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PERSPECTIVES

To be or not to be a nanomaterial

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Abstract In early 2021, the new definition of the term "nanomaterial" proposed by the European Commission (EC) was subject to a stakeholder consultation and in June 2022, the EC published its updated definition. Based on an independent analysis of the different versions of the definition and the results of the stakeholder consultation, the aim of this paper is to identify key aspects to be considered when deciding whether a material should be regarded as a nanomaterial. More than 130 comments submitted during the stakeholder consultation by various organizations, companies, citizens, and authorities were analyzed. We find that the introduction of new terms such as "solid particles" has added clarity to terms used in the former definition. Our analysis shows that stakeholders seemed inclined to maintain the default number-based 50% threshold value, but were opposed to (1) the possible flexibility of varying the threshold in specific sectorial legislation, (2) the default inclusion of carbonaceous materials < 1 nm, and (3) the use of volume specific surface area (VSSA) other than for excluding materials from being defined as nanomaterials. Overall, we find that the updated definition addresses many of the limitations of the former definition. However, the updated definition also creates new challenges that will have to be addressed via development of new regulatory guidance. Apart from the relatively minor change of the VSSA threshold from 5 to 6 m^2/cm^3, it generally seems that no arguments from the stakeholder consultation made the EC reconsider its position.

Keywords Regulation · Nanomaterials · Definition · Stakeholder consultation · Particle size distribution · Volume-specific surface area · European Commission

Introduction

In 2011, the European Commission adopted a recommendation on the definition of a nanomaterial for the purpose of regulating nanomaterials within the European Union [1] (henceforth, the former definition). Since then, several issues regarding the regulatory usefulness of the definitions have been noted, such as lack of methods for measuring particle size distributions of nanomaterials [2]. In early 2021, a new definition proposed by the European Commission was subject to a stakeholder consultation, which ended 30 June 2021 [3] (henceforth, the proposed definition). Eventually, this led to the adoption of an updated definition in June 2022 (henceforth, the updated definition) [4]. The three definitions are shown in Box 1.

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Box 1 European Commission's former, proposed, and updated definitions of a nanomaterial

Former definition (2011)

"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. 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%. Fullerenes, graphene flakes and single-wall carbon nanotubes should furthermore be considered as nanomaterials by default."

Proposed definition (2021)

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

a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; or

b) the particle has an elongated shape, such as a rod, fibre or tube, the external dimensions of which do not

satisfy point a), but where at least one external dimension is smaller than 1 nm; or

c) the particle is in a plate-like shape, the external dimensions of which do not satisfy point a), but where

one external dimension is smaller than 1 nm

Particles with at least two orthogonal external dimensions larger than 100 µm shall not be counted for the purpose of the number size distribution

A material with a specific surface area by volume of 5 m^2/cm^3 or less shall not be considered a nanomaterial."

Updated definition (2022)

"'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:

(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 m2/cm3 shall not

be considered a nanomaterial."

In total, the European Commission received 138 comments during the consultation from various organizations, companies, citizens and authorities. After analyzing all stakeholder responses in detail, the Commission decided that the definition from 2011 should be replaced. The Staff Working Document (SWD) that accompanies the Review of the Commission Recommendation 2011/696/EU provides a detailed statistical analysis of the structured responses and the Commission's summary response to the stakeholder comments [5]. Here, we provide an independent analysis of the results of the stakeholder consultation where we aim to identify key aspects for consideration when a revised regulatory nanomaterials definition is to be decided upon. Furthermore, we discuss the extent to which the proposed definition has resolved the previous issues or created new ones and to which extent different stakeholder comments seem to have influenced the revision.

The stakeholder consultation

The stakeholder consultation consisted of a range of questions that can broadly be categorized into four groups. The first series of questions focused on the stakeholders themselves, their origin, contact information, and expertise. Questions included the following: Are you a citizen or answering on behalf of an organization?; Name of organization?; Declared area of self-competence and interest; and intended use of the definition by the respondent. For many of these questions, predefined drop-down options were available only, e.g., least relevant, relevant, most relevant. The second group of questions focused on the general format, fitness for purpose and consistency of the recommendation on the definition of nanomaterial under review. A third group of questions related to specific changes that the EC had implemented in the proposed definition, e.g., Does the change from 'containing' to 'consisting of' clarify the scope of the definition?; Do you agree with the restriction to solid particles only?; Do you agree with the replacement of the reference to the 'unbound state'?; Do you agree with the reference to the 'identifiable constituent' particles?; Do you agree that particles with at least two orthogonal external dimensions larger than 100 µm should not

be counted for the number based size distribution?; and Do you agree not to consider single molecules as "particles" in the definition?

