

Reply form
for the public consultation on
Proposal for a Commission definition of the term "nanomaterial"
Send to ENV-NANO-CONSULTATION@ec.europa.eu

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*With this consultation we are seeking your reasoned opinion, to be described below. Please note we **do not accept** comments in track changes in the European Commission proposed text. The consultation closes on 19 November 2010.*

European Environmental Bureau (EEB) ID number: 06798511314-27

International and European environmental, health, and animal protection NGOs welcome the publication of a European Commission draft recommendation on the definition of the term "nanomaterial".

The adoption of an overarching, broadly applicable definition of nanomaterials will enable long awaited regulatory activities to start catching up with market development to ensure safe and responsible product development.

In particular, NGOs welcome the specific provisions of:

- **Paragraph 7**, calling for a regular review of the definition;
- **Paragraph 8**, in particular provisions based on SCENIHR's recommendation to base size distribution on particle numbers rather than mass concentration;
- **Paragraph 9**, in that it specifies the inclusion of aggregates and agglomerates,
- **Paragraph 10**, about the provision of additional guidance, but insist that the preparation and implementation of such guidelines should not delay the use and implementation of the recommended definition, nor undermine the objective of high level of protection of humans and the environment;
- **Paragraph 11**, in particular the reference to the possible inclusion of other materials, notably, materials such as fullerenes, smaller than 1nm;
- **Paragraph 12**, as the only way to give coherence to the burgeoning field of nanomaterials regulation in the EU.

On the draft proposed definition itself, environmental, health and animal protection NGOs would like to make the following comments:

The present understanding of nanomaterials properties and potential health and environmental impacts is still very limited and therefore warrants much research and careful evaluation.

Based on early evidence showing that some particles up to several hundred nanometers share many of the novel properties of nanomaterials under 100nm that are critical for risk assessment¹, and on SCENIHR's acknowledgment that science cannot set an upper size limit value for nano-properties, NGOs favour a larger size range (i.e. 0,3 to 300 nm²) to define nanomaterials. This larger size range would allow more research and a better understanding of all nanomaterials, and whether particular nanomaterials may present concerns for human health or not³, and importantly, in what size range.

In this context, and as described in the technical comments provided to the SCENIHR's opinion, we call for the undertaking of a sensitivity analysis, to verify that the adopted size range captures as much material as possible about which there is already concern, while avoiding materials that do not give rise to nano scale-related concerns. This study should start immediately after the adoption and implementation of the proposed definition in order to be considered in the future revision process of the definition mentioned in paragraph 7 of the Commission's proposal.

In the meantime, signatories welcome the adoption of a reasonable and workable 1% threshold of the particle number size distribution as a way to include in the definition, and put under scrutiny, certain materials, which may exhibit nano specific hazardous properties in the larger size range.

Should this 1% threshold be modified pursuant to this consultation, it is our position that the size range chosen in this definition (1-100nm) should also be modified to a higher range

¹ These novel properties include very high reactivity, bioactivity and bioavailability, increased influence of particle surface effects, strong particle surface adhesion and strong ability to bind proteins. Cedervall et al, 2007; Garnett and Kallinteri 2006; Linse et al. 2007.

² See for example Friends of the Earth Australia's Discussion paper on nanotechnology standardisation and nomenclature issues, August 2008, available at http://www.ecostandard.org/downloads_a/2008-10-06_foea_nanotechnology.pdf

³ As stressed by SCENIHR's opinion that "[the] uncertainty (...) warrants the careful evaluation of possible risks associated with nanotechnology products" and that "Although the existing toxicological and ecotoxicological methods are appropriate to assess many of the hazards associated with the products and processes involving nanomaterials, they may not be sufficient to address all the hazards (...) it cannot be assumed that current scientific knowledge has elucidated all the potential adverse effects of nanomaterials" (SCENHIR-June 2007)

(such as 0,3-300 nm) to allow the definition to capture as much material as possible about which there is already concern (including fullerenes).

We would like to emphasise that any attempt to narrow the scope of a definition for nanomaterials at this stage could lead to potentially harmful substances escaping scrutiny, as well as to the potential exclusion in the future of substances that are presently not engineered to nano-sizes and configurations. Such a narrowed definition would deprive legislators of the necessary flexibility that is critical for the regulation of present issues, as well as for more complex upcoming challenges, including future generations of nanomaterials.

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