



Joint Position and Proposals on the review of the EU recommendation on a revised definition of the term “nanomaterial”

European regulatory approach to nanomaterials:

Under the European approach, nanomaterials are defined solely based on size. The mere fact that a material has 1 or more dimensions in the range of 1 to 100 nm does not justify the additional provisions, data requirements or assessments in downstream legislation. We deeply regret that the Authorities and European Agencies (specially EFSA) stigmatise nanomaterials and consider them *de facto* as potentially hazardous prior to any assessment.

European legislation shall ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles. This is equally true for all materials.

The burden of proof for industry to demonstrate any nanomaterial is safe in a given application is extremely high and disproportionate. This is particularly true for nanomaterials that do not exhibit nano properties or products that have been on the markets for centuries (e.g. clays) and that have been newly identified as nanomaterial under the EC recommended definition.

Proposals to improve the definition of nanomaterial

A mineral is (i) a naturally occurring inorganic element or compound with (ii) a characteristic ideal chemical composition and (iii) a known 3-dimensions crystal structure. Thus, the structure of minerals is typically described in terms of grains, crystals, crystallites or polycrystals. The EC recommended definition of nanomaterial however uses the term ‘particle’, ‘aggregate’ and ‘agglomerate’. This EC terminology cannot be transposed one to one on industrial minerals. To ensure a correct implementation of the EC definition, it is essential to clarify which relevant physical boundaries of particles shall be considered for naturally occurring mineral products. Our industry suffers from a recurrent misinterpretation of the nanomaterials definition where crystallites are wrongly identified as particles.

This exclusion of grains and polycrystal materials does not explicitly appear in the text of the EC definition of nanomaterials, but is mentioned in at least two JRC reports providing evidence-based scientific support to the European Commission. To resolve this crucial issue for the industrial minerals sector, IMA-Europe proposes to introduce the modifications in blue below for the term ‘particle’, ‘aggregate’ and ‘agglomerate’ in the revised EC recommended definition of nanomaterial:

1. Clarification on the term ‘particle’

Our first concern relates to the definition of the term ‘particle’. This issue is already recognised and highlighted by the JRC in the report “An overview of concepts and terms used in the European Commission’s definition of nanomaterial, (2019)” as follows:

*“Defined physical boundaries also separate crystallites in a polycrystalline solid material. These crystallites are called grains, and they are usually formed during solidification of a liquid cooled down below its melting temperature, or by recrystallization of an already solidified material. **The presence of grains alone does not make these materials particulate materials, and therefore they do not fall in the scope of the EC NM definition.** Such materials may be used as a basis for the preparation of nanomaterials, e.g. by milling or grinding. However, **the pre-existing intergranular boundaries do not constitute ‘particle boundaries’.** Only the external dimensions of the particles newly created in the comminution process are particle boundaries.*

*In any case, for classification as nanomaterial the morphological identification of particles is needed. This identification may be difficult for a heavily sintered aggregate. In such cases, the knowledge of the production process can serve to **distinguish polycrystalline materials (which are not nanomaterials) from heavily aggregated materials (which may be nanomaterials).**”*

In other words, the newly created particle boundaries formed during the processing of minerals (e.g. grinding) are the relevant boundaries for the implementation of the definition. The inner structure of the material consisting of crystals or crystallites shall not be considered as individual particles.

Accordingly, IMA-Europe proposes the following modification to the EC recommended definition of nanomaterial:

*(a) “particle” means a minute piece of matter with defined physical boundaries; [E2] single molecules **and crystallites** are not considered ‘particles’*

2. Clarification on the terms ‘aggregate’ and ‘agglomerate’

Specific to crystals and polycrystals, the JRC further clarifies in its report “Identification of nanomaterials through measurements”, (2019) that:

*“Constituent particles are all **particles that once were individual particles** but appear as parts of aggregates or agglomerates as well as particles that appear separate from one another. **This excludes the possible seed particle and individual crystals of polycrystalline particles,** but includes the particles that make up agglomerates and the particles that are combined to form aggregates.”*

IMA-Europe thus proposes to introduce the clarification that aggregates, and agglomerates consist of particles that once were individual particles. A proposal is available in blue below.

*(b) “agglomerate” means a collection of weakly bound particles **that once were individual 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 **collection** ~~particle comprising~~ of strongly bound or fused particles **that once were individual particles.***

The proposal also contains a small correction about the definition of aggregate as it appears odd to define an aggregate as a particle comprising of particles.



Commission Guidance on the implementation of the Recommendation of the definition of nanomaterial

IMA-Europe supports the development of a Commission Guidance to implement the recommendation of the definition of nanomaterial.

To truly support the implementation, the Commission guidance shall consider the broad variety of materials potentially covered by the definition and describe complex cases such as size-polydisperse materials, coarse materials having a nano-tail, substances of unknown or variable composition, complex reaction products or of biological materials (UVCB) and materials of different solubility under physiological and environmental conditions. We also recommend including concrete case-studies with the support of industry.

Comments on change 3: Restriction of the particles to be considered for counting

IMA-Europe disagrees with the exclusion of “*Particles with at least two orthogonal external dimensions larger than 100 micrometres*” from the counting for the number size distribution.

Any exclusion of particles from the counting will potentially result in more materials falling within the scope of the definition of nanomaterial. Particles of all sizes shall be included in the size distribution and have the same probability of being counted to avoid analytical bias.

In addition, the range 100 micrometres to 1 nm is still too large to achieve analytical improvement or to ease the implementation or the definition. More particularly, there is still no method available that can provide a number-based particle size distribution over the complete size range of 100 micrometre to 1 nm. Although electron microscopy may offer the possibility to visualise the full range of particle sizes, there is no counting method that can combine the number-based particle size distribution obtained at different magnifications.

For the reasons outlined above, we recommend the removal of this provision from the definition.

Comment on Change 2: a material with a specific surface area by volume of 5 m²/cm³ or less shall not be considered a nanomaterial.

IMA welcomes the introduction of a screening criteria in the EC recommended definition of nanomaterial. It shall however be emphasised that the exclusion of materials based on specific surface area (SSA) is only an exclusion criterion and that materials having a volume-specific surface area (VSSA) above the threshold require further analysis to conclude on their nanomaterials status.

Despite our support for the introduction of the SSA exclusion criterion, we disapprove the introduction of a single threshold of 5 m²/cm³.

This approach is in contradiction with the conclusions of the NanoDefine project which provides a scientific basis for **shape dependent VSSA cut-off values**. There is sufficient scientific data available to



support the introduction of shape-based criteria in the recommended definition and applicable thresholds are already established in the NanoDefine Methods Manual (2020).

Accordingly, we propose the following modification to the definition:

“A material with a specific surface area by volume of:

- 24 m²/m³ for spherical particles (aspect ratio <3:1:1, D=3)

- 16 m²/cm³ for elongated, fibre-like particles fibre-like (aspect ratio >3:1:1, D=2)

- 8 m²/cm³ for Flat, platelet (aspect ratio >3:3:1, D=1)

or less, shall not be considered a nanomaterial.”

To conclude this point, we also recommend that the Commission clarifies the density of the material to be used in the calculation from SSA to VSSA. This shall be done in the Commission Guidelines, or by referring to the NanoDefine Methods Manual (2020).