

Persistent, Bioaccumulative and Toxic (PBT) substances – identification, assessment and regulatory decision making with a special focus on socio-economic aspects



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Wednesday 14th May 2014, 13:55 – 16:00, room: Boston 1

A range of European legislation, including REACH (Regulation EC No 1907/2006), the Plant Protection Products Regulation (EC No 1107/2009) or the Biocidal Products Regulation (EC No 528/2012) contain provisions to identify substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), with the overall goal to minimize the use of such substances. Similar assessment and identification concepts for PBT-substances are used elsewhere, including the US, Canada, Japan and Korea, but differences exist in the applied threshold values and in the methods employed to determine the properties. Additionally, many aspects of the PBT-assessment are currently controversially discussed by stakeholders, including e.g. the suitability of specific degradation tests, the role of non-extractable residues for determining substance properties, appropriateness of methods for determining bioaccumulation, the inclusion of the terrestrial compartment in the assessment schemes, etc. Other aspects under discussion are, for example, if and how to apply weight of evidence approaches, and the use of methods like Read Across, quantitative structure activity relationships (QSARs) or other computational methods when determining PBT properties of chemicals.

Of similar interest are regulatory consequences once a PBT or vPvB substance is identified. Some regulatory frameworks (e.g. REACH) require manufacturers or users of such substances to apply for an authorization, including demonstration that socio-economic benefits resulting from the use outweigh the negative impacts on human health or the environment. Consequently, the aim of a socio-economic assessment (SEA) is to identify and assess all impacts arising from the continued use of a PBT substance, and to weigh them against all impacts of policy scenarios where the substance is removed from the market or replaced by an appropriate substitute. How to perform benefit and (environmental) impact assessments, what data to use and how to transform existing toxicological data into values for decision-making is largely unclear. Although few conceptual approaches for balancing benefits against impacts have been suggested, there is an urgent need to guide decision-makers in industry and regulatory agencies on how these approaches can be operationalized.

This session aims to bring together stakeholders from academia, industry and regulatory authorities from different parts of the world, offering a platform to present and discuss all kinds of issues related to PBT assessment. Contributions comparing existing concepts for PBT assessment are of interest, as are presentations addressing challenges in the determination of the properties themselves. A special focus lies on conceptual and methodological approaches that address all aspects of the assessment, valuation and balancing of benefits and impacts of SVHCs in an SEA.

SESSION TYPE: Platform, Poster Spotlight and Poster