

SUMMARY REPORT OF THE 27th PBT EXPERT GROUP MEETING

The PBT Expert Group (PBT EG) meeting was virtually hosted by ECHA on 11-12 May 2021. PBT EG was consulted on the persistence assessment approach of PFAS as a class of substances developed for the PFAS restriction proposal. Action plan of WG on terrestrial bioaccumulation was presented. WG aims to develop an assessment concept for mammals and other air-breathing organisms by the end of 2021. The European Commission reported on the timelines foreseen for the CLP criteria development for PBT/vPvB and PMT/vPvM and requested support by the PBT EG. ECHA presented an update on the review of the ECHA guidance update needs and related action plan.

Advice was provided on the assessment of **nine substances** in closed and open sessions including group assessment of five benzotriazoles. All substances are REACH substances of which three currently are under substance evaluation (SEv), five are non-CoRAP substances and one is NONS. The discussion outcomes are listed in the table below. In addition, the outcomes of **two written procedures** (WP) and one ad-hoc meeting was reported.

45 participants representing 17 Member States, Norway, Switzerland, Commission and 4 accredited stakeholder organisations (CEFIC, Concawe, ECETOC and EEB) attended the meeting.

Main outcomes of the substance discussions

Closed session

- EC 309-912-6; Benzenamine, reaction products with aniline hydrochloride and nitrobenzene (CCH 2016, follow up, CoRAP 2019, assessed by DE): PBT-EG agreed that 1) the OECD TG 309 with enhanced suspended matter concentration was reliable with some refinements needed and 2) the constituent tested was one of the three worst case structures and main constituents present in all samples of this UVCB substance. Testing to proceed on bioaccumulation.
- EC 701-385-4 (old 253-249-4); Bis(nonylphenyl)amine (CoRAP 2021, assessed by FR): PBT EG found the results of the OECD TG 309 difficult to interpret (UVCB, adsorptive), and recommended to revise the calculation of the DT50, and if no conclusion possible, to consider further testing. More information on the available Japanese OECD TG 305 study including details of the test material monoalkylated constituent is needed.

Open session

- EC 221-573-5, EC 274-570-6, EC 422-600-5, EC 223-445-4, EC 219-470-5; group of benzotriazoles (non-CoRAP, assessed by DE): PBT EG agreed that EC 223-445-4 (UV-326) can be considered vP. More refinement of the P assessment based on QSARs, degradation in sediment, soil, aquifer system and a read across for a sediment simulation study is needed for the other substances. The PBT EG supported DE's proposal on vB -conclusion for UV-326. EC 219-470-5 (UV-P) could be considered not B for aquatic organisms, due to log Kow below the trigger value and low fish BCF. However, as it screens B for air-breathing organisms, further assessment in that regards is needed. Further refinement of the B assessment is needed for EC 221-573-5 (UV-329), EC 274-570-6 (UV-234) and EC 422-600-5 (UV-928). The B assessment of UV-928 was based on read across to EC 274-570-6 (UV-234).

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- EC 404-740-9; Ethyl 3,5-dichloro-4-hexadecyloxybenzoate (CoRAP 2016, assessed by SI): PBT EG agreed that based on the provided enhanced screening study with several enhancements applied, including considerably high suspended solids concentration, it was not possible to conclude 'not P' and further testing on persistency is needed.
- EC 250-709-6; Tris(2,4-ditert-butylphenyl)phosphite (NONS, assessed by ES): PBT EG recommended, prior to considering further testing with this substance, to evaluate information on two of its degradation products (CAS 95906-11-9 and EC 202-532-0) or a similar substance (EC 701-028-2), which all are currently under assessment. The available information on the bioaccumulation potential of EC 250-709-6 however shows limited uptake potential.

PFAS restriction proposal

PBT EG was consulted on the persistence assessment approach of PFAS as a class of substances. Assessment presented by NO CA is part of the restriction proposal for PFAS which is under development by Germany, the Netherlands, Denmark, Sweden and Norway. There was general agreement on the approach taken by NO CA, which includes the description of the persistence of key PFAS subgroups or common structure elements of PFAS.

CLP criteria update

The European Commission (COM) is developing CLP criteria for PBT/vPvB and PMT/vPvM substances. COM reported on the timelines foreseen for the CLP criteria development and requested PBT EG support for the scientific discussions related to this work.

General PBT assessment related guidance and approach development topics

- Study on validation of the ***Hyalella azteca* bioconcentration test (HYBIT)** was presented. In the study fish BCFs for difficult to test substances was compared with BCFs derived with HYBIT tests. All substances with fish BCFs > 2000 were also identified as B with HYBIT test but not vice versa. There is a need for further discussion on the applicability of this test in regulatory context. Standardisation on the test method is ongoing in OECD.
- **Working group (WG) on terrestrial bioaccumulation** consists of 16 members from government, industry and academia. Tiered approach including screening phase and definitive assessment for bioaccumulation in terrestrial mammals and other air-breathing organisms is under development. WG aims to develop the concept for further discussion by end of 2021.
- NL presented an **overview of the half-life data in mammals and humans for PFHpA** and related substances as a basis for discussion on its use in regulatory B assessment.
- ECHA presented the status of the review of the ECHA PBT assessment **guidance update needs**. It was agreed that for selected priority topics the content development will start in 2021.
- CEFIC presented the project LRI ECO31.2: 'A multivariate approach to identify key parameters influencing the degradation rates of organic chemicals in water, water-sediment, and activated sludge systems - Clustering and benchmarking: emerging approaches for assessing variable degradation of chemicals in the environment'.

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Substances discussed at the 27th PBT EG meeting:

MS	EC number	Substance Name	Outcome of the discussion	Session	Notes
DE	309-912-6	Benzenamine, reaction products with aniline hydrochloride and nitrobenzene	P: Refine assessment, vP based on one constituent B: Testing needed	Closed	CoRAP 2016
FR	701-385-4	Bis(nonylphenyl)amine	P: Further refinement or possibly testing needed B: Further information needed Follow up in written procedure	Closed	CoRAP 2021
DE	221-573-5 274-570-6 422-600-5 223-445-4 219-470-5	Group of benzotriazoles	P: Refine group assessment B: Refine group assessment vPvB: EC 223-445-4	Open	Non-CoRAP
SI	404-740-9	Ethyl 3,5-dichloro-4-hexadecyloxybenzoate	P: Testing needed	Open	CoRAP 2016
ES	250-709-6	Tris(2,4-ditert-butylphenyl)phosphite	B: Wait for test results with potential read across substances	Open	Non-CoRAP

Written procedures and ad-hoc meetings between 26th and 27th meeting

MS	EC number	Substance Name	Session	Notes
ES	407-000-3 400-820-2 400-830-7 630-348-4	Group of benzotriazoles degrading to M1	Closed	WP
DE	208-008-8	3,7,11,15-tetramethylhexadec-1-en-3-ol	Closed	WP
ES	422-040-1	Cassifix (a mixture of: 4-(2,2,3-trimethylcyclopent-3-en-1-yl)-1-methyl-2-oxabicyclo[2.2.2]octane; 1-(2,2,3-trimethylcyclopent-3-en-1-yl)-5-methyl-6-oxabicyclo[3.2.1]octane; spiro[cyclohex-3-en-1-yl-[(4,5,6,6a-tetrahydro-3,6',6',6'a-tetramethyl)-1,3'(3'aH)-...])	Open	Ad-hoc meeting 25.11.2020