SUMMARY REPORT OF THE 28th PBT EXPERT GROUP MEETING

The PBT Expert Group (PBT EG) meeting was virtually hosted by ECHA on 21-22 September 2021. PBT EG was consulted on the concept to consider non-extractable residues (NER) in P assessment. The European Commission reported on the timelines foreseen for the next steps of the CLP criteria development for PBT/vPvB and PMT/vPvM hazard classes. 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 **7 substances** in closed and open sessions. All substances are REACH substances of which five currently are under substance evaluation (SEv), one is a non-CoRAP substance and one SVCH proposal under preparation. The discussion outcomes are listed in the table below. In addition, the outcomes of **four written procedures** (WP) and two ad-hoc meetings were reported.

48 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 273-227-8; 1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives (BENPAT) (CoRAP 2013, assessed by DE):
  The validity of the available OECD 309 study was discussed along with the role of the transformation product diimine. Further refinement of the data and evaluation of relevant information on the transformation product are expected to facilitate data interpretation.

- EC 248-948-6; Ditolyl ether (CoRAP 2014, assessed by NL):
  In an OECD 309 study, only one isomer of the UVCB was identified with a half-life above 40 days. The experts were of the opinion that the isomer identified as persistent was the most relevant constituent for further testing on bioaccumulation. It was recommended to perform an OECD 305 feasibility study to clarify whether use of non-radioactive test material would be acceptable.

Open session

- EC 400-370-7; 6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene (CoRAP 2021, assessed by FI):
  Five of the six constituents were considered potentially PBT/vPvB. Experimental data on physicochemical properties of the constituents was seen necessary, to clarify if the constituents screen as potentially B/vB, and to select most appropriate constituent(s) for further testing on the PBT/vPvB properties (if necessary).

- EC 271-867-2; Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene (CoRAP 2016, assessed by ES):
  There was support on B/vB conclusion based on dietary OECD TG 305 with mixture of selected constituents. Further testing needed on persistence by performing a simulation test with the most relevant constituent in soil and/or sediment. Further information may also be needed on aquatic toxicity.

- EC 247-426-5; Bis(2-ethylhexyl) tetrabromophthalate (SVHC dossier proposal,

assessed by SE):
vPvB properties on two analogues (CAS 109230-28-6 and CAS 56720-208) were discussed. Refinement of the plausible read across to EC 247-426-5 was proposed.

- EC 201-236-9; 2,2,6,6-tetrabromo-4,4-isopropylidenediphenol (CoRAP 2015, assessed by DK):
The experts discussed the interpretation of the test results of OECD 309 studies (conducted at 12°C and at 20°C) and an OECD 307 study for the mono-methylated and di-methylated transformation product, respectively. The di-methylated transformation product is vP, and depending on the proposed revised modelling of the OECD 309 study, the mono-methylated transformation product could be P or vP. Due to the ionizability of the mono-methylated transformation product and the dependency of the water solubility and hydrophobicity from the pH, a fish dietary study may be the better choice for bioaccumulation testing.

- EC 403-080-9; Sodium 3-(2H-benzotriazol-2-yl)-5-sec-butyl-4-hydroxybenzenesulfonate (non-CoRAP, assessed by ES):
There was support to conclude the substance as vP and not B/vB. The conclusion was supported among other information by read across to EC 630-348-7 (M1), physico-chemical properties, and QSAR predictions on biotransformation. The potential mobility concern can be followed up once the mobility criteria are established.

NER in P-assessment: an effort to combine existing approaches

The German Environment Agency (UBA) and their consultants presented their latest results from their project aiming to develop a harmonised concept to consider non-extractable residues (NER) in P assessment. The presented approach is also under public consultation by UBA (LINK). PBT EG members were welcomed to provide comments on the proposals presented by UBA Further discussions on the topic are expected to follow.

PBT Expert Group ad-hoc meeting on CLP criteria update by Commission 28 May 2021 and Second PBT Expert Group ad-hoc meeting on CLP criteria update by Commission 28 June 2021

Commission appreciated support of the PBT EG on the scientific and technical aspects of CLP criteria development for PBT/vP and PMT/vPvM. Commission's suggestion on the new hazard classes (PBT, vPvB, PMT and vPvM), as well as categorisation aspects and related hazard communication will be discussed at ad hoc CARACAL meeting on the 30 September 2021. Impact assessment will be prepared by a consultant by early 2022.

