Brief report from the 15th PBT EG meeting (Helsinki, 23-24 May 2017)

It total 29 participants were present in the meeting representing 17 member states, COM and 5 stakeholder organisations.

Five substances were on the meeting agenda. Two were discussed in open session, one of these being the biocide permethrin. Three substances were discussed in closed session. Seven further substances had been commented in written consultation between the 14th and the 15th meetings.

- Final conclusions on the PBT or vPvB properties proposed for several substances were not yet broadly supported, but refinement and further information were deemed necessary.
- ➤ For the biocide permethrin it was considered necessary to search for further available information in order to refine the P-assessment of the cis-isomer and to explain the differences in half-lives between the available degradation studies. Environmental monitoring data compiled in the context of the Water Framework Directive and for other purposes might also be helpful. The refined assessment should be reviewed by the PBTEG. Depending on the outcome of the refined P-assessment, the B-assessment might need to be revised in order to address potential differences of cis- and trans isomers.
- ➤ For two of the substances discussed the assessors were asked to better exploit together with the registrants the possibilities of informal data acquisition. The members were optimistic that further testing might not be needed in order to enable a conclusion on the PBT/vPvB properties.
- ➤ Terphenyl, hydrogenated (EC 262-967-7), a UVCB substance assessed by Finland and due to the complexity of the substance commented in a series of written consultations by the PBTEG in the past, is now proposed to fulfil at least the vPvB criteria based on the properties of a relevant constituent.

DE presented their proposal for a concept on persistent, mobile and toxic (PMT) substances. The group preliminarily welcomed the focus to address the specific concern of drinking water and groundwater quality and the idea of identifying substances eliciting concern by assessment of a combination of specific properties. Members, however, expressed reservations with regard to the proposed details. Some members asked to more extensively justify and potentially adjust the criteria, in particular the proposed M-criterion (the proposed parameters and the values). DE also raised the question why Carc. and Mut. Cat. 2 substances are not part of the Annex XIII T-criterion and proposed to cover them in the PMT concept. The proposal is subject to written consultation by the RiME and PBT expert groups until 22 June 2017. A follow-up discussion by the PBTEG is envisaged for August 2017.

ECHA thanked for input of the PBTEG on the screening approach and provided an overview of the plans for the next few years. More emphasis will be given to grouping of substances for regulatory work and pilot projects on manual screening of groups are already running.

The group also discussed possibilities to accelerate the PBT assessments based on an overview of options compiled by ECHA. Currently the regulatory work and data generation seems to take ca. 5 to > 10 years, depending on whether and which kind of test data needs to be generated. Shortening the period between identification of the PBT or vPvB concern and the implementation of regulatory risk management is in particular critical for PBT/vPvB substances, as for these exposures will continuously increase and are difficult to reverse even after onset of risk management measures. Informal acquisition of information, shortcutting the need to pursue the formal decision processes, was highlighted as a relevant and promising option. This would however in many cases need more intensive dialogue and collaboration between MSs, ECHA and registrants. Also the possibility to require simultaneous testing in formal decisions was touched by the group.

ECHA also pleaded for more courage to reach out for and better harness the already available information and for trying to make more use of similarities between substances.

A thought starter was presented by ECHA as to which properties a substance might need to have in order to be identified as being of equivalent level of concern to a substance fulfilling the PBT/vPvB -criteria. The members welcomed that this issue was broached by ECHA. There was understanding among the members that indeed such substances would not necessarily need to have the same combination of properties than PBT/vPvB substances, but that the combination of properties would need to elicit an equivalent level of concern. It was considered that a more detailed proposal would be necessary to get a better understanding of which combination(s) of properties this could be.

ECHA presented the result of the approach development topic prioritisation carried out in the PBTEG during the winter. The topics ranked highest (high, short-term priority) are already covered by on-going projects carried out by DE and ECHA. ECHA reminded the members to keep the PBTEG updated on planned and ongoing approach development work in order to ensure coherent and coordinated efforts.

Substances discussed in the 15th meeting:

EC	Substance	Authority
number		
-	Polyfluoro-5,8,11,14-tetrakis(polyfluoralkyl)-polyoxaalkane <i>(CoRAP 2017)</i>	DE
247-759-6	Tris (nonylphenyl)phosphite (or TNPP) (CoRAP 2013)	FR
401-680-5	A mixture of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol; isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n=5 or 6 (or UV-571)	ECHA
247-660-8	Diisotridecyl adipate	ES
258-067-9	m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (or Permethrin)	IE