Finally, a group of question focused on the expected impact of the proposed definition, e.g., Please identify your materials, their approximate volume on the market and use (present or planned) that you consider would be affected by the suggested change, and the dimensions of their particles or another feature, to the extent you know them, that would make them affected by the considered changes to the definition. This category also included questions such as which EU or national regulations with nanomaterial specific provisions do you see being applied to the material(s)? and the impact of categorization of the material(s) as nanomaterial on the placement on the market and innovation. For many of the questions, it was possible to provide comments.

Fitness of the former definition

The former definition has been subject to an interim review by the Commission as well as the Commission's Joint Research Centre (JRC). They found that the former definition is "fit for purpose" in the way that its main elements are generally accepted. However, uptake of the definition in EU regulations has not been as comprehensive as anticipated because of insufficient clarity about key elements of the definition. For example, the term "particle" remains challenging according to the JRC as universally applicable standardized particle size measurement methods, especially for imaging, are lacking. Moreover, the default inclusion of some carbon-based materials (fullerenes, graphene flakes and single wall carbon nanotubes) was considered outdated [6]. During the stakeholder consultation of the proposed definition [7], 60% of all the stakeholders mostly agreed with these interim findings; 17% fully agreed and 17% mostly disagreed (Fig. 1). Citizens and companies mostly agreed, whereas seven organizations noted that they only agreed with the former definition being fit for purpose and its implementation challenging. In contrast to the interim findings by the JRC [6], several companies and trade organizations, such as EFfCI—The European Federation for Cosmetic Ingredients, AISBL, CEFIC, and the German Chemical Industry Association (VCI), concluded that the former definition is not fit for purpose or that the purpose of the definition is not clear. The poor regulatory uptake of the former definition reflects, according to some organizations, its poor quality, and limited utility. Other stakeholders, such as some EU Member State (MS) authorities, agreed that the former definition was not fit for purpose for all sectors, such as food, and argued this is why sectoral legislation has not yet been harmonized. Also, several EU MS authorities explained that not all regulations have been opened for review and hence, the former definition could for practical reasons not have been adopted yet [7].

New terms introduced

During the stakeholder consultations, the former definition was often mentioned to have many unclear terms in need of further clarification, such as "particle," "unbound," "aggregate," and "agglomerate" [7]. The proposed definition introduces a series of changes to the materials covered. Many of these changes were positively received by the respondents, including the change from "material containing" to "material consisting of"; the restriction to "solid particles" only; and the replacement of "unbound state" with "present on their own" (Box 1). For these three changes, 80% or more of the respondents either agreed or mostly agreed. Hence, it comes as little surprise that these changes were maintained in the updated definition. Several stakeholders call for regulators to ensure the new terms introduced are clearly understood by all stakeholders and verifiable by standardized quantification methods adequate for regulatory decision making. Seven respondents suggested that coatings/films/layers should be explicitly excluded if these are not intended to be included. Interestingly, the EC's own scientific committees on consumer safety (SCCS) and health, environmental, and emerging risks (SCHEER) argue that the term "solid" should be extended to include "soft" natural or synthetic nanomaterials/constructs since they may behave similarly to solid nanomaterials in biological systems [7].