Learnings from recent Court judgements relating to PBT assessment

ECHA provided a summary of the recent Court judgments on four cases concerning PBT/vPvB assessment. The court confirmed various aspects of the PBT/vPvB assessment which among others include: (i) the use of 20 degrees C as an appropriate temperature to perform the OECD TG 308 aiming at identifying the transformation products, (ii) Arrhenius equation can be used to adjust the degradation half-life, (iii) ready biodegradability tests are 'screening information' within P assessment, (iv) Annex XIII does not require that the P and B criteria are met in one and the same environmental compartment and (v) SVHC identification can take into account the PBT/vPvB properties of relevant impurities.

General PBT assessment related guidance and approach development topics

- ECHA presented the status of the ongoing preparatory work on the ECHA PBT assessment **guidance update needs**. Topics related to persistence assessment of difficult to test substances and bioaccumulation assessment (use of toxicokinetics information/elimination half-life/metabolization) are planned to be discussed at the 29th meeting.

- CEFIC presented the project LRI ECO44.2 / 55/ 54

    - The LRI-ECO44.2 project titled "Integrating Bioaccumulation Assessment Tools for Mammals (IBAT-Mam)" is a continuation of a support tool with focus on toxicokinetic information. EAS-E suite (beta) (www.eas-e-suite.com) makes the tools more accessible for the general public. It contains curated empirical in vitro & in vivo toxicokinetic databases, as well as bioaccumulation and physiologically based toxicokinetic (PBTK) models. The project further produced two new software for predicting toxicokinetic parameters – QSARINS-Chem and IVBP-Suite which will be released in October 2021.
    - The LRI-ECO55 project titled "Assessing the impact of sample collection on microbial population and validity criteria in the OECD 309 surface water mineralisation test". The project is currently ongoing.
    - The LRI-ECO54 project titled "Developing a tiered modelling framework in support of risk assessment of chemical substances associated with mobility concerns". The project is currently ongoing.

Substances discussed at the 28th PBT EG meeting:

MS	EC number	Substance Name	Outcome	Session	CoRAP year
DK	201-236-9	2,2,6,6-tetrabromo-4,4-isopropylidenediphenol	P: Refine assessment B: Testing needed	Open	2015
FI	400-370-7	6-(1-phenylethyl)-1,2,3,4-tetrahydronaphthalene	P: Testing needed B: Testing needed	Open	2021
DE	273-227-8	1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives (BENPAT)	P: Refine assessment and potentially further testing needed	Closed	2013
ES	403-080-9	Sodium 3-(2H-benzotriazol-2-yl)-5-sec-butyl-4-hydroxybenzenesulfonate	not PBT/vPvB	Open	
ES	271-867-2	Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene	B: B/vB P: further testing needed	Open	2016
SE	247-426-5	Bis(2-ethylhexyl) tetrabromophthalate	Refine read-across assessment on two analogues Dihexyl 3,4,5,6-tetrabromobenzene-1,2-dicarboxylate (CAS 109230-28-6) and Dioctyl 3,4,5,6-tetrabromobenzene-1,2-dicarboxylate (CAS 56720-20-8) (vPvB)	Open	
NL	248-948-6	Ditolyl ether	B: Testing needed	Closed	2014

Written procedures and ad-hoc meetings between 27th and 28th meeting

MS	EC number	Substance Name	Session	Notes
NO	205-492-2	Dodecamethylpentasiloxane	Closed	WP
FR	701-385-4 ; old EC 253-249-4	Reaction products of diphenylamine with nonene, branched	Closed	WP

BE	201-344-6 226-866-1	Perylene-3,4:9,10-tetracarboxydiimide and 2,9-dimethylanthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	Closed	WP
IT	284-660-7	Benzene, mono-C10-13-alkyl derivs., distn. residues	Closed	WP
COM	n/a	PBT Expert Group ad-hoc meeting on CLP criteria update by Commission 28 May 2021	Open	Ad-hoc meeting 28.06.2021
COM	n/a	Second PBT Expert Group ad-hoc meeting on CLP criteria update by Commission 28 June 2021	Open	Ad-hoc meeting 28.05.2021