Title *

Nanomaterial dosimetry in inhalation toxicology: Bridging the gaps between *in-vitro*and *in-vivo* models as well as real world exposure

Abstract *

Dose-controlled aerosolized delivery of engineered nanomaterials (ENMs) to animal (*in vivo*) or cell-based (*in vitro*) models of the lung is a technological challenge. For translation of preclinical ENM toxicity into risk assessment tissue-delivered dose rather than exposure levels play the most important role. Hence, it is essential to understand the relationship between exposure and tissue-delivered dose, which depends on various parameters including aerosol size, density and shape as well as lung morphology, respiratory conditions and exposure time.

Various methods for dose-controlled *in vitro* and *in vivo* testing of ENMs will be discussed with particular emphasis on the tissue-delivered dose. If tissue delivered dose cannot be measured directly by e.g. Inductively Coupled Plasma Mass Spectrometry (ICP-MS) or Quartz Crystal Microbalance (QCM), publicly available lung-deposition/particokinetics models should be used for reliable tissue-dose estimates accouting for non-spherical paricle shape effects using the effective density approach.

Finally, typically observed *in vitro* and *in vivo* dose-response curves are put into perspective with real-world exposure scenarios revealing that surprisingly high tissue-doses are required to induce toxicity in the currently used *in vitro* models of the lung. The potential for bridging these gaps is probably related to the use of more biomimetic and clinically relevant models of the lung and to our understanding of physiological doses encountered during realistic exposure scenarios.

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