



**ANEC/BEUC reply to the European Commission public
consultation on
"Proposal for a Commission definition of the term
"nanomaterial"**

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Introduction

ANEC, The European Consumer Voice in Standardisation and BEUC, the European Consumers' Organisation have for many years been calling on the European Commission to take action in order to ensure that products containing manufactured nanoparticles are safe and do not lead to new human health and environmental risks. However, the lack of a specific definition for the term "nanomaterial" has led to legal uncertainties and hampered the development of urgently legal requirements. In addition, it has hindered the development of adequate test and measurement methods¹.

The lack of an agreed definition creates legal uncertainties as shown in recent finalized or ongoing revision processes of important EU legislation which aims at protecting consumers and the environment such as for example the Regulation on Cosmetics Products, Biocidal Products and on Novel Foods and on the Directives on the Restriction of Hazardous Substances (RoHS) and on Waste Electrical and Electronic Equipment (WEEE) as the definitions of nanotechnology are different.

To ensure a coherent approach, we see an urgent need to develop a common definition at EU level which could be applied to different pieces of legislation and we therefore welcome the Commission initiative aimed at developing a definition of nanomaterial for regulatory purposes. However, we propose that the Commission recommendation will not be restricted to the size range of 1-100nm only and will also take into account the functional properties of nanomaterials.

¹ Small is beautiful but is it safe? ANEC/BEUC joint position paper on Nanotechnology - June 2009 (ANEC-PT-2009-Nano-002final)

1. The proposed size range of up to 100nm is too limited

The Commission draft recommendation foresees basing the term “nanomaterial” on the size range of 1nm to 100nm. Those are also the limits contained in the ISO 27687 standard published in 2008². However, most recent scientific knowledge seems to point out that this size limit seems to be too restrictive and risks that certain nanomaterials will not be properly risk assessed with regard to their potential toxicity³.

Recent studies finding that carbon nanotubes can cause the same disease as asbestos fibres received world wide attention (Poland et al. 2008; Takagi et al. 2008). Yet many of the nanotubes in the studies measured >100nm and so would not be considered to be ‘nanomaterials’ using a <100nm size-based definition. Poland et al. (2008) found that two samples of long, tangled multi-walled carbon nanotubes caused asbestos-like pathogenicity when introduced into the stomachs of mice. One of their two samples had a diameter of 165nm and a length of greater than 10µm⁴. Similarly, Takagi et al. (2008) found that in a long term study, more mice died from mesothelioma following exposure to multi-walled carbon nanotubes than died following exposure to crocidolite (blue) asbestos. In this study >40% of sample nanotubes had a diameter >110nm.⁵

Today, we still do not know enough about the new properties of materials at the nanoscale. For this reason, it will be crucial to apply a broad definition to

² ISO/TS 27687, Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate

³ Friends of the Earth Australia, 2008

⁴ Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study, *Nature Nanotechnology* 3, 423 - 428 (2008)

⁵ Induction of mesothelioma in p53+/- mouse by intraperitoneal application of multi-wall carbon nanotube, *J Toxicol Sci.* 2008 Feb;33(1):105-16

nanomaterials. This is also confirmed by the SCENIHR's opinion that "there is no scientific evidence to qualify the appropriateness of the 100 nm value"⁶.

The approach to go beyond 100nm has already been followed by some public authorities such as the Federal Office for Public Health and the Federal Office for the Environment in Switzerland which recommend 500nm to be used as the limit of the nanoscale in order to avoid excluding any nano-specific risk⁷.

Concrete examples where a limitation to 100nm may cause problems:

- At a workshop on nanotechnologies which had been organised by DG SANCO on 22 October, it has been discussed that in the case of pharmaceuticals the size range of 100nm may be inadequate. As nanomedicines may be at the range of about 1000nm, a definition which is not appropriate for nanomedicines may hamper research and risk assessment. Thus, an EU definition needs to take into account the specific needs of nanomedicines.

- The current REACH legislation shows severe shortcomings when it comes to nanomaterials. We see an urgent need to consider all nanomaterials as new substances under REACH. Moreover, the volume threshold for registration of 1 ton per annum seems to be inadequate for nanomaterials and should be lowered to e.g. 10kg. Limiting the definition of nanomaterials to 100nm could create a new loophole in the future as substances which are slightly bigger than 100nm may escape from the above mentioned requirements that should apply to all nanomaterials.

⁶ Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Scientific Basis for the Definition of the Term "Nanomaterial", pre-consultation opinion, 6 July 2010

⁷ Federal Office of Public Health: FAQs and responses on the Precautionary Matrix, Version 2.0, 5.3. 2010, <http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=en>



2. Definition should include agglomerates and aggregates

A definition for regulatory purposes should include agglomerates and aggregates as they often show physiochemicals properties which may pose safety concerns. For this reason we welcome that the Draft Recommendation includes nanoparticles that have a specific surface area by volume greater than 60 m²/cm³.

3. Revision date

As this definition is for regulatory purposes and is therefore rather a political than a scientific definition, we welcome the proposal to revise the definition in the light of further scientific evidence.

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