SUMMARY REPORT OF THE 31st PBT EXPERT GROUP MEETING

The first hybrid PBT Expert Group (PBT EG) meeting was hosted by ECHA on 27-28 September 2022 in Helsinki.

The PBT EG was consulted on the proposed revisions of the ECHA guidance Chapter R.11 and relevant sections in Chapter R.7b and R.7c which were in consultation with the PBT EG until 7th of October 2022. PEG consultation of the draft guidance documents is planned to be started in November 2022 and to be followed by the PEG meeting planned in March 2023.

PBT EG members provided advice on the assessment of **two substances** in closed session and **one substance** in open session. All substances are REACH substances of which two are currently under substance evaluation (SEv). The discussion outcomes and **three written procedures** for which the outcome was reported at the meeting are listed in the tables below.

36 participants representing 13 Member States, Norway, and 4 accredited stakeholder organisations (CEFIC, Concawe, ECETOC and EEB) participated.

Main outcomes of the substance discussions

Closed session

- EC 214-946-9; 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran (galaxolide) (CoRAP 2022, assessed by FR): Information on persistence including field studies and monitoring data was considered to indicate persistence. Further simulation testing was seen necessary to obtain half-life derived in relevant conditions. Substance was considered to meet at least B criteria. Further refinement of existing information was recommended to assess whether the substance meets also the vB criteria.

- EC 201-247-9; Bis(4-chlorophenyl) sulphone (non-CoRAP, assessed by AT): In the 23rd PBT EG meeting the substance was considered vPvB. Current discussion focused on toxicity, particularly if the observed effects on Chironomids (OECD TG 218 and OECD TG 219) would meet the T criteria. Refinement of the assessment was recommended to address e.g. statistics in emergence rate assessment, used test concentrations, verification of the origin of the chironomids to exclude resistance and benchmarking. Chronic fish toxicity data was not available. Indications for endocrine disruption were observed in available *in vitro* data – particularly regarding an androgen antagonistic mode of action.

Open session

- EC 284-366-9; 1,1'-(ethane-1,2-diyl)bis[pentabromobenzene] (CoRAP 2012, assessed by SE): The substance is a brominated flame retardant, used as replacement for the restricted decabromodiphenyl ether. Refinement of the assessment was recommended for interpretation of field studies indicating vB and limited absorption in a dietary study.

General PBT assessment related guidance and approach development topics

PBT EG was consulted on proposed revisions of the ECHA guidance Chapter R.11 and relevant sections in Chapter R.7b and R.7c:

- Persistence: Approach on quantification and characterisation of non-extractable

residues, data interpretation/degradation kinetics, sterile controls and volatile substances in biodegradation studies, enhanced biodegradation and weight-of-evidence and use of examples.
- Bioaccumulation: ITS for air-breathing organisms (mammals), use of *Hyalella azteca* test, *in vitro* methods and *in vitro-in vivo* extrapolation (IVIVE), determination of logKow, surfactants, and benchmarking approach for bioaccumulation assessment.
- Toxicity: Assessment of substances containing multiple constituents.

Project presentations by CEFIC supporting experts:
- LRI-ECO43 "Improving sediment toxicity testing design and data interpretation for very hydrophobic chemicals",
- LRI-ECO47 "Searching for refined in vitro Approaches to Predict bioconcentration in FISH (SNAPFISH)" aiming to develop alternative approaches to derive BCFs based on *in vitro* and in silico experiments,
- "Persistence Assessment Tool (PAT tool)". Development of a software tool to provide support to practitioners in the evaluation of persistence under regulatory frameworks.

Substances discussed at the 31st PBT EG meeting:

MS	EC number	Substance Name	Outcome	Session	CoRAP year
FR	214-946-9	1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran (galaxolide)	Testing needed (P) Refine assessment (B)	Closed	2022
AT	201-247-9	Bis(4-chlorophenyl) sulphone	P/vP B/vB Potentially T: Refine assessment	Closed	
SE	284-366-9	1,1'-(ethane-1,2-diyl)bis[pentabromobenzene]	Refine assessment (B)	Open	2012

Written procedures and ad-hoc meetings between 30th and 31st meeting

MS	EC number	Substance Name	Session	Notes
AT	204-279-1	2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol	closed	WP
FR	701-028-2	tris (4-nonylphenol, branch) phosphorous acid ester	closed	WP
NL	N/A	PBTEG 30 follow up from AP 11.4 Corrections for food lipid content and growth dilution	open	WP