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SCIENCE NEWS FLASH:
ECETOC publishes report on new information and weight-of-evidence in PBT/vPvB assessment of chemicals

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An ECETOC task force has reviewed the new information and 'weight-of-evidence' approach set out in Annex XIII of REACh as amended in 2011, to better assess whether a chemical substance is persistent, bioaccumulative and toxic (PBT), or very persistent /very bioaccumulative (vP/vB). An integrated evaluation strategy is proposed with focus on P and B assessment (on T sufficient guidance exists). In principle, if the available screening information indicates the absence of PBT or vPvB properties, there is no need or obligation for higher-tier assessment and/or further testing. Weight-of-evidence analysis depends on the available information and may include several hypotheses and lines of evidence. Further research is recommended on several topics (endpoints), to fill gaps in knowledge before developing new criteria and specific guidance that allow regulatory conclusions to be drawn, in particular for terrestrial B assessment.

Specifically, it is recommended to confine the PBT assessment primarily to the 'compartment(s) of concern' to which most of the substance to be assessed would be initially partitioning. Non-extractable residues (NERs) are strongly bound to sediment or soil and they are not bioavailable, i.e. neither P, B, nor T.

Screening level assessment of the B potential (in the aquatic environment) is based on the solubility of the substance in water and octanol, its octanol-water and octanol-air partition coefficients, results of in vitro studies and model calculations.

Higher-tier assessment information for B can comprise classical bioconcentration studies in fish, fish dietary biomagnification studies, determination of laboratory and field bioaccumulation factors, field studies on biomagnification and trophic magnification in food chains. The different parameters ('metrics') can be normalised based on their fugacity. While the assessment of B in the aquatic environment is usually well defined, terrestrial B assessment is currently compromised by a lack of science-based threshold levels, scarcity of experimental methods and their interpretation.

Organ-specific bioconcentration factors are probably of limited use, depending on the contribution of the respective organ to the total body burden and on the function of the organ. Extrapolation to whole-body may not be possible for certain classes of substances or because of species and organ-specific characteristics.

While human/environmental (bio)monitoring may detect a substance in an organism, the presence per se is no indication of B potential. The latter requires correlating the levels of a substance in an organism with those in the surrounding environment and all potential sources of exposure.

Finally, classical mammalian toxicokinetic studies can inform on the absorption, distribution, metabolism and elimination of a substance, particularly for the assessment of B in terrestrial food chains. Some toxicokinetic models associate the elimination half-life with the B behaviour of a substance.

The document is published as ECETOC Special Report 18: *Information to be considered in a weight-of-evidence-based PBT/vPvB assessment of chemicals (Annex XIII of REACH).*

The Summary and free PDF of the report are available at http://bit.ly/ecetoc-sr18

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