Public consultation - "Scientific Hearing on Nanotechnology"

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Contact details

Name
Steffi Friedrichs

Address
Nanotechnology Industries Association NCI Business Centre Square de Meeus 38-40 1000 Brussels Belgium

Do you write as an individual or on behalf of an organisation?	Organisation

Name of Organisation
Nanotechnology Industries Association

Type of organisation	Business

E-mail address
steffi.friedrichs@nanotechia.org

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Consultation Response Form

Comments [max. 4.000 characters with spaces included (approximately 1 page)]

We agree with SCENIHR that '[t]he hypothesis [...]', (p 53) the case-by-case approach recommended (p 56), & the finding that '[f]or (partially) soluble [...]' (p 7). It is important to distinguish the linearly particle size-dependent increase of surface area from the unique properties that are observable below a primary particle size of approximately 100nm only. More research is needed to characterise the transport properties of primary particles in biological systems, determine if agglomerates or aggregates can revert to primary particles in biological systems, & to shed light on the suggestion that '[f]or low solubility [...]' (p 7). We do not support the introduction of an additional parameter to uniquely describe nanoscale properties by 'extending the [...]' (p 7); it represents a direct dependence on particle size & contradicts the conclusion that '[t]he hypothesis [...]'' (p 53). While we support the notion of a minimum surface area, below which no material shall be considered to be a nanomaterial, we do not support the definition of NMs on one physico-chemical property alone. The cosmetic industry has worked with the EC on the definition laid down in the Cosmetics regulation & is preparing notification of NMs to the EC along the lines of the legal definition for regulatory compliance purposes; discussion of "definition" should acknowledge the existence of this regulatory development. We don't agree with the questioning of the terminology 'nanomaterial' (see '[d]epending on the [...]' (p 7)), cf. ISO TS 27687. We agree that many of the existing NMs in commercial use have been extensively studied & have been found to present no significant hazard. Significant progress on reference materials (p 7) is being achieved by the OECD WPMN [2,3]; industry & regulators are committed to making resources & funding available, & a repository of these & other reference NMs is being established by the JRC. Further coordinated research is required to investigate the transport & fate of primary NPs in biological systems, & to achieve the necessary verification of speculation that suggest 'from the lung [...]' (p 8). The existing history of NMs needs to be reviewed. NMs are created in large volumes in nature (e.g. by volcanoes). How life forms have evolved to handle NMs must be better understood. We agree that further coordinated research is required to investigate the effects of primary NPs on cardiovascular systems (see'[b]ased on the observation [...] (p 8)); and the mechanism of tox. effects of NMs (in particular primary NPs) on biological systems; without conclusive determination of the transport & fate of primary NPs, the detection of ROS generation in hazard studies remains speculative. SCENIHR summarises inconclusive evidence by stating that 'there is some evidence [...]' (p 9), but all studies of mechanism of tox. effects must be conducted using exposure-relevant experimental protocols & tests. Walker et al. concluded that 'the specific composition of an in vitro & in vivo test system will likely play a huge role in how a [NM] interacts with a cell, or other biological target. [...] Depending on the experimental conditions used, [...], what was "tested" may often bear little resemblance to the material as it exists in the real world or in a different test system.' [1] The OECDC WPMN SG8 finds that '[e]ven in the absence of specific exposure limits or guidelines for engineered [NPs], exposure measurements can still be used to determine the need for & effectiveness of engineering controls or work practices.' [2,3] We agree that more coordinated research is required to improve the understanding of derivatisation of NMs in the environment, & welcome the conclusion on the hazard assessment of CNTs: '[w]hether such nanotube [...]' (p 9). Others found that'[a]fter 24 months, [...] MWCNT [...] did not induce mesothelioma [...]. The incidence of tumors other than mesothelioma was not significantly increased across the groups'.[5]

References
[Should you have any questions, please contact: **SANCO-Nanohearing@ec.europa.eu**]

[1] Walker, N. J. and Bucher, J. R., 'A 21st century paradigm for evaluating the health hazards of nanoscale materials?' Toxicol Sciences, in press 2009. [2] We wish to note that, as part of the OECD Sponsorship Programme, the NIA is leading a consortium, which develops detection and tracking equipment (using isotope tracking) and tests the ecotoxicology and environmental fate of two of the agreed 14 nanomaterials (i.e. ZnO and CeO2) in detail. It is anticipated that prototypes of detectors will be developed that allow the isotope tracking of these and other suitable particles in different media. We agree with SCENIHR that '[t]here is a need to further establish reliable and standardised measurement techniques, to develop measurement strategies, and to further implement screening/ monitoring of nanoscale particles in sensitive work areas.' [3] For more information on the OECD Sponsorship Programme of Manufactured Nanomaterials, please follow this link: http://www. nanotechia.org/news/global/oecd-launches-sponsorship-programme-to-test-a-repr [4] Poland C, et al., 'Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study'. Nat Nanotechnol 2008; 3:423-8. [5] Muller, J. et al., 'Absence of carcinogenic response to multi-wall carbon nanotubes in a 2-year bioassay in the peritoneal cavity of the rat.' Toxicol Sciences, in press 2009. [6] summary: In summary, we recommend the following issues to be considered for further focus by the Scientific Committees: • distinction, description and determination of unique nanoscale effects and properties (as opposed to those that are extrapolations from a larger size, such as surface area dependent reactivity) • support of technology- and science-based terminologies and definitions agreed by international fora • coordinated research in the following area needs to be advanced and the resulting findings reviewed: o release and fate, and exposures of nanomaterials within the environment o transport and fate of primary nanoparticles in biological systems o mechanism of toxicological effects caused by nanomaterials in biological systems o establishment of reliable and standardised measurement techniques, [...] and implementation of screening/monitoring of nanoscale particles o improvement of the understanding of derivatisation and alteration of nanomaterials in the environment.