Most (80%) of the stakeholders mostly or fully agreed that single molecules should not be considered "particles." Among citizens, there is a concern

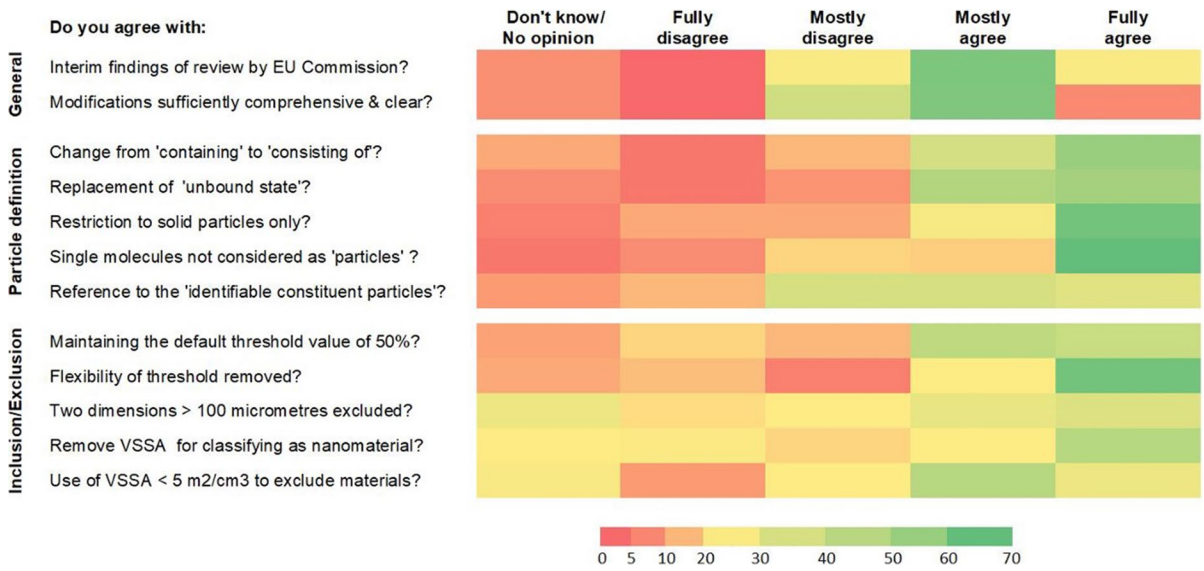

Fig. 1 Heatmap ranging from 0 to 70% over the questions subject to the European Commission's stakeholder consultation on the term "nanomaterial"

that this type of limitation leads to confusion in relation to, e.g., ions, surfactants, coatings and polymers. This potential ambiguity is echoed in the company and organizational stakeholder groups, which call for further clarification of what is meant by single molecules, and argue that fullerenes and nanoplastics typically only consist of single molecules. Concerns were also raised that the updated definition would still include common materials containing nanostructures, such as wood [7]. In the updated definition, single molecules are not be considered "particles" [4] and the EC generally dismisses the argument that the term "single molecule" is not well defined. Guidance to be developed will provide further illustrative cases where this differentiation may be challenging, e.g., plastics, according to the EC SWD [5].

The proposed definition also amends the wording when it comes to particles in aggregates and agglomerates, specifying that particles should be present as an "identifiable constituent" in aggregates or agglomerates. However, only 55% of the respondents either agreed or mostly agreed with this amendment (Fig. 1), yet it was eventually included in the updated definition (Box 1). About ten stakeholders expressed that the term "identifiable" may leave room for interpretation and should be further elaborated on in terms of its practicality, whereas three stakeholders questioned the inclusion of strongly bound agglomerates and aggregates as these "do not behave like nanoparticles." In general, there is a common concern expressed across all stakeholder groups about the lack of science-based criteria for agglomerated/aggregated states of particles as it leaves room for interpretation. Several companies called for guidance on how to apply the definition, especially in relation to whether the aggregated/agglomerated state would be in the pure form, particles enclosed in matrices or present in products. The EC acknowledges that the identification of constituent particles highly depends on the applied measurement procedure/method, while also noting that dedicated guidance has already been developed and made available by the EC's Joint Research Centre and that there is an ongoing effort in OECD to validate and standardize relevant methods [5].

Finally, several organizations strongly agreed that the specific mentioning of some carbon-based materials in the former definition is outdated, as it implies these three materials share the same toxicological profile. Others cautioned that the consequences of changing the derogation paragraph for carbonaceous materials below 1 nm

to all platelets and fibres need to be carefully considered to avoid unintended consequences, e.g., including metal monolayers used in semiconductor applications [7]. In the updated definition, there is no specific mentioning of any carbon-based materials as in the proposed definition and the derogation paragraph was maintained. The SWD explains that the common features of particulate graphene materials are effectively addressed in the updated definition that includes a condition (c) for particles that have a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm [5].

