SUMMARY REPORT OF THE 25th PBT EXPERT GROUP MEETING

The PBT Expert Group (PBT EG) meeting was virtually hosted by ECHA on 2-3 September 2020. A study report was presented which demonstrated a high level of coherence between the PBT EG advice and subsequent regulatory outcomes. Further actions to help ensure the EG maximises its support to the regulatory processes were also discussed and agreed. Advice was provided on the assessment of five substances in closed and open sessions. Three substances were REACH substances and are currently under substance evaluation (SEv). One of the substances was concluded not PBT/vPvB and four assessments needed further refinement. The outcome of two written procedures (WP) was reported with indication of further actions. For one case, Members States consider to propose the substance as SVHC. The discussion on approach developments focused on advances in assessing PBT/vPvB properties of ionic and ionisable substances.

42 participants representing 18 Member States, Switzerland and 3 accredited stakeholder organisations (ECETOC, CEFIC and Concawe) attended the meeting. The feedback from the participants at the end of the meeting was positive.

Main outcomes of the substance discussions

Closed session

- EC 274-581-6, 1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione (CoRAP 2015, assessed by DE): Low mineralisation, formation of degradation products and fast distribution from water to sediment was observed in the new (preliminary) information received (OECD TGs 309 and 308). The substance is likely not P in water but P or even vP in sediment depending on the consideration of the high amount of non-extractable residues (NER). The available information is sufficient to conclude on the B criterion (MSC 51). LT toxicity test on fish is pending. Further assessment needed.

Open session

- EC 206-420-2, perfluamine (CoRAP 2020, assessed by BE): The substance A substance that is used in a read-across approach showed 0% degradation in OECD 310 test. The possibility of considering the substance as vP based only on screening level information and the structure with strong C-F bonds known to resist degradation was discussed. PBT EG advised to refine the assessment by addressing the stability of the C-N bond, modelling and read across. Fish dietary OECD 305 study was the preferred test to be requested due to the high volatility and poor solubility of the substance.

- EC 418-550-9, Hexadecyl 4-chloro-3-[2-(5,5-dimethyl-2,4-dioxo-1,3-oxazolidin-3-yl)-4,4-dimethyl-3-oxopentamido]benzoate (non-CoRAP, assessed by ES): The substance showed 0% degradation in OECD 301B test. PBT EG discussed B and concluded that the fish dietary test similar to OECD 305 is valid and that the substance is not B/vB for aquatic organisms. Based on toxicokinetic data on mammals, PBT EG concluded that the substance is not B/vB in air-breathing organisms. The substance is not likely to be T. PBT EG was of the view that substance is not PBT/vPvB.

- EC 422-040-1, 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)-[2H]cyclopenta[b]furan]; spiro[cyclohex-3-en-1-yl-[4,5,6,6a-tetrahydro-4,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclopenta[b]]furan], (CoRAP 2016, assessed by ES): The experts discussed the interpretation of the results from an OECD TG 309 simulation study. The main discussion points were the limited substance recovery and how to address volatilisation for the calculations of the half-lives for the four main constituents. Due to the complexity of the case further discussion is needed.

- EC 416-250-2, 3,6-bis(4-tert-butylphenyl)-1H,2H,4H,5H-pyrrolo[3,4-c]pyrrole-1,4-dione (non-CoRAP, assessed by DE): The substance showed 0% degradation in OECD 301B test. PBT EG discussed the validity of a fish dietary test (OECD 305) especially the influence of the high concentration in feed, uptake kinetics, difference in growth, depuration phase and rate. PBT EG was of the opinion that there are some limitations in the study and provided advice on how to refine the B assessment.

The impact study on how the advice given by the PBT EG is reflected in the outcomes of the substance evaluation (SEv) and substances of very high concern (SVHC) identification processes was presented. The study covered all cases concluded since 2012. The results of this review demonstrate that the PBT EG advice has been followed in the majority of the cases and is useful support of the eMSCAs in carrying out their assessments as well as of the MSC in its decision making in the SEv and SVHC regulatory processes. ECHA also presented an Expert Group Action Plan proposing actions which should help the EG to maximise its support of the regulatory processes. The actions, which included increased use of ICT, as well as improved planning, documentation and information flow, were discussed and agreed.

General PBT-related approach development topics

The following approach development related projects were presented:

- Ionic or ionisable substances have been identified by the expert group as a priority topic for the approach development. At the meeting, a block of three different contributions to this topic were presented and discussed:
    - Persistency: RWTH Aachen, Institute for Environmental Research together with the German Environment Agency presented persistence assessment of a positively and a negatively charged substance in comparison with a neutral analogue substance in biodegradation simulation studies. Results indicate that a positive charge reduces the ultimate degradation in simulation studies, and leads to the formation of high amounts of remobilisable non-extractable residues (NER Type I) in soil. It is proposed that for cationic compounds, simulation tests according to OECD 308 (or OECD 307) should be performed first. Further studies with ionic or ionisable substances are planned including OECD 301 ready biodegradability tests.
    - Bioaccumulation: Fraunhofer Institute for Molecular Biology and Applied Ecology IME and Technical University of Denmark DTU. For two cationic and four anionic substances, tested in an OECD 305 bioaccumulation dietary study, low BMF values were found, likely due to slow uptake and/or fast elimination. The experts raised the question whether the same behaviour would be shown also under field conditions. Poly- and perfluorinated substances have so far been the driver for the concern of bioaccumulation of ionisable substances, but not exclusively. An analysis for screening parameters has shown that K(fish/water) correlates better than other parameters with BMF results, even though none correlates very well. More research is needed.

- Eawag, Department Environmental Toxicology presented a PhD project on alternative methods to measure bioaccumulation and biotransformation of ionic and ionisable substances aiming to evaluate whether fish cell lines are applicable for bioaccumulation assessment.

- German MSCA presented a description of the project aiming to develop a harmonised concept to consider non-extractable residues (NER) in P assessment. German Environment Agency will organise a Workshop in February 2021 to present their proposal on a standardised approach for NER assessment.

- A critical literature review of analytical methods applicable to environmental studies was presented by the contractor Peter Fisk Associates. It will be published in the ECHA website by the end of 2020.

- The following two project plans were presented by CEFIC:

  - LRI-ECO54 - Next generation risk assessment methods for substances associated with mobility concerns.

  - LRI-ECO55 - Assessing the Impact of Sample Collection on Microbial Population and Validity Criteria in the OECD 309 Surface Water Mineralisation Test.

Substances discussed at the 25th PBT EG meeting:

EC number	Substance name	Submitted by
206-420-2	perfluamine	Belgium
274-581-6	1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione	Germany
416-250-2	3,6-bis(4-tert-butylphenyl)-1H,2H,4H,5H-pyrrolo[3,4-c]pyrrole-1,4-dione	Germany
418-550-9	Hexadecyl 4-chloro-3-[2-(5,5-dimethyl-2,4-dioxo-1,3-oxazolidin-3-yl)-4,4-dimethyl-3-oxopentamido]benzoate	Spain
422-040-1	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)-[2H]cyclopenta[b]furan]; spiro[cyclohex-3-en-1-yl-[4,5,6,6a-tetrahydro-4,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclopenta[b]]furan]	Spain