

SUMMARY REPORT OF THE 29th PBT EXPERT GROUP MEETING

The PBT Expert Group (PBT EG) meeting was hosted virtually by ECHA on 3-4 November 2021. PBT EG was consulted on the concept to consider volatile substances in persistence assessment and relevance of including sterile controls in degradation studies. The Working Group on toxicokinetics presented a tiered screening strategy for substances with potential for bioaccumulation in air-breathing organisms. ECHA presented a status update on the ongoing activities under the review of the ECHA guidance update needs.

Advice was provided on the assessment of **6 substances** in closed and open sessions. All substances are REACH substances of which two are currently under substance evaluation (SEv), one is a dossier evaluation case, three are non-CoRAP substances. The discussion outcomes are listed in the table below.

45 participants representing 15 Member States, Norway, Switzerland, Commission, 4 accredited stakeholder organisations (CEFIC, Concawe, ECETOC and EEB) and Toxicokinetics working group attended the meeting.

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

- EC 700-242-3; Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate (CoRAP 2017, assessed by NL): Based on the biomonitoring study in volunteering workers at the manufacturing site, the substance was considered less bioaccumulative than other PFAS already identified as B via the SVHC process, e.g. PFHxS. In the absence of an agreed threshold value for the elimination half-life and uncertainties with the half-life in humans, 'not B' conclusion was not reached. The substance is included in the Candidate list of SVHC based on Article 57(f).
- EC 271-756-9; Quaternary ammonium compounds, C20-22-alkyltrimethyl, chlorides (Dossier evaluation, assessed by ECHA): More data are needed for the conclusion on persistency of the constituents. The weighted mean value for BCF was considered as not appropriate and the known-constituents approach should be used instead. High adsorption to the skin was observed in the OECD TG 305 study. Interpretation of the skin adsorption in bioaccumulation assessment to be further discussed. Available data on bioaccumulation from similar substances indicate that B concern cannot be ruled out.
- EC 427-090-8 ; A mixture of: ethyl (2R,3R)-3-isopropylbicyclo[2.2.1]hept-5-ene-2-carboxylate; ethyl (2S,3S)-3-isopropylbicyclo[2.2.1]hept-5-ene-2-carboxylate (NONS, assessed by NL): Available information indicates that parent substance is likely not persistent. Metabolites seem to be more polar than the parent substance and thus less likely to bioaccumulate. Kinetic information from the OECD TG 305 study and distinction on bioaccumulation potential between the stereoisomers are to be further examined. Further data needs, if any, will be considered after thorough assessment of the information submitted just prior to the meeting (OECD TG 309 pre-test and OECD TG 305).
- EC 438-390-3; Alkane 6 (NONS, assessed by ES): The block profiling approach was used for the assessment. Available information indicate that the substance could be considered as likely not persistent and likely not bioaccumulative. However, refinement of the assessment was suggested regarding potential

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degradation products and verification of the reliability of the predictions and read across. Available information indicates towards the substance being not PBT.

Open session

- EC 216-653-1; tert-butyl methyl ether (CoRAP 2014, assessed by FR): MTBE was considered very mobile. Screening studies showed that the substance is potentially P/vP. Discussion focused on the information on non-standard studies on persistence. Half-lives derived in ground water or with adapted inocula cannot be directly compared with Annex XIII criteria. Comparison with some reference substances may support interpretation of the available non-standard studies. Anaerobic degradation was not observed. Information on persistence to be further refined to clarify if further testing in surface water is needed.
- EC 203-615-4; Melamine (non-CoRAP, assessed by DE): The substance was concluded P/vP based on surface water half-life of > 60 days, T due to classification as STOT RE 2 and very mobile based on Weight of Evidence. Inefficient removal in the sewage treatment plant has been reported. Monitoring data confirmed the presence in the environment and drinking water.

Discussions on P assessment approaches: assessment of volatile substances and sterile controls

The draft discussion paper on the volatile substances was developed by ES. It included a review on the currently used volatility thresholds, options to address volatile substances under simulation studies and approaches on data treatment and interpretation. Members proposed that the use of modelling tools and distribution parameters for predicting volatility could be further elements relevant to consider in the guidance update. Further comments on the draft discussion paper will be collected in an upcoming consultation.

The draft discussion paper on the use of sterile controls in biodegradation studies was developed by FI following a discussion at the Member State Committee (2019). The draft discussion paper includes the current approaches on the use of sterile controls accompanied by analysis of example cases, a critical view on relevance, proposals for technical advice, and data interpretation approaches. It was agreed that further guidance is needed on the use of sterile controls however allowing flexibility in a case-by-case approach. Further comments on the draft discussion paper will be collected in an upcoming consultation.

Reporting back from toxicokinetic working group

Toxicokinetics WG consists of 16 members from government, industry, and academia. It was established in 2019 to develop guidance on assessment of terrestrial bioaccumulation focusing on mammals. The aim is to seek practical solutions on how to use the toxicokinetic data in the assessment and develop a tiered screening approach for (de)prioritisation of substances with potential for bioaccumulation in air-breathing organisms. WG presented main elements and related uncertainties to be considered in the screening tier of the assessment. It was proposed that the threshold values of log Kow, and log Koa and biotransformation half-lives should be referenced to a BMF of 1. Some other factors considered were chemical uptake, natural variability, model species, and applicability domain of current tools/data. WG will further develop the tiered strategy to include also definitive assessment step in collaboration with PBT EG.

General PBT assessment related guidance and approach development topics

- ECHA presented the status of the ongoing preparatory work on the identified priority topics for ECHA PBT assessment guidance update. Substance adsorption on skin in aquatic bioaccumulation studies was identified as a new approach development topic.
- Project presentations by CEFIC supporting experts:
 - The LRI-ECO40 'Investigations on the bioconcentration of xenobiotics in the freshwater amphipod *Hyalella Azteca* and inter-laboratory comparison of a new BCF test protocol'. Publications on the ring trial are under preparation and OECD TG finalization and adoption by OECD WNT is envisaged for 2023.
 - The LRI-ECO41 'Enhanced Screening Methods to Determine Bioaccumulation Potential of Chemicals in Air-Breathing Species'. Development and testing of an in vitro screening approach for assessing bioaccumulation of neutral hydrophobic organic chemicals from mammalian liver S9 biotransformation bioassays was presented. Results were found to be reproducible and correlated well with in-vivo biotransformation rates.

Substances discussed at the 29th PBT EG meeting:

MS	EC number	Substance Name	Outcome	Session	CoRAP year
DE	203-615-4	Melamine	P: P/vP T: T Very mobile	Open	
NL	427-090-8	A mixture of: ethyl (2R,3R)-3-isopropylbicyclo[2.2.1]hept-5-ene-2-carboxylate; ethyl (2S,3S)-3-isopropylbicyclo[2.2.1]hept-5-ene-2-carboxylate	P: Refine assessment to clarify if further testing is needed B: Refine assessment	Closed	
ES	438-390-3	Alkane 6	P and B: Refine assessment	Closed	
FR	216-653-1	tert-butyl methyl ether	P: Refine assessment, further information may be needed	Open	2014
NL	700-242-3	Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate	B: Inconclusive	Closed	2017
ECHA	271-756-9	Quaternary ammonium compounds, C20-22-alkyltrimethyl, chlorides	P: Further data needed B: Refine assessment	Closed	