Default threshold of 50% or more

The former definition includes materials containing particles "…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." Several stakeholders note that the upper limit of a 100 nm and the cutoff value in the form of a percentage of the particle size distribution (i.e., 50% or more) is not based on science but is rather arbitrarily set as a consequence of a policy balancing between being implementable and accurate. The benefit of a 50% threshold is not considered self-evident for safety issues either; several companies and organizations comment that hazards, fate, exposure, risks and occupational safety are not considered in neither the former nor proposed definitions. A mass- or volume-based threshold is mentioned several times as more convenient instead of — or as a supplement to — a number-based particle threshold in percentages, as this is claimed to be more in line with available and affordable measurement methods [7].

Several scientific EU committees and national public authorities recommend a lower threshold than 50% as it is considered too high for risk management purposes. This is in line with the recommendations made by one of the EC's own scientific committees prior to the adoption of the former definition [8]. In contrast, others argued that a lower threshold will impose an even higher burden on industry without ensuring higher safety. Finally, about ten industry stakeholders argue in favor of keeping the status quo as economic operators are now used to working with the 50% threshold and consider it an "acceptable minimum" [7]. In its updated definition, the EC largely ignored all of these comments and maintained the wording in the proposed definition except making it clear that it is "…50% or more of these particles in the number-based size distribution…" instead of "50% or more of the particles in the number size distribution…". The chosen 50% is not arbitrary according to the SWD as it considered to be "a convention" that links naming/classification of a material as a nanomaterial to the majority fraction of the relevant aspect of composition, in this case the particles [5].

The former definition allows for flexibility in the number-based threshold, which the proposed and updated definitions do not. Seven stakeholders argue that the flexibility in the former definition has not yet been used, and might thus not be needed. According to them, having a single value for the threshold will increase transparency and is considered essential to avoid a specific material being considered a nanomaterial under one regulatory framework, but not under another. Also, one stakeholder argued that keeping the flexibility will leave too much room for disputes and take away focus, while allowing for some flexibility for the regulators to intervene if a particular particle size and shape proves to be particularly hazardous. Ten companies and organizations argued that given the deliberately broad definition, it is possible that it will include both materials requiring measures in specific sectoral legislation as well as materials for which such measures are not necessary. According to them, this flexibility must therefore be maintained to manage different nanomaterials with different measures, suitable to meet the respective regulatory objective of a given sectoral legislation. According to the EC SWD, no arguments were put forward during the stakeholder consultation that would make the Commission reconsider its position on the flexibility as having a single threshold, which will support an implementation that is much more targeted and effective [5].

Upper limit value

The new nanomaterial definition proposes that particles with at least two orthogonal external dimensions larger than 100 µm should not be counted for the purpose of the number-based size distribution. Half of the respondents fully or mostly agree with the proposed upper limit value of 100 µm (Fig. 1). A group of companies finds the change to be "very well motivated" due to the emergence of large sheets with thin layered materials. One EU or MS authority states that they are in favor of the change as "very large particles can be technically problematic." Nearly a third (29%) of the respondents either fully or mostly disagree with the new upper limit, finding either that "the implicit exclusion of very large but thin (1–100 nm) platelets is not appropriate" and that "the definition should explicitly allow flexibility in whether particles larger than the upper limit are included or excluded in the tally." Less than ten respondents stress that an upper limit is beneficial but that the proposed one is inappropriate and/or that an upper limit should only apply to certain particle types. A common argument against the proposed upper limit is that exclusion of particles from the size distribution will create a bias towards smaller particles. Another argument relates specifically to metals and states that surface area is a more relevant criterion than shape because the toxicity of metal nanomaterials is defined by the surface release rate. Five of the stakeholders proposed an upper limit lower than 100 µm, e.g., 200–250 nm, 500 nm or less, 1 µm, or 10 µm. In addition, it was suggested to add a percentage by mass as an additional criterion. Lastly, a few stakeholders point to the need for more clarification on which kind of materials that would not be included in the updated definition. For the updated definition, the EC decided to go with the proposed upper limit value of 100 µm, while acknowledging that specific guidance will be required to allow for a responsible use of this provision. The Commission argued the new volume-specific surface area (VSSA) criterion would prevent the false identification of any "realistic materials" as a nanomaterial even if it consists of large > 100-µm particles and a fraction of particles < 100 nm. The suggestion to have an additional mass-based criterion was dismissed with the argument that it would make the definition more complex.

