

## Minimal analytical characterisation of engineered nanomaterials need for hazard assessment in biological matrices

Hans Bouwmeester<sup>1</sup>, Iseult Lynch<sup>2</sup>, Michael Riediker<sup>3</sup> and Flemming R. Cassee<sup>4</sup>

<sup>1</sup> RIKILT-Institute of Food Safety, Wageningen UR, P.O. Box 230, 6700 AE Wageningen, The Netherlands

<sup>2</sup> University College Dublin, Centre for BioNanoInteractions, Belfield, Dublin 4, Ireland

<sup>3</sup> Institute for Work and Health, Rue du Bugnon 21, CH-1011 Lausanne, Switzerland

<sup>4</sup> National Institute for Public Health and the Environment, Bilthoven, The Netherlands

Keywords: engineered nanomaterials, hazard assessment, biological matrices, characterisation.

The safe and responsible development of engineered nanomaterials (ENM), nanotechnology-based materials and products, together with the definition of regulatory measures and implementation of “nano”-legislation in Europe require a widely supported scientific basis and sufficient high quality data upon which to base decisions. At the very core of such a scientific basis is a general agreement on key issues related to risk assessment of ENMs which encompass the key parameters to characterise ENMs, appropriate methods of analysis and best approach to express the effect of ENMs in widely accepted dose response toxicity tests.

The following major conclusions were drawn:

Due to high batch variability of ENMs characteristics of commercially available and to a lesser degree laboratory made ENMs it is not possible to make general statements regarding the toxicity resulting from exposure to ENMs.

- Concomitant with using the OECD priority list of ENMs, other criteria for selection of ENMs like relevance for mechanistic (scientific) studies or risk assessment-based studies, widespread availability (and thus high expected volumes of use) or consumer concern (route of consumer exposure depending on application) could be helpful. The OECD priority list is focussing on validity of OECD tests. Therefore source material will be first in scope for testing. However for risk assessment it is much more relevant to have toxicity data from material as present in products/matrices to which men and environment are be exposed.
- For most, if not all characteristics of ENMs, standardized methods analytical methods, though not necessarily validated, are available. Generally these methods are only able to determine one single characteristic and some of them can be rather expensive. Practically, it is currently not feasible to fully characterise ENMs.

Many techniques that are available to measure the same nanomaterial characteristic produce contrasting results (e.g. reported sizes of ENMs). It was recommended that at least two complementary techniques should be employed to determine a metric

of ENMs.

The first great challenge is to prioritise metrics which are relevant in the assessment of biological dose response relations and to develop analytical methods for characterising ENMs in biological matrices.

It was generally agreed that one metric is not sufficient to describe fully ENMs.

- Characterisation of ENMs in biological matrices starts with sample preparation. It was concluded that there currently is no standard approach/protocol for sample preparation to control agglomeration/aggregation and (re)dispersion. It was recommended harmonization should be initiated and that exchange of protocols should take place. The precise methods used to disperse ENMs should be specifically, yet succinctly described within the experimental section of a publication.
- ENMs need to be characterised in the matrix as it is presented to the test system (in vitro/ in vivo).
- Alternative approaches (e.g. biological or in silico systems) for the characterisation of ENMs are simply not possible with the current knowledge.

**Contributors:** Iseult Lynch, Hans Marvin, Kenneth Dawson, Markus Berges, Diane Braguer, Hugh J. Byrne, Alan Casey, Gordon Chambers, Martin Clift, Giuliano Elia<sup>1</sup>, Teresa F. Fernandes, Lise Fjellsbø, Peter Hatto, Lucienne Juillerat, Christoph Klein, Wolfgang Kreyling, Carmen Nickel<sup>1</sup>, and Vicki Stone.



This abstract presents results created by NanoImpactNet - The European Network on the Health and Environmental Impact of Nanomaterials. NanoImpactNet is a Coordination Action sponsored by the EC's 7th Framework Programme. However, the abstract does not necessarily reflect the opinion of NanoImpactNet or the European Commission.