

Brief report from the 16th PBT EG meeting (Helsinki, 28-29 September 2017)

In total 25 participants were present in the meeting representing 16 member states, COM and 5 stakeholder organisations. The group has again worked very hard even over the summer. Ten substances were on the meeting agenda. Two substances were discussed in open session, eight in closed session. Three further substances and five generic topics had been commented in written consultation and for one substance a separate Webex had been arranged in August.

The high number of substances in the closed session was because DE (with six substances in this meeting) and AT discuss their CoRAP substances in closed sessions only in order to avoid interference with their ongoing decision-making processes.

Substance highlights of the meeting were four perfluorinated substances, including "Adona" and "GenX", which have received plenty of attention in the media worldwide during this decade due to widespread occurrence in groundwater and drinking water. These substances are currently also under assessment by, e.g., the U.S.EPA and Environment Canada. Several challenges have been encountered because current conventional assessment methods cannot sufficiently address their properties. Similar experience has been made, e.g., with PFOA as well, which was identified in 2014 as PBT to the Candidate List and subsequently restricted while relying in the assessment much on non-standard data. New type of data never requested before under Sev to clarify the PBT properties of a substance are now being considered by the eMS Germany based on the recommendations of the PBTEG (e.g. data on protein binding, toxicokinetics and human biomonitoring).

Substance 2,4,6-tri-tert-butyl phenol (BE; CoRAP 2017) raised discussion on whether it would be possible to identify the substance as PBT already based on current data. The discussion focused in particular as to whether the P-assessment could with the currently available screening data and with few additional arguments be finalised with the conclusion that the substance is persistent (P). According to ECHA Guidance and by example of several preceding SVHC dossiers (cf. perfluorinated substances) this should in principle be possible as no quantification of the degradation half-life is absolutely necessary, as long as there is reasonable justification that the P criteria are met.

In relation to the proposal of a new protection concept for drinking and ground water (DE's PMT concept proposal) the group had expressed in a written commenting procedure during the summer that in principle there was general support to further discuss the merits of establishing such a concept but also the proposed numeric identification criteria and the regulatory context in which to implement the concept. DK presented in the meeting an overview of their preliminary screening of more than 2372 mono-constituent organic substances that are registered under REACH, using Danish QSAR database. DK had found out that 0.3-4.1% to 0.3-1.3% would be identified as "PMT" or "vPvM" substances respectively, depending on the selected values of the criteria. The PBTEG and RiME are currently commenting DE's revised proposal in written procedure with a deadline on 4 December 2017. It was raised during the meeting that the priority for development of this new concept would need to be discussed at the policy level before any further technical refinement.

Substances discussed in the 16th meeting:

EC number	Substance	Authority
915-730-3	reaction mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	FR
444-340-1	Wässrige loesung des MV31-Kaliumsalz	DE
480-310-4	ammonium 2,2,3 trifluor-3-(1,1,2,2,3,3-hexafluoro-3-trifluormethoxypropoxy), propionate	DE
700-242-3	ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate	DE
700-323-3	ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)ethoxy]acetate	DE
221-374-3	N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (or 7PPD)	AT
244-617-5	1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]	DE
306-832-3	1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromo-2-methylpropoxy)benzene]	DE
211-989-5	2,4,6-tri-tert-butylphenol	BE
700-579-6	Sepisol Fast Blue 85219	NL