Volume-specific surface area

In the former definition, the VSSA was allowed as a surrogate to particle size distribution measurements for classifying materials as nanomaterials. The ability of VSSA to accurately describe nanomaterials has been discussed in the scientific literature, e.g., Lecloux et al. [9] and Gibson et al. [10]. During the consultation of the proposed definition, stakeholders were asked whether they thought the option of using VSSA as a surrogate should be removed. As indicated in Fig. 1, 56% of the respondents were positive to this, 30% disagreed, and the rest did not know or had no opinion. The most common argument for removing VSSA as surrogate was that it can lead to both false negatives (i.e., nanomaterials defined as non-nanomaterials) and false positives (i.e., non-nanomaterials defined as nanomaterials). Certain classes of materials were mentioned as especially prone to such mistakes, e.g., few-layer graphene and porous particles. An argument pointed out by several respondents for keeping VSSA as a surrogate is its "cost effectiveness." Many respondents commented that VSSA can provide useful information, but needs to be supported by other measurement techniques, such as electron microscopy. Four respondents also mentioned that the EC should provide recommendations on how the density of materials should be used when calculating the VSSA as the product of the specific surface area and the density.

Stakeholders were also asked whether a VSSA threshold of 5 m^2/cm^3 might be used to *exclude* materials from being defined as nanomaterials, meaning that materials with a VSSA less than 5 m^2/cm^3 are not defined as nanomaterials. Here, 61% of the respondents agreed, 21% disagreed, and 18% did not know or had no opinion. Thus, there seems to be considerable support for a VSSA-based exclusion threshold in a nanomaterial definition. However, many respondents referred to the NanoDefine project, where 6 m^2/cm^3 rather than 5 m^2/cm^3 was

proposed as threshold [11], and described the 5 m^2/cm^3 threshold as "arbitrary." Eventually, the EC included a VSSA-based exclusion threshold of 6 m^2/cm^3 in its updated definition based on the feedback received during the stakeholder consultation. The Commission also noted that guidance will be provided to facilitate the use of VSSA measurement and address potential challenges in its interpretation [5].

Updated definition – stakeholder influenced?

It is important to understand that the EC's former, proposed, and eventually updated definitions of "nanomaterial" are stipulative, i.e., proposed for a specific purpose, namely that of regulating nanomaterials within the EU [12]. Stipulative definitions cannot be objectively correct or incorrect, but only evaluated on whether they are "fit for purpose." This is contrary to, e.g., lexical definitions, which attempt to capture the common use of a term and can thus be evaluated as more or less correct. Overall, most stakeholders agreed with the interim findings of the EC with regard to the former definition and found the suggested modifications to be sufficiently comprehensive and clear. Including a VSSA threshold for excluding non-nanomaterials also received considerable support. The introduction of new terms such as "solid particles" and the clarification that single molecules should not be considered as "particles" seems to also have addressed the use of unclear terms in the former definition. However, new terms, such as "identifiable constituent particles," have been introduced in the proposed definition, resulting in many stakeholders calling for further clarification. If the EC would have decided to follow the results of the stakeholder consultation, the implications would have been that the default number-based threshold value of 50% would be maintained, whereas the possible flexibility of varying the threshold in specific sectorial legislation, the default inclusion of carbonaceous materials below 1 nm and the option of using VSSA as a surrogate would not. Apart from changing the VSSA-based exclusion threshold from 5 to 6 m^2/cm^3, it generally seems that no arguments were put forward during the stakeholder consultation that made the Commission reconsider its position on any of the questions raised by them during the stakeholder consultation. This could reflect the Commission having been well prepared before the proposed definition was subjected to stakeholder consultation, as targeted stakeholder consultation and a stakeholder workshop had already been completed many years before as part of the initial phase of the review process.

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Declarations

Conflict of interest The authors declare no competing interests.

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