EUROPEAN COMMISSION

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COMMISSION RECOMMENDATION

of […]

on the definition of the term "nanomaterial"

Draft

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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 Communication "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 EU legislation with a view to determine the applicability of the existing regulations to the potential risks of nanomaterials. The results of the review was contained in the Communication "Regulatory aspects of nanomaterials"[2] and the accompanying Commission staff document "Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures[3]. Nanomaterials are not mentioned specifically in Union legislation but the Communication concluded that current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials.

(3) The European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials[4] called for the introduction of a comprehensive science-based definition of nanomaterials in Union legislation as part of nano-specific amendments to relevant horizontal and sectoral legislation and further called on the Commission to promote the adoption of a harmonised definition of nanomaterial at the international level and to adapt the relevant European legislative framework accordingly.

(4) The European Commission Joint Research Centre Reference Report "Considerations on a Definition of Nanomaterials for Regulatory purposes"[5] suggests that a definition should only address particulate nanomaterials, be broadly applicable in Union

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1 COM(2005) 243 final
2 COM(2008) 366 final
3 SEC(2008) 2036
4 PA_T6(2009) 0328
5 EUR 24403 EN, June 2010

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. Enforceability of the definition requires the adoption of guidance on how such limits can be applied for particulate materials with size distribution.

(5) The Commission invited 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 adopted for public consultation on 6 July 2010[6]. SCENIHR concluded that size is universally applicable to nanomaterials and is a key element to a definition. 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 qualify 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 its standard deviation to refine the definition. In addition the SCENIHR identifies certain specific cases where the application of the definition can be facilitated by using the volume specific surface area as proxy for the internal or surface structure.

(6) The International Organization for Standardization (ISO) has been working on developing vocabulary and core terms for nanomaterials and nanotechnologies since 2005; the resulting vocabulary and core terms refer to the size range between approximately 1 nm and 100 nm[7].

(7) The definition of the term "nanomaterial" should be based on available scientific knowledge. The technological development and scientific progress continue with great speed. The definition should therefore be subject to regular reviews to ensure that it corresponds to the needs as identified by the objectives of the legislation in which it is going to be used. The definition of the term "nanomaterial" in this Recommendation should be used for regulatory purposes.

(8) The definition in this recommendation should cover nanomaterials consisting of particles in the size range 1 nm - 100 nm. The number size distribution should cover the typical case where a nanomaterial consists of particles present in different sizes in a particular distribution. The definition of the term "nanomaterial" in this Recommendation builds on the recognition that without specifying the number size distribution it will be difficult to determine if a material meets the definition when some particles are below 100 nm while others are greater. This approach conforms with the opinion of SCENIHR and others that the size distribution of a material should be presented as size distribution based on the number concentration (i.e. the particle number) and not on the mass concentration of a nanomaterial product as a small mass concentration may contain the largest number fraction. The one percent figure in this Recommendation is chosen in the absence of full scientific and technical knowledge about the actual distributions and available measuring techniques.

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6 http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_030.pdf

7 http://cdb.iso.org

(9) The definition in this Recommendation should also include agglomerates, aggregates and structured particles, including composites, in the size range 1 nm - 100 nm. The term "internal structure" should mean that nano-composites and even certain consumer products fall within the definition in this Recommendation. For agglomerates, aggregates and structured particles, including composites, no universally measurable minimum threshold figure is available. For dry solid materials, the specific surface area by volume can be used to distinguish nanomaterials with internal or surface structures in one or more dimensions in the size range 1 nm – 100 nm from materials not fulfilling that criterion.

(10) Guidance should be provided to explain legislative provisions where necessary. Typically guidance should inter alia address issues such as size distribution of particulate samples, how to further interpret the criterion in Article 2 (1) second indent in the absence of a universally measurable minimum threshold figure taking into account a high level of protection of humans and the environment, proportionality and practicality of implementation and enforcement, particle size stability and measurement of the specific surface area by volume, measured in accordance with the standardised methods when such have been developed or, in the absence of such methods with best available methods.

(11) The definition in this recommendation should determine when a material should be considered as a nanomaterial for legislative and policy purposes in the Union. It should cover all nanomaterials, whether they are of natural, incidental or manufactured origin. It should not prejudge nor reflect the scope or application of different pieces of Union legislation or of any provisions potentially determining requirements on nanomaterials, including those of a risk management nature. It may be necessary to exclude certain nanomaterials from the scope of application of specific legislation or legislative provisions which are deemed inappropriate for these nanomaterials. It may also be necessary to include other materials including notably some materials with a size smaller than 1 nm into the scope of application of specific legislation or legislative provisions because these materials are similar to nanomaterials.

(12) The Commission intends to use the definition for the term "nanomaterial" contained in this Recommendation as an overarching, broadly applicable reference term for any Union communication or legislation addressing nanomaterials.

HAS ADOPTED THIS RECOMMENDATION:

Article 1

1. This Recommendation concerns the definition of the term "nanomaterial" used in Union policies and legislation applied within the European Union and the European Economic Area.

2. Member States, the Union agencies and Industry are invited to use the definition of the term "nanomaterial" when adopting and implementing legislation and programmes concerning products of nanotechnologies.

Article 2

1. Nanomaterial: means a material[8] that meets at least one of the following criteria:

   – consists of particles, with one or more external dimensions in the size range 1 nm - 100 nm for more than 1 % of their number size distribution;

   – has internal or surface structures in one or more dimensions in the size range 1 nm – 100 nm;

   – has a specific surface area by volume greater than 60 m^2/cm^3, excluding materials consisting of particles with a size lower than 1 nm.

2. Particle: means a minute piece of matter with defined physical boundaries (ISO 146446:2007)

Article 3

1. The Commission will carry out a public consultation by 2012 and if appropriate review the adequacy of Article 2 taking into account experience gained, scientific knowledge and the technological development.

Article 4

1. This Recommendation is addressed to the Member States, Union agencies and Industry.

Done at Brussels, […]

For the Commission
[…]
Member of the Commission

[8] The term "material" is replaceable with other terms for an object used in the specific legal context.