



EUROPEAN COMMISSION

Brussels, XXX
[...] (2011) XXX draft

COMMISSION RECOMMENDATION

of XXX

on the definition of nanomaterial

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) The Commission Communication of 7 June 2005 "Nanosciences and nanotechnologies: an action plan for Europe 2005-2009"¹ defines a series of articulated and interconnected actions for the immediate implementation of a safe, integrated and responsible approach for nanosciences and nanotechnologies.
- (2) The Commission, in line with the commitments made in the Action Plan, carefully reviewed relevant Union legislation with a view to determine the applicability of the existing regulations to the potential risks of nanomaterials. The result of the review was contained in the Commission Communication of 17 June 2008 "Regulatory aspects of nanomaterials"². The Communication concluded that the term "nanomaterials" is not mentioned specifically in Union legislation but that existing legislation in principle covers the potential health, safety and environmental risks in relation to nanomaterials.
- (3) The European Parliament in its resolution of 24 April 2009 on regulatory aspects of nanomaterials³ called *inter alia* for the introduction of a comprehensive science-based definition of nanomaterials in Union legislation
- (4) The definition in this Recommendation should be used as a reference for determining whether a material should be considered as a "nanomaterial" for legislative and policy purposes in the Union. The definition of the term "nanomaterial" in Union legislation should be based solely on the size of the constituent particles of a material, without regard to hazard or risk. This definition, based only on the size of a material, covers natural, incidental or manufactured materials.

¹ COM(2005) 243 final

² COM(2008) 366 final

³ P6_TA(2009) 0328

- (5) The definition of the term "nanomaterial" should be based on available scientific knowledge.
- (6) Measuring size and size distributions in nanomaterials is challenging in many cases and different measurement methods may not provide comparable results. Harmonised measurement methods must be developed with a view to ensuring that the application of the definition leads to consistent results across materials and over time. Until harmonised measurement methods are available, best available alternative methods should be applied.
- (7) The European Commission Joint Research Centre Reference Report "Considerations on a Definition of Nanomaterials for Regulatory purposes"⁴ suggests that a definition of nanomaterials should address particulate nanomaterials, be broadly applicable in Union legislation and be in line with other approaches worldwide. Size should be the only defining property which necessitates a clear definition of the nanoscale limits
- (8) The Commission mandated the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to provide scientific input on elements to consider when developing a definition of the term "nanomaterial" for regulatory purposes. The opinion "Scientific basis for the definition of the term 'Nanomaterial'" was subject to a public consultation in 2010. In its opinion of 8 December 2010⁵, the SCENIHR concluded that size is universally applicable to nanomaterials and the most suitable measurand A defined size range would facilitate a uniform interpretation. The lower limit was proposed at 1 nm. An upper limit of 100 nm is commonly used by general consensus, but there is no scientific evidence to support the appropriateness of this value. The use of a single upper limit value might be too limiting for the classification of nanomaterials and a differentiated approach might be more appropriate. For regulatory purposes, the number size distribution should also be considered using the mean size and the standard deviation of the size to refine the definition. The size distribution of a material should be presented as size distribution based on the number concentration (i.e. the number of objects within a given size range divided by the number of objects in total) and not on the mass fraction of nanoscale particles in the nanomaterial as a small mass fraction may contain the largest number of particles. The SCENIHR identified certain specific cases where the application of the definition can be facilitated by using the volume specific surface area as proxy to determine if a material falls within the defined nano size range.
- (9) The International Organization for Standardization defines the term "nanomaterial" as "material with any external dimensions in the nanoscale or having internal structure or surface structure in the nanoscale". The term "nanoscale" is defined as size range from approximately 1 nm to 100 nm.⁶
- (10) The number size distribution should cover for the fact that nanomaterials most typically consist of many particles present in different sizes in a particular distribution. Without specifying the number size distribution, it would be difficult to determine if a specific material complies with the definition where some particles are below 100 nm

⁴ EUR 24403 EN, June 2010

⁵ http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf

⁶ <http://cdb.iso.org>

while others are not. This approach is in line with the opinion of SCENIHR that the particle distribution of a material should be presented as the distribution based on the number concentration (i.e. the particle number).

