

PUBLIC CONSULTATION ON THE DRAFT COMMISSION RECOMMENDATION ON THE DEFINITION OF THE TERM 'NANOMATERIAL'

Brussels, 19 November 2010

ETRMA welcomes and appreciates the effort of the European Commission for developing a proposal for a definition of the term "nanomaterial" that is intended to be used as an overarching, broadly applicable reference term for any European Union communication or legislation addressing nanomaterials.

ETRMA welcomes the fact that the European Commission has been taking note of the ongoing work at the international level, in particular the International Standards Organization (ISO), towards a range of harmonized and scientifically based definitions for nanomaterials and nanotechnologies. ETRMA would like to stress the strong need for consistency between any EU definition on nanomaterials and definitions elaborated by ISO. This is vital to ensure protection of workers, consumers and the environment by virtue of scientific advances, to establish common standards at the global marketplace and to ensure sustainability of the European industry.

ETRMA strongly supports the concept that the base for developing an appropriate definition of **nanomaterial for regulatory purposes** is to ensure that any risk which might arise from the use of such materials is adequately covered in the EU legal framework. For this purpose, any regulatory definition should help to clearly and correctly identify those materials with a potential health and environmental concern, i.e. "those materials which are in a particulate form at the nanoscale, and are mobile in their immediate environments", as discussed in the JRC reference report on nanomaterial definition¹.

Therefore, with specific reference to the Commission proposal for definition, (Article 2 of Recommendation) ETRMA believes that:

- The term "**particulate nanomaterial**", as proposed in the JRC report, *needs to be introduced* in order to best distinguish "nanomaterials in the form of free particles" from "macroscopic materials with designed internal structure at the nanoscale". Such a term, as discussed in JRC report, would also exclude atoms and molecules, thus resolving the ambiguity at the lower limit of 1nm mentioned in SCENHIR report.
- Materials containing small quantity of "particulate nanomaterials" should be managed by treating the minority component (the particulate nanomaterial) as an impurity. With specific reference to the first criterion introduced under Art. 2.1 of the Commission proposal, **ETRMA disagrees with the use of 1% NUMBER** size particle distribution threshold; instead a standard

¹ JRC Reference Report "Considerations on a Definition of Nanomaterial for Regulatory Purpose", 2010.

approach based on percentage WEIGHT should be used. Additionally, any cut-off value should be based on scientific evidences of a health and/or environmental concern.

- The second criterion introduced under Art. 2.1 of the Commission proposal should be abandoned as:
 - o it does not identify materials with a potential health and environmental concern
 - o it is far too generic: it would lead to the classification as “nanomaterials” of almost all “generic materials”: **all** materials (except those in gaseous state) **do have** some kind of “internal structure in the size range 1-100 nm”

- The third criterion introduced under Art. 2.1 of the Commission proposal should be abandoned as:
 - o it does not identify materials with a potential health and environmental concern: many common materials such as active carbons, silica gel dessiccant and common pigments display high specific surface area, while they are not considered “nanomaterials” and do not appear to deserve specific attention in the legislation
 - o it lacks a broad applicability: “specific surface area” can be measured essentially only for dry solids

Not least, ETRMA would like to stress the need to identify test methods (preferably ISO test methods) for checking the fulfillment of the criteria for establishing if a given material is or not a “particulate nanomaterial”.

Link to ETRMA NANO PAPER:

- **ETRMA (2010) “Reinforcing Fillers in the Rubber Industry: Assessment of Carbon Black and Silica as potential nanomaterials (focus on tyres)”**

Available upon request or temporarily at the following link:

<http://www.etrma.org/pdf/201009%20ETRMA%20Fact%20Sheet%20-%20Carbon%20Black%20and%20Silica.pdf>

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