECHA):

The PBT EG supported P/vP conclusion based on the available OECD TG 309 study, and suggested some further refinements to address the incomplete mass balance. The OECD TG 305 study provided BCFs for intestine, head and edible part of the fish but a BCF for the whole fish was not reported. PBT EG recommended to explore possibilities to further refine the available OECD TG 305 results before requesting further data on bioaccumulation. PBT EG took note of the need for data generation for HH (i.e. PNDT) and ENV (i.e. long-term fish) toxicity of the substance.

- EC 246-678-3; [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (CoRAP 2014, assessed by NL):

New information received on degradation, bioaccumulation and aquatic toxicity (OECD TG 309, OECD TG 305, OECD TG 211 and OECD TG 210) was presented by NL. Only persistency and toxicity assessments were discussed. The PBT EG generally supported the conclusion of the substance as P/vP and suggested some further refinements to address the incomplete mass balance. It was not possible to conclude on toxicity based on the aquatic toxicity tests due to the uncertainty of the actual exposure concentrations and sorption of the substance. Further discussion is needed on how to overcome these types of uncertainties in general. Available information on toxicity to human health is to be assessed before requesting further information on aquatic toxicity.

- EC 700-960-7; Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol (CORAP 2012, assessed by DK):

This multi-constituent substance has been evaluated by DK to clarify PBT/vPvB and ED concerns. The results of the new OECD TG 309 study, information on bioaccumulation and ecotoxicity of the dimer constituent were presented. Information on the composition and bioaccumulation of the trimer constituent were also presented. The PBT EG generally supported the read-across on degradation from dimer to trimer constituent and recommended that justification for the read-across could be improved by including considerations on molecular structure, QSAR data and comparison of degradation pathways for the dimer and trimer constituents. The PBT EG generally supported the vP conclusion for the dimer constituent and the vPvB conclusion for the substance relying on the vPvB conclusion of the trimer constituent.

### Open session

- EC 202-394-1; 1H-Benzotriazole (RMOA, assessed by DE):

The substance belongs to the group of benzotriazoles. Information on the widespread occurrence in the surface and ground waters as well as in the drinking water were presented. The PBT EG supported that read across between 1H-BT and its corresponding sodium salt is plausible due to the expected dissociation of the sodium salts to the corresponding sodium cation and benzotriazolidine anion. The PBT EG supported P/vP conclusion based on available data, including two OECD TG 309 studies and M conclusion based on the available adsorption/desorption data (OECD TG 106) and the CLP criteria for mobility. The PBT EG recommended further refinement of the mobility assessment before

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considering vM conclusion. Endocrine Disrupter Expert group (ED EG) supported the ED ENV conclusion ([Summary report of the 22nd ED Expert group meeting](#)).

- EC 249-596-6; Methyl-1H-benzotriazole (RMOA, assessed by DE):

The substance belongs to the group of benzotriazoles. Information on the widespread occurrence in the surface and ground waters as well as in the drinking water were presented. The PBT EG supported that read across between Methyl-1H-BT and its corresponding sodium salt is plausible due to the expected dissociation of the sodium salt to the corresponding sodium cation and methyl benzotriazolide anion. The PBT EG supported P/vP conclusion based on the available data, including a OECD TG 309 study. Based on the available adsorption/desorption data (OECD TG 106) and the CLP criteria for mobility, M conclusion was supported. There was also some support for vM conclusion. However, it was recommended to further assess the adequacy of available adsorption/desorption data before considering vM conclusion. Furthermore, it was noted that based on a newly conducted study, both, Methyl-1H-BT and its corresponding sodium salt, are self-classified by registrants as Repro cat. 2. This indicates that the substances may meet the T criterion.

- EC 203-372-4; bis(2-ethylhexyl)amine (CoRAP 2019, assessed by PT):

Testing strategy for the persistence and bioaccumulation was discussed taking into account new data from enhanced ready biodegradability test showing no degradation in 61 days. The PBT EG supported the need to generate simulation degradation data by requesting an OECD TG 307 study. In addition, it was recommended to address highly variable screening level information by applying a Weight-of-evidence approach. It was agreed that further testing is needed to clarify B concern. Feasibility of a fish bioaccumulation study via aqueous exposure vs dietary exposure was discussed. It was also suggested that a study on *Hyaella azteca* could be considered as part of the bioaccumulation testing strategy.

#### Project presentations:

- Bioaccumulation of Ionisable Organic Compounds in Fish Cell Lines by Fabian Balk, Department of Environmental Toxicology, Eawag, CH.
- Impact of Physicochemical Properties on Accumulation and Decontamination of PCBs in Beef Cow and Calf (PhD thesis) by Sylvain Lerch, AgroPOP project, Agroscope, CH.
- Cefic LRI-ECO53 project: A chemical categorization approach for Long-Range Transport Potential (LRTP) assessment, Knut Breivik, Norwegian Institute for Air Research, NO.

#### Substances discussed at the 33<sup>rd</sup> PBT EG meeting:

MS	EC number	Substance Name	Outcome	Session	CoRAP year
NO	241-867-7	1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane	Refine assessment (vPvB)	Closed	

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NO	217-496-1	1,1,1,3,5,5,5-heptamethyltrisiloxane	Refine assessment (vPvB)	Closed	
ECHA	251-020-3	[3R-(3 $\alpha$ ,3 $\alpha\beta$ ,7 $\beta$ ,8 $\alpha\alpha$ )]-1-(2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl)ethan-1-one	P/vP B: Refine assessment	Closed	
NL	246-678-3	[1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide	P/vP B: not discussed T: Refine assessment	Closed	2015
DK	700-960-7	Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol	vPvB	Closed	2012
DE	202-394-1	Benzotriazole	P/vP M vM: Refine assessment	Open	
DE	249-596-6	Methyl-1H-benzotriazole	P/vP M vM: Refine assessment	Open	
PT	203-372-4	bis(2-ethylhexyl)amine	Testing needed	Open	2019

**Written procedures between 32<sup>nd</sup> and 33<sup>rd</sup> meeting**

MS	EC number	Substance Name	Session	Notes
DE	219-470-5 (UV-P) 221-573-5 (UV-329) 274-570-6 (UV-234) 422-600-5 (UV-928)	Group of phenolic benzotriazoles (UV-P, UV-329, UV-234 and UV-928)	Open	WP
ES	N/A	Phenol, 4-nonyl-, branched	open	WP