Brief report from the 20th PBT EG meeting (Helsinki, 24-25 October 2018)

In total 24 external participants were present at the meeting, representing 14 member states and 5 stakeholder organisations. Additionally, 3 members of the PetCo group attended the common PetCo - PBT EG session on issues regarding the use of the hydrocarbon block method for PBT assessment of petroleum and coal UVCBs. The meeting agenda further comprised discussions of three substance cases and some PBT-guidance and approach development related issues. All agenda items were discussed in open session.

Main points of substance discussions:

- HHBC (1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran)(Galaxolide) was under pre-REACH legislation concluded to be 'not PBT'. However, in the meantime, criteria for persistence in soil have been added to the P-criteria under REACH and studies indicating bioaccumulation potential and persistence in soil became available. The expert group therefore recommended to re-open the case and to further refine the assessment of the P and B properties. Carrying out the assessment in a group approach with further musk substances should be considered as well.
- For the UVCB substance Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol (OAPP, CoRAP 2012) a reversed B – P testing order is applied. The results of a dietary biomagnification study are pointing towards B/vB for two constituent groups. Hence, a simulation test for P may need to be requested. The group extensively discussed options for the choice of the test item(s) for the simulation test, indicating again the challenges associated with identifying and selecting the appropriate test items for UVCB testing.
- For the assessment of n-butyltin trichloride (MBTC) the PBT EG advised to refine the assessment and for this to draw on the substantial body of literature that should be available on organotin/butyltin compounds.

The discussion in relation to applicability and use of the hydrocarbon block method (HCBM) for PBT assessment of petroleum and coal stream UVCBs was continued in form of a common session of the PetCo group and the PBT EG. Approaches to P and B assessment where proposed and discussed for the group of 3-ring PAHs and their alkylated derivatives as an example. A written procedure allowing to provide more comments on the issues raised has been agreed as follow-up.

The revised draft guidance text on non-extractable residues (NERs) was discussed. It was agreed that some text passages and figures would be modified before submission of the draft guidance text for PEG review. In addition, it was agreed that any additional major issues on the content could be sent as written comments.

ECHA gave a presentation on indicative generic building blocks for assessment of substance properties giving rise to Equivalent Level of Concern (ELoC) to CMRs and/or PBT/vPvBs. It reiterated the generic concern elements, which have been identifiable in ELoC cases so far and therefore would be useful to address. ECHA also underlined that in ELoC assessment comparison with numeric criteria existing for CMR/PBT/vPvB endpoints was not essential. One of the main reflections of the group was that ELoC indeed should function as a safety net.

The outcome of the prioritisation of the approach development topics, which had been carried out by the EG members prior to the meeting, was presented. The results will help to focus the resources on the most important topics. Work on some of the topics is close to finalisation and the PBT EG will need to consider how the results should be implemented and communicated. A written procedure to further explore the group's view on different possible options will be launched.

Substances discussed in the 20th PBT EG meeting:

EC number	Substance Name	Submitted by
214-946-9	HHBC (1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran)(Galaxolide)	France, Netherlands
700-960-7	Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol (OAPP)	Denmark
CAS: 1118-46-3	n-butyltin trichloride (MBTC)	France