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COMMISSION RECOMMENDATION

of 10.6.2022

on the definition of nanomaterial

(Text with EEA relevance)

{SWD(2022) 150 final}

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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) Commission Recommendation 2011/696/EU¹ has been applied as a reference for determining whether a material should be considered a 'nanomaterial' for legislative and policy purposes in the Union, supporting efficient and consistent implementation across sectors. Recommendation 2011/696/EU refers to a later review of the definition of nanomaterial in the light of experience and of scientific progress.
- (2) Between 2013 and 2021, the Commission carried out such a review of Recommendation 2011/696/EU, addressing the objective, scope, clarity and use of its definition of nanomaterial. The review in particular focused on whether the particle number-based 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 nanocomponent materials including nanoporous and nanocomposite materials that may be used in specific sectors.
- (3) Technical and scientific elements underpinning the review of the definition of nanomaterial in Recommendation 2011/696/EU were summarised and published in the Commission's Joint Research Centre's (JRC) Science for Policy reports 'Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Part 1², 2³ and 3⁴ on the experience of stakeholders with the implementation of the definition and with the identification of possible points of revision. In addition, JRC published two reports providing guidance on the implementation of the definition^{5,6} including relevant developments in standardisation by the International Organization for

¹ Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38).

² Towards a review of the EC Recommendation for a definition of the term "nanomaterial; Part 1: Compilation of information concerning the experience with the definition; EUR 26567 EN; doi:10.2788/36237 (2014).

³ Towards a review of the EC Recommendation for a definition of the term "nanomaterial; Part 2: Assessment of collected information concerning the experience with the definition; EUR 26744 EN; doi: 10.2787/97286 (2014).

⁴ Towards a review of the EC Recommendation for a definition of the term "nanomaterial; Part 3: Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation; EUR 27240 EN; doi:10.2788/678452 (2015)

⁵ An overview of concepts and terms used in the European Commission's definition of nanomaterial; EUR 29647 EN; doi:10.2760/459136 (2019)

⁶ Identification of nanomaterials through measurements ; EUR 29942 EN; doi:10.2760/053982 (2019)

Standardization (ISO) and the European Committee for Standardization (CEN), results of the NanoDefine project of the Commission's 7th Framework Programme for Research⁷, and further information available in the public domain.

- (4) Elements for possible modifications of the definition were the subject of a targeted stakeholder consultation between 6 May and 30 June 2021. Information received during that consultation was considered in the Commission's review of the definition of nanomaterial.
- (5) The results of the review and the stakeholder consultation, the description of the modifications made and their rationale are explained in the Commission staff working document (SWD(2022)150) accompanying this Recommendation.
- (6) A definition of nanomaterial that is appropriate in the general context of Union policy and legislation ('the definition') should be recommended, covering natural, incidental or manufactured materials.
- (7) The definition should be based on the relative fraction of particles in a defined range within the particle number-based distribution of the external dimension of the constituent particles of a material, irrespective to its potential inherent hazardous properties or risks to human health and the environment.
- (8) The definition and its core terms should, where applicable, be based on existing scientifically defined and standardised terms adopted by the international communities (ISO, CEN). The core terms used in the definition should remain sufficiently specific and should enable practical implementation of the definition within the Union regulatory context. Implementation should be supported by guidance that should be developed by the JRC and kept updated with evolving science and technical progress, listing recommended measurement methods and best practice tools⁷.
- (9) The term nanomaterial should address materials consisting of particles in solid state, present on their own or bound as constituent parts of aggregates or agglomerates. The term 'consist of' rather than 'contain' should be used to acknowledge that the particles are the principal component of the material. Other non-particulate components potentially present (e.g. additives necessary to preserve its stability or solvents that may be separated without affecting the particle size distribution) are part of the (nano-) material but should not be taken into account when assessing whether a material is a nanomaterial.
- (10) The definition should exclude non-solid (i.e. liquid and gaseous) particles. This should ensure that the highly dynamic nature of the external dimensions of non-solid particles, such as micelles or nanoscale droplets in emulsions or sprays, does not prevent the use of the external dimension as the defining qualifier in the definition.
- (11) The definition should not cover large solid products or components, even when they have an internal structure or a surface structure at the nanoscale, such as coatings, certain ceramic materials and complex nanocomponents, including nanoporous and nanocomposite materials. Some of these products or components may have been manufactured by using nanomaterials and may even still contain them.
- (12) The definition should continue to follow the 2010 opinion of the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)⁸ by defining 'nanoscale' as the size range from 1 nm to 100 nm.

⁷ The NanoDefine Methods Manual ; EUR 29876 EN; doi:10.2760/79490 (2020)

