

SUMMARY REPORT OF THE 32nd PBT EXPERT GROUP MEETING

The 32nd PBT Expert Group (PBT EG) meeting was hosted by ECHA on 22 November 2022 remotely. PBT EG members provided advice on the assessment of **one CoRAP substance** in open session. The discussion outcome and **two written procedures** for which the outcome was reported at the meeting are listed in the tables below. Commission provided an update on the new hazard classes in CLP and REACH revision.

The PBT EG was informed that 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 at 21st November and runs until 22nd December 2022.

32 participants representing 15 Member States, Norway, Switzerland, Commission and 4 accredited stakeholder organisations (CEFIC, Concawe, ECETOC and EEB) participated.

Main outcomes of the substance discussions

Open session

- EC 284-325-5; Phenol, 4-nonyl-, branched (CoRAP 2014, assessed by ES): Persistence and bioaccumulation properties were discussed. Some degradation half-lives based on non-standard or read across studies demonstrate low degradation potential in aquatic environment (water and sediment). Bioaccumulation in aquatic invertebrates and field studies indicate potential for bioaccumulation. However, unclarities of the substance composition and the relevance of the information on read-across substance hindered the conclusion of the assessment. Further refinement of the assessment is needed. Depending on the outcome of the refinement a follow-up WP may be proposed.

Update from the Commission on the new hazard classes in CLP and REACH revision

Commission provided a status update on the ongoing revisions on CLP and REACH Regulations. It was informed that Delegated Act for new hazard classes, ED HH, ED ENV, PBT/vPvB and PMT/vPvM is foreseen to be adopted in December 2022 and published in Q1 2023. There will be 24 months transition period for substances and 42 months for mixtures. Expert groups will be consulted for the CLP guidance for these new hazard classes. New hazard classes will also be proposed for the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). REACH revision will entail more information requirements including NAMs, polymer registration, use and exposure and mixture assessment factors. Indicative timing for the adoption of the revision is Q4 2023.

Update on ECHA's work on groups – Hydrocarbylsiloxanes as an example

ECHA's integrated regulatory strategy to achieve our strategic priority, to address all substances requiring regulatory action, was presented. ECHA provided an overview of the ongoing work on the assessment of regulatory needs (ARN) and grouping of substances. So far about 6500 substances belonging to 250 groups have been screened to clarify the regulatory needs. Hydrocarbylsiloxanes was used as an example of such a grouping process.

General PBT assessment related guidance and approach development topics

Integrating new methods in bioaccumulation assessment:

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Overview of the available New Approach Methods (NAMs) for bioaccumulation assessment was presented. Options on how to integrate NAMs such as aquatic invertebrate test using *Hyalella azteca* and biotransformation assays in combination with *in vitro-in vivo* extrapolation in bioaccumulation assessment was discussed. The draft ECHA Guidance IR&CSA (under consultation) will include further advice on how to use NAMs and information on air-breathing organisms as part of the ITS for bioaccumulation.

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 32nd PBT EG meeting:

MS	EC number	Substance Name	Outcome	Session	CoRAP year
ES	284-325-5	Phenol, 4-nonyl-, branched	Refine assessment (P&B)	Open	2014

Written procedures and ad-hoc meetings between 31st and 32nd meeting

MS	EC number	Substance Name	Session	Notes
AT	201-247-9	Bis(4-chlorophenyl) sulphone	closed	WP
ES	422-040-1	Cassifix	open	WP