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Commission adopts the first-ever international definition of nanomaterials for regulatory purposes

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The European Commission's hesitation to provide a legal definition of nanomaterials came to an end last week when its services adopted and released a long-awaited and much-debated recommendation for a regulatory definition for nanomaterials on 18 October. The definition builds on a draft definition released last year, but includes a number of substantial changes.

The Commission's definition is in the form of a recommendation that is not legally binding. The intention is that it will be incorporated into sector- or product-specific legislation and that that legislation will then be legally enforceable.

Background

Nanomaterials are increasingly used in a wide range of innovative applications and products, and are currently governed by several pieces of EU legislation that, apart from the new Cosmetic Products Regulation, do not provide operational definitions and clear descriptions of what can and cannot be considered nanomaterials. The lack of a common definition had become a source of ambiguity and confusion for all those involved in the regulatory control and assessment of nanomaterials (especially in the field of chemicals). The initiative to frame a definition for regulatory purposes follows a long period of deliberation and an extensive public consultation that involved market participants, consumer and non-governmental organisations, academia, national governments and national competent authorities.

Recommendation on the definition of a nanomaterial

The major aspects of this definition are as follows: *'"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. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials. 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 %.'*[1]

For reasons of clarity and ease of application, the size of the constituent particles has been selected as the only common 'property' of objects in the nanometre region. The Commission's definition departs from the standard ISO definition of the term 'nanomaterial' in terms of being limited to materials consisting of particles (excluding non-particular materials) and excluding

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[1] http://eur-lex. europa. eu/LexUriServ /LexUriServ.do? uri=OJ:L: 2011: 275:0038:0040:EN:PDF

nanostructured materials (i.e. solid products, parts or components) with an internal or surface structure in the range between 1-100 nm, such as computer chips.

The goal of the recommendation is to provide a legal reference for defining nanomaterials when adopting new or implementing existing legislation, as well as setting out clear and unambiguous criteria for the identification of nano-materials. The definition is broad in its coverage but does not prevent the adoption of sector-specific qualifiers or other "nano"-terms for certain products -- such as pharmaceuticals -- that do not necessarily follow the 1 nm – 100 nm nanoscale. The Recommendation exclusively concerns the defining aspects of materials within a specific size range, without making a causal link between nano size alone and hazards.

The Commission considers size to be the only universally applicable, clear and measurable criterion which can be used to identify materials which, due to their particle size, may exhibit specific properties or risks, and which therefore should be characterised as nanomaterials, and for which special considerations might apply. In fact, one purpose of the definition is to provide clear and unambiguous criteria for the relevant risk assessment procedures that aim at determining whether the nanomaterial is hazardous and whether or not further action is justified.

The Recommendation's scope covers nanomaterials when they are substances or mixtures, but implicitly not when they are final products. This approach is identical to that followed by the ISO. This means that if a nanomaterial is used together with other ingredients in a formulation, the entire product will not become a nanomaterial.

Comment

The adopted definition is neutral, and is expected to help companies to assess their registration dossiers and determine when they should consider their products to be nanomaterials. At the same time however, it seems too broad in scope to be valuable and to require the adoption of special guidance notes on how such limits can be applied for nanoscale materials with size distributions.

There is a notable absence of scientific reasoning or justification for the appropriateness of the criteria and size limits distinguishing nano- from non-nanomaterials within a regulatory setting. It remains unclear where the scientific basis for the 50% threshold lies, how this applies to aggregates and agglomerates, and how diameter is defined. In fact, the 50% threshold introduced for nano-content significantly departs from the respective recommendation of the Scientific Committee on Emerging and Newly Identified Health Risks (0.15%), whereas the clause introduced regarding the environment, health, safety or competitiveness concerns places a considerable burden of proof on those called to demonstrate that certain nanomaterials can cause harm. (*'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 %'*).In fact, the use of a single upper limit value and the focus of its scope on unbound particles and their aggregates and agglomerates based solely on the size of the constituent particles of a material, without regard to hazard or risk or to materials with internal or surface structures in the nano-range, might prove to be too limiting for the classification of nanomaterials in practice. The definition might therefore be simply unusable.

The Commission has said it intends to revisit all aspects of this definition by December 2014.

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