- (13) The review of the definition did not identify scientific evidence that the default threshold of 50 % of particles with external dimensions at the nanoscale should be increased or decreased to address particular concerns or cover or exclude specific types of materials. The flexibility of the default threshold value in specific cases, provided in Recommendation 2011/696/EU, should be removed to ensure regulatory consistency and coherence, and to avoid that a specific material is considered a nanomaterial under one regulatory framework but not under another, hence avoiding legal uncertainty for economic operators, consumers and regulators.
- (14) The definition should cover both particles on their own and identifiable constituent particles in agglomerates or aggregates. The review of the definition highlighted that the identification and measurement of constituent particles in aggregates can be very challenging. Thus, the qualifier 'identifiable' is bound by practical considerations pertaining to their identification. These considerations should be further elaborated in guidance.
- (15) The term 'particle' should be defined as a minute piece of matter with defined physical boundaries, thus pursuant to the definition of 'particle' adopted in ISO 26824:2013. Any technical aspects of the definition of particle, e.g. with regard to its mobility, should be further clarified in guidance.
- (16) A single molecule, including a macromolecule such as a protein that may be larger than 1 nm, should not be considered as a particle. In very specific cases, the distinction may depend on a precise understanding of the term 'single molecule'. Illustrative cases and explanations should be presented in guidance.
- (17) SCENIHR indicated that setting the 1 nm to 100 nm range may lead to a limited number of materials, such as (nano)tubes that would have a diameter smaller than 1 nm and a length exceeding 100 nm, not to be considered as nanomaterials . To address this potential omission, Recommendation 2011/696/EU included in the definition fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm as nanomaterials. However, other materials may have the same size characteristics as these carbon-based materials. It is also likely that scientific progress and innovation will result in more similar materials, requiring regular and continuous updates of the scope of the definition. To avoid this, the definition should therefore include all solid particles with at least one external dimension smaller than 1 nm in the tally of particles at the nanoscale to be compared against the 50 % threshold, if at least one of the other dimensions of these particles exceeds 100 nm.
- (18) Due to their much smaller number in all reasonably foreseeable and relevant situations, particles with at least two orthogonal external dimensions larger than 100 µm do not significantly influence the relative contribution of 1 nm to 100 nm particles in the total number of particles, and therefore do not affect to a significant extent the classification of materials. The definition should allow to restrict the determination of the particle number-based size distribution only to constituent particles with at least two orthogonal external dimensions below 100 µm, provided that the choice is documented by appropriate measurement results. Practical application of this option should be presented in guidance.

⁸ http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf

- (19) Experience has shown⁹ that use of specific surface area as a proxy indicator when identifying a nanomaterial can lead to interpretation and technical difficulties, for example, as a high specific surface area may be due to an internal nanostructure rather than indicate the presence of a large number of small constituent particles. Therefore, the review of the definition identified that the related option provided in point 5 of Recommendation 2011/696/EU was not appropriate and should be removed from being a qualifier in the definition of a nanomaterial.
- (20) The NanoDefine⁹ project demonstrated, based on a large set of different industrial materials, that there were no inconsistencies in classification of non-nanomaterials, based on the median value determined from the particle number-based size distributions and on the volume specific surface area being less than 6 m²/cm³ (even if particle shape is unknown), respectively. Therefore, a material with a volume specific surface area less than 6 m²/cm³ should not be considered a nanomaterial.
- (21) The nanomaterial definition in Recommendation 2011/696/EU should therefore be updated.
- (22) Scientific and technical progress continues and may affect the rationale behind the elements used for identifying a nanomaterial. A review of the definition should therefore be considered whenever new scientific evidence or regulatory experiences demonstrate that the definition is no longer adequate.
- (23) The definition should neither affect nor reflect the scope of application of any instrument of Union legislation or of any provisions establishing, for a group of materials, additional or specific requirements (including those for safety). It may in some cases be considered necessary to exclude certain materials from the scope of application of specific legislation or legislative provisions even if they are nanomaterials according to this Recommendation. It may likewise be considered necessary to develop regulatory requirements for additional materials not falling under the definition of the present Recommendation, in the scope of application of specific Union legislation or legislative provisions targeting nanomaterials. Such legislation should, however, aim to differentiate between a 'nanomaterial' and a member of such subgroup as to maintain consistency with the definition and consequently other legislation.
- (24) The definition in this Recommendation may serve different policy, legislative and research purposes when addressing materials or issues concerning products of nanotechnologies. It may even be used in another act providing a definition of nanomaterial for horizontal policy and legislative use adopted by the Commission or Union legislator, in which case such act would replace this Recommendation.

HAS ADOPTED THIS RECOMMENDATION:

1. 'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions:

⁹ NanoDefine, Evaluation report on the applicability ranges of the volume specific surface area (VSSA) method and the quantitative relation to particle number-based size distribution for real-world samples, Deliverable number 3.5, 2015 and Reliable nanomaterial classification of powders using the volume-specific surface area method”, J Nanopart Res 19, 61 (2017); DOI: 10.1007/s11051-017-3741-x

- (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm;
- (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;
- (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.

In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100 µm need not be considered.

However, a material with a specific surface area by volume of $< 6 \text{ m}^2/\text{cm}^3$ shall not be considered a nanomaterial.

2. For the purposes of point 1, the following definitions apply:

- (a) ‘particle’ means a minute piece of matter with defined physical boundaries; single molecules are not considered ‘particles’;
- (b) ‘aggregate’ means a particle comprising of strongly bound or fused particles;
- (c) ‘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.

3. It is recommended that the definition of the term ‘nanomaterial’ set out in the latest recommendation or other act providing a definition of nanomaterial for horizontal policy and legislative use adopted by the Commission or Union legislator is used when addressing materials or issues concerning products of nanotechnologies:

- (a) by the Commission, when preparing legislation, policy programmes or research programmes and when implementing such legislation or programmes also with other Union institutions and agencies;
- (b) by Member States, when preparing legislation, policy programmes or research programmes and when implementing such legislation or programmes;
- (c) by economic operators, when preparing and conducting their own policies and research.

4. This Recommendation updates Recommendation 2011/696/EU.

Done at Brussels, 10.6.2022

For the Commission
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Member of the Commission