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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

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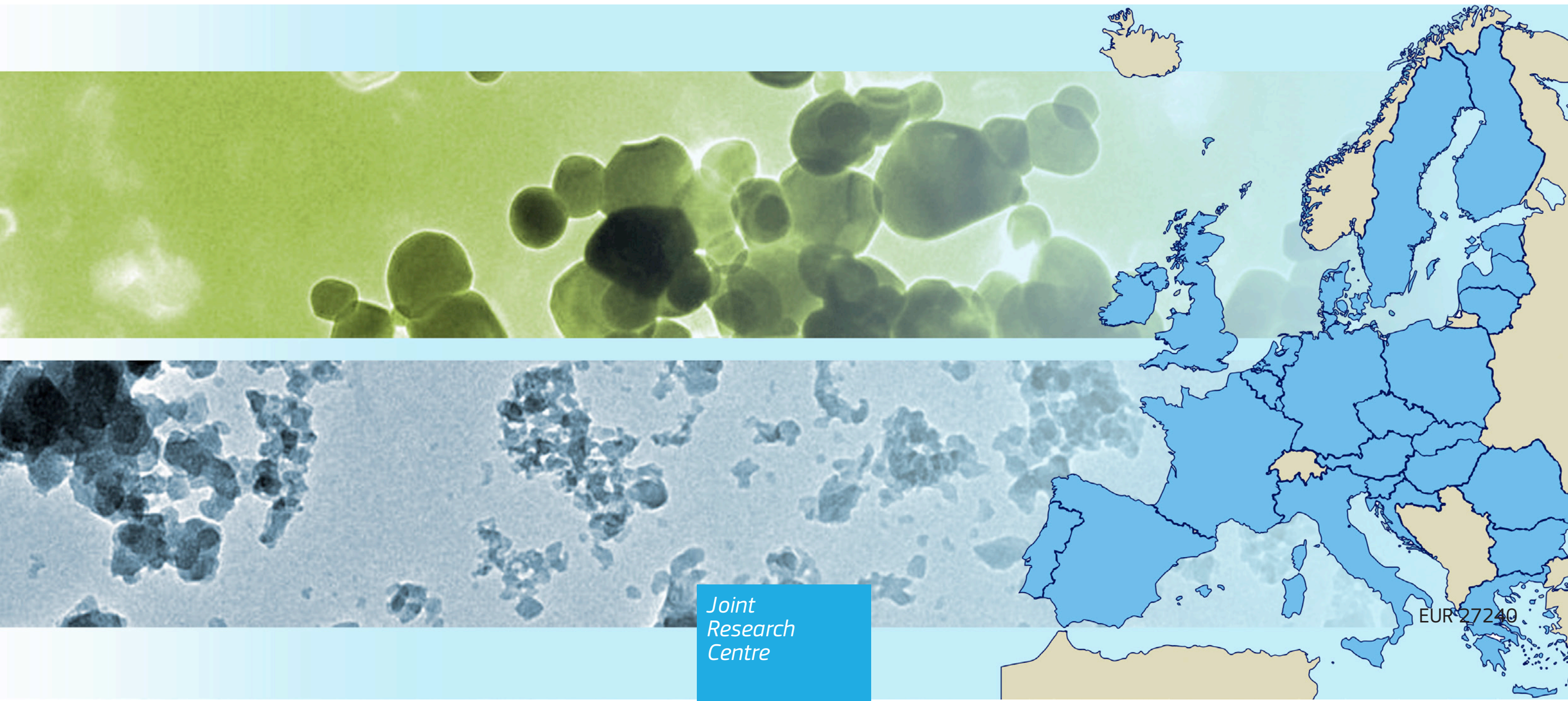

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Abstract

This report provides the JRC's scientific-technical evaluation of options to clarify the EC Recommendation on a definition of nanomaterial, published in 2011 (EC Recommendation 2011/696/EU). It is a follow-up report of two previous JRC publications, which compiled feedback on the experiences of stakeholders with the EC nanomaterial definition collected by JRC in 2013 and early 2014 (EUR 26567 EN, 2014), and provided an assessment of the collected information (EUR 26744 EN, 2014). The three JRC reports are part of the review process foreseen in the 2011 EC Recommendation. The evaluation shows that the scope of the definition regarding the origin of nanomaterials should remain unchanged, addressing natural, incidental as well as manufactured nanomaterials. Moreover, because of the regulatory purpose of the definition, there is little evidence to support deviating from size as the sole defining property of a nanoparticle or from the range of 1 nm to 100 nm as definition of the nanoscale. Besides the need for clarification of some terms used in the definition additional implementation guidance would be useful. The role of the volume specific surface area deserves clarification and a method to prove that a material is not a nanomaterial would be helpful. A strategy how to avoid unintended inclusion of materials and the list of explicitly included materials deserve also attention.

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Part 3: Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation

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Executive summary

In 2011 the European Commission (EC) published a Recommendation (2011/696/EU) for a definition of the term *nanomaterial*, which was developed to provide a common basis for regulatory purposes across all areas of European Union (EU) policy. At the same time the EC announced that the recommended definition would be reviewed in 2014.