- (11) There is no unequivocal scientific basis to suggest a specific value for the size distribution below which materials containing particles in the size range 1 nm – 100 nm are not expected to exhibit properties specific to nanomaterials. The scientific advice was to use a statistical approach based on standard deviation with a threshold value of 0.15%. Given the widespread occurrence of materials that would be covered by such a threshold and the need to tailor the scope of the definition for use in a regulatory context, the threshold should be higher. A nanomaterial as defined in this recommendation should consist for 50 % or more of particles having a size between 1 nm – 100 nm. In accordance with the SCENIHR's advice, even a small number of particles in the range between 1 nm – 100 nm may in certain cases justify a targeted assessment. However, it would be misleading to categorise such materials as nanomaterials. Nevertheless there may be specific legislative cases where concerns for the environment, health, safety or competitiveness warrant the application of a threshold below 50 %.
- (12) Agglomerated or aggregated particles may exhibit the same properties as the unbound particles. Moreover, there can be cases during the life-cycle of a nanomaterial where the particles are released from the agglomerates or aggregates. The definition in this Recommendation should therefore also include particles in agglomerates or aggregates whenever the constituent particles are in the size range 1 nm - 100 nm.
- (13) At present it is possible to measure the specific surface area by volume for dry solid materials or powders with the nitrogen adsorption method (“BET-method”). In those cases the specific surface area can be used as a proxy to identify a potential nanomaterial. New scientific knowledge may expand the possibility to use this and other methods to other types of materials in the future. There can be a discrepancy between the measurement of the specific surface area and the number size distribution from one material to another. Therefore it should be specified that results for number size distribution should prevail and it should not be possible to use the specific surface area to demonstrate that a material is not a nanomaterial.
- (14) Technological development and scientific progress continue with great speed. The definition including descriptors should therefore be subject to a review by December 2014 to ensure that it corresponds to the needs. In particular, the review should assess whether the number size distribution threshold of 50 % should be increased or decreased and whether to include materials with internal structure or surface structure in the nanoscale such as complex nano-component nanomaterials including nano-porous and nano-composite materials that are used in some sectors.
- (15) Guidance and standardised measurement methods as well as knowledge about typical concentrations of nanoparticles in representative sets of materials should be developed where feasible and reliable to facilitate the application of the definition in a specific legislative context.
- (16) The definition set out in this Recommendation should not prejudge nor reflect the scope of application of any piece of Union legislation or of any provisions potentially establishing additional requirements for those materials, including those relating to

risk management. It may in some cases be necessary to exclude certain materials from the scope of application of specific legislation or legislative provisions even if they fall within the definition. It may likewise be necessary to include additional materials, such as some materials with a size smaller than 1 nm or greater than 100 nm in the scope of application of specific legislation or legislative provisions suited for a nanomaterial.

- (17) Given the special circumstances prevailing in the pharmaceutical sector and the specialised nano-structured systems already in use, the definition in this Recommendation should not prejudice the use of the term "nano" when defining certain pharmaceuticals and medical devices,

HAS ADOPTED THIS RECOMMENDATION

1. Member States, the Union agencies and economic operators are invited to use the following definition of the term "nanomaterial" in the adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies.
2. "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.
3. By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.
4. For the purposes of point (2), "particle", "agglomerate" and "aggregate" are defined as follows:
 - (a) "Particle" means a minute piece of matter with defined physical boundaries;
 - (b) "Agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
 - (c) "Aggregate" means a particle comprising of strongly bound or fused particles.
5. Where technically feasible and requested in specific legislation, compliance with the definition in point (2) may be determined on the basis of the specific surface area by volume. A material should be considered as falling under the definition in point (2) where the specific surface area by volume of the material is greater than $60 \text{ m}^2 / \text{cm}^3$. However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with the definition in point (2) even if the material has a specific surface area lower than $60 \text{ m}^2/\text{cm}^3$.

6. By December 2014, the definition set out in points (1) to (5) will be reviewed in the light of experience and of scientific and technological developments. The review should particularly focus on whether the number size distribution threshold of 50 % should be increased or decreased.
7. This Recommendation is addressed to the Member States, Union agencies and economic operators.

Done at Brussels, [...]

For the Commission

[...]

Member of the Commission