

Cefic interpretation of some elements of the EU Commission Recommendation on the definition of nanomaterial

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Introduction

This document is trying to outline an interpretation of the Commission Recommendation of a Definition for Nanomaterials (2011/696/EU) to help Cefic's membership to comply. The following document has been used and discussed with company experts in the drafting of this paper;

- Recommendation itself (2011/696/EU), Annex 1
- Commission Q&A document, Annex 2

General Remarks

According to Chapter 1 of the Commission's Q&A document, the definition will primarily be used to identify materials for which special provisions (concerning for example risk assessment or ingredient labelling) might apply. Those special provisions are not part of the definition but of specific legislation in which the definition will be used. According to Chapter 19 of the Q&A document, the implementation of the definition will happen through various pieces of specific legislation, as the definition as such does not contain any direct obligations for Member States and economic operators.

According to Chapter 13 of the Q&A document, the Recommendation's scope covers nanomaterials when they are **substances** or **mixtures**, but implicitly not when they are final products. This means, as the Q&A document says, that if a nanomaterial is used amongst other ingredients in a formulation the entire product will not become a nanomaterial.

Recommendation Point 2, para 1

"Nanomaterial" means a

- (1) natural, incidental or manufactured**
- (2) material**
- (3) containing particles,**
- (4) in an unbound state or as an aggregate or as an agglomerate**
- (5) 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.**

General remarks:

As the Recommendation [only] covers nanomaterials when they are **substances** or

mixtures, nanomaterials are, dependent on the specific case, either forms of a substance, or substances on its own; or they are mixtures of substances, but, in Cefic's opinion, **only if the mixture contains particles**.

- ad (3):

The word “**particle**” means, according to point 4 of the Recommendation, “a minute piece of matter with defined physical boundaries”. In Cefic's opinion this should be understood as a minute piece of matter of a **solid** substance.

Large molecules unless they are explicitly mentioned like fullerenes, and non-particular materials such as proteins or micelles, are, according to Chapter 3 of the Q&A document, not nanomaterials.

- ad (4):

According to Chapter 10 of the Q&A document and Recital 12 of the Recommendation, the Commission considers **aggregates and agglomerates** of nanoparticles as nanomaterials, as agglomerated or aggregated particles may exhibit the same properties as unbound particles. Moreover, as the Commission continues, there can be cases during the life-cycle of a nanomaterial where the particles are released from weakly bound agglomerates or under certain conditions even from more strongly bound aggregates. The Commission states that the definition in the Recommendation therefore includes particles in agglomerates or aggregates whenever the “**constituent particles**” (**sic!**) are in the size range 1 nm - 100 nm.

According to Chapter 12 of the Q&A document, the recommendation only concerns particulate nanomaterials but is equally applicable to particles in an unbound stage as well as when they are aggregated or agglomerated. Reading this, Cefic comes to the conclusion that the “**particles**” **must be either in an unbound state, or the “particles” must be aggregated, or the “particles” must be agglomerated**; the 50 % threshold for the particles in the number size distribution with one or more external dimensions in the size range 1 nm - 100 nm therefore includes the “**constituent particles**” of agglomerates or aggregates.

- ad (5):

As far as the **threshold for the “nano” fraction** is concerned, the definition says that for 50 % or more of the particles in the number size distribution, one or more external dimensions must be in the size range 1 nm - 100 nm. As already elaborated above, Cefic concludes that the 50 % threshold for the particles in the number size distribution, with one or more external dimensions in the size range 1 nm - 100 nm, **includes** the “**constituent particles**” of agglomerates or aggregates.

It should be noted that this requires, theoretically, the ability to measure particles down to 1 nm in all external dimensions and, on the other side, to a medium micrometer range. No such measurement method is known today. If measurement methods are to be developed, e.g. by JRC, they have to be suitable, robust, standardized and to be at a reasonable cost.

In Cefic's opinion **the definition does not explicitly require measuring a size distribution**. It asks, as a minimum, for a division of the particles into two "boxes": one box with particles having one or more external dimensions in the size range 1 nm - 100 nm and one box for bigger particles, and then comparing the number of particles in both boxes.

Recommendation Point 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 (VSSA). 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 $60 \text{ m}^2 / \text{cm}^3$.

- VSSA can be used as a "**proxy**" to identify a potential nanomaterial "where technically feasible and requested in specific legislation". It is, therefore, specified in the Recommendation that **results for the 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.
- If a product has a VSSA **greater than $60 \text{ m}^2 / \text{cm}^3$** , the product can be considered as a nanomaterial without further investigation on the number size distribution. But as the number size distribution shall prevail, Cefic concludes that if an analysis of the number size distribution shows that **less** than 50 % of the particles have one or more external dimensions in the size range 1 nm - 100 nm, then the product is **no** nanomaterial even if the VSSA is greater than $60 \text{ m}^2 / \text{cm}^3$.
- If a product has a VSSA **lower than $60 \text{ m}^2 / \text{cm}^3$** , the product cannot automatically be considered as not being a nanomaterial. This conclusion can only be drawn if **less** than 50 % of the particles in the number size distribution have one or more external dimensions in the size range 1 nm - 100 nm.

Final remarks

As long as there are no valid methods available for determination of the number size distribution, an interim agreement between the Commission, ECHA, national authorities and industry has to be made on how to comply with the recommendation.