



**Reply form**  
**for the public consultation on**  
**Proposal for a Commission definition of the term "nanomaterial"**  
**Send to [ENV-NANO-CONSULTATION@ec.europa.eu](mailto: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 Trade Union Confederation ID number is 06698681039-26**

The European Trade Union Confederation (ETUC) contributes to the consultation of a proposal for a definition of the term "nanomaterial" that the European Commission intends to use as an overarching, broadly applicable reference term for any European Union communication or legislation addressing nanomaterials

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

The ETUC welcomes and agrees with the Commission that:

The definition of the term 'nanomaterial' used for regulatory purposes should be based on available scientific knowledge and should be subject to regular reviews. It should be based on the size distribution based on particle numbers and not on mass concentration, and include agglomerates, aggregates and structured particles.

The definition should cover all materials and in particular others with a size smaller than 1nm such as fullerenes.

Since a definition of nanomaterials is the first step to give coherence to any communication or legislation addressing them, the definition guidance should also be provided to explain legislative provisions; however the ETUC remarks that the preparation and the implementation of such guidelines should not delay the use and implementation of the definition, and should not undermine the objective of high level of protection of humans and the environment.

The ETUC particularly comments on **article 2** and notes large discrepancies between criterion 1 and 3. The criterion on the specific surface area by volume (VSSA) has been derived by assuming that the density of the bulk material is equal to 1 g/cm<sup>3</sup> and that the material is made up of pure

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spherical particles of 100 nm in diameter. Based on this assumption the discrepancy between the fraction of material in the nanoform according to criterion 1 and 3 is substantial and merit a modification.

This is supported by the following arguments.

Any nanomaterial of pure spherical forms consists of a range of diameters. The size distribution normally is represented by a normal or log-normal distribution. Assuming a normal or log-normal distribution of purely spherical particles with *average size of 100 nm* (the size used to derive the value of 60 m<sup>2</sup>/cm<sup>3</sup>) such a distribution means that **50% of the material is below 100 nm**. The difference of 50% and 1% between criterion 1 and 3 is out of proportion.

While most nanomaterials (NM) that are currently marketed have a bulk density larger than 1 g/cm<sup>3</sup> an important group of nanomaterials do not, notably the Carbonanotubes (CNT). This means that in case the specific density of the material is larger than 1 g/cm<sup>3</sup> and for a VSSA of 60 m<sup>2</sup>/cm<sup>3</sup> the fraction of the material (assuming pure spherical objects) is less than 50% below 100 nm, when assuming a specific density of 1 g/cm<sup>3</sup>. On using a density smaller than 1 g/cm<sup>3</sup> and a limit value of 60 m<sup>2</sup>/cm<sup>3</sup> *more than 50%* of the material (assuming purely spherical objects) is still in the nanoform. Therefore a correction for the density of the material should be included in criterion 3. In addition a density of 0.25 g/cm<sup>3</sup> for CNT and of 5 g/cm<sup>3</sup> for a metal oxide is not uncommon. Therefore if the density is not included a variation of a factor of 20 in the 60 m<sup>2</sup>/cm<sup>3</sup> is not uncommon. This variation for nanomaterials based on the VSSA is out of proportion.

In case the *average diameter* of the Nanomaterial measured by e.g. Dynamic Light Scattering is 100 nm but the surface is not smooth then the actual surface is larger than when a smooth surface is assumed. In that case a VSSA of 60 m<sup>2</sup>/cm<sup>3</sup> is reached for an average diameter that is smaller than 100 nm. Then a value smaller than 60 m<sup>2</sup>/cm<sup>3</sup> still may possess a large fraction (even higher than 50%) of Nanomaterials. Clearly such situations should be avoided.

Since the VSSA is based on assumptions related to size and shape, the value itself therefore does not give any discrimination between size and shape. This may lead to complications in the risk assessment.

Based on the concept of spherical objects one can estimate the mass fraction of the total mass that is in the thermodynamic surface phase assuming a surface thickness of 1 nm (the proposed minimum limit and reasonably in line with crystallographic measurements). The surface phase is the characteristic thermodynamic phase for Nanomaterials. Assuming a diameter of spherical particles of 100 nm, around 6% (5.9%) of the total mass is in the thermodynamic surface phase. On using the limit fraction of 1% in the surface phase as can possibly be concluded as well from the first criterion one would require a diameter of 600 nm only to reach a fraction of 1% that is in the characteristic surface phase. This corresponds to a VSSA of **10 m<sup>2</sup>/cm<sup>3</sup>**.

The large difference in fractions of nanomaterials that can be present according to criterion 1 and 3 hampers a proper risk assessment of the material since the characteristic fraction of the surface phase causing the difference in properties between the nanomaterial and the bulk is different.

The SCENHIR opinion does not indicate that a discussion on the advantages and disadvantages of the 60m<sup>2</sup>/m<sup>3</sup> has taken place. The ETUC strongly disagrees that such criterion can be included without a proper analysis of those advantages and disadvantages. The points indicated above show large discrepancies between criterion 1 and 3 proposed by the European Commission.

Therefore the ETUC calls on the European Commission to:

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1.- Adjust criterion 3 related to the specific surface area by volume (VSSA) to make it more coherent with criterion 1. This is to avoid situations where the same material is considered nanomaterial by one criterion but it is not by the other, in case both criteria are applicable and meaningful. Based on the arguments provided hereabove, ETUC proposes to lower the value of the specific surface area by volume used in criterion 3 from  $60 \text{ m}^2/\text{cm}^3$  to  **$10 \text{ m}^2/\text{cm}^3$** .

2.- Make clear that criterion 1 refers to the “primary” particles (directly produced after the production process).

3- Verify and make it transparent to the public that the three proposed criteria capture as much material as possible about which there is already concern, while avoiding materials that do not give rise to nano-scale-related concerns.

4.- The ETUC has developed a flow diagram that is based on the primary particle size distribution to distinguish a substance in the nanoform from the bulk form but also to decide in which respect a nanomaterial should be considered as a different substance in case of surface modifications (see <http://www.etuc.org/a/7817>). In case no primary particle distribution is known or stated by a producer but a VSSA of the same material only is provided, then the produced and marketed material with a VSSA higher than  $10 \text{ m}^2/\text{cm}^3$  should be regarded as nanomaterial.