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## Feasibility of using in vitro toxicity studies for human risk assessment of nanomaterials

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Abstract: Given ethical, technical and economical considerations, the use of in vitro testing of nanomaterials is considered a preferred alternative to in vivo testing. However, the use of in vitro testing for human health risk assessment is still challenging. The hazard data generated within the Sanowork project is based on a battery of in vitro studies. The nanomaterials included in the project have several safer by design modifications. In an attempt to use as much as possible in vitro data on the risk assessment, we developed a theoretical approach to extrapolate provisional worker exposure limits on the basis of such in vitro studies. This approach was mainly based on the hypothesis that comparing the in vitro toxicity profile of the Sanowork nanomaterials and Benchmark nanomaterials together with in silico dosimetry modelling, would allow calculating approximated human reference values. Benchmark nanomaterials were selected so that they share relevant toxic mechanisms of action, and human reference values or in vivo relevant data are available. Prior to applying the Sanowork Approach, a proof of concept of the whole process was performed using a group of TiO<sub>2</sub> nanomaterials for which we were able to obtain both in vitro and in vivo data from the literature.”

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