In 2013, the Joint Research Centre of the European Commission (JRC) started to develop a series of three scientific-technical reports with a common header: “Towards a review of the EC Recommendation for a definition of the term nanomaterial”. The reports are based on a list of tasks addressing specific points of the Recommendation, which were agreed initially between policy DGs and the JRC. In this third report of the series, JRC describes scientific and technical options to clarify the wording and facilitate the implementation of the definition. The options presented in the report are provided to the EC policy services, which will assess whether and how the definition should be revised or supported with additional guidance.

This report, Part 3 in the series, builds on the previous two: *Part 1: Compilation of information concerning the experience with the definition* (Report 1) and *Part 2: Assessment of collected information concerning the experience with the definition* (Report 2). For each specific element of the definition, for which a request for clarification or change was identified in Report 1, and for which the arguments were assessed as valid in Report 2, this Report 3 lists available options. The option not to change a specific element is always considered and the resulting consequences are discussed. Other options that imply a change of the definition are presented as well, together with possible technical or scientific consequences.

This Report 3 supports that the scope of the definition regarding the origin of nanomaterials should remain unchanged, addressing natural, incidental as well as manufactured nanomaterials. Moreover, because of the regulatory purpose of the definition, there is little evidence to support deviating from size as the sole defining property of a nanoparticle or from the range of 1 nm to 100 nm as definition of the nanoscale.

Of all the issues discussed in this report, the following seem to deserve the most attention in terms of clarification of the definition and/or provision of additional implementation guidance:

- The term "particle": This term should be defined more rigorously for the purposes of the definition, to leave less room for interpretation, or detailed guidance for the interpretation of the term should be provided.
- The terms "(particle) size" and "external dimension": "Particle size" and "external dimension", or more precisely "minimum external dimension", should be better defined, or more precise guidance on what is considered as (minimum) external dimension should be provided.
- The term "constituent particle": This term is important for the understanding of the definition, but does not appear in the definition itself. The term could be explicitly included in the definition, and/or guidance could be issued on the meaning of the term.
- There is a conceptual difference between a threshold which refers to the number fraction of particles with external dimensions between 1 nm and 100 nm in a material (currently 50 %), and a content threshold for such materials in a product. Using the phrase "mainly consisting of particles" in the definition (rather than the currently used "containing particles ...") could prevent the misunderstanding that products containing nanoparticles become nanomaterials themselves.
- Consequences of the possibility of varying thresholds for the particle number fraction in the definition: variable thresholds may allow regulators to address specific concerns in certain application areas, but may also confuse customers and lead to an inconsistent classification (as nanomaterial or not) of the same material based on the field of application.
- Ambiguity on the role of volume-specific surface area (VSSA): The potential use of VSSA should be clarified and ambiguities arising from the current wording should be eliminated. VSSA could either be retained as a proxy or additional criterion but with clearer wording about its use in specific cases, or it could be moved from the definition into guidance as

one screening method (among several) for practical implementation of the definition.

- The methods to prove that a material is not a nanomaterial: The definition makes it very difficult to prove that a material is not a nanomaterial. This implementation issue could be resolved by adding an additional criterion, which might be based on mass, on VSSA, or on additional size-based parameters.
- The challenge to avoid unintended inclusion of certain materials under the current nanomaterial definition: This could be addressed by adding an additional criterion.
- The list of explicitly included materials: This list also covers materials already regulated, but does not include non-carbon based materials with a structure similar to carbon nanotubes. A modification (or removal) of the current derogation could avoid inconsistencies.
- The alignment of the EU definition with other international terminology, if relevant.
- The status of nanostructured materials.

Many of the above listed issues could in principle be clarified by developing new or improved guidance. Also the need for specific guidance beyond clarification of the definition itself is identified. The report provides a number of suggestions on scientific-technical guidance documents that could help in facilitating the practical implementation of the definition. However, relying only on guidance documents for essential parts of the definition may lead to unintended differences in the implementation and decision making. Therefore, also the possibilities to introduce more clarity in the definition itself are listed above and discussed in the report.

1. Introduction

1.1. Background

In 2011, the European Commission published a Recommendation (2011/696/EU) with a proposed definition for the term *nanomaterial*, specifically for regulatory use,[1] covering natural, incidental and manufactured materials and based solely on the size of the constituent particles of a material, without regard to specific functional or hazardous properties or risk:

> "'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.
>
> 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 %."

The Recommendation further specifies:

> "By derogation [...], fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.
>
> [...] "particle", "agglomerate" and "aggregate" are defined as follows:
>
> (a) "particle" means a minute piece of matter with defined physical boundaries;
>
> (b) "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;
>
> (c) "aggregate" means a particle comprising of strongly bound or fused particles.
>
> Where technically feasible and requested in specific legislation, compliance with the definition [...] may be determined on the basis of the specific surface area by volume. A material should be considered as falling under the definition [...] where the specific surface area by volume of the material is greater than 60 m^2/cm^3. However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with the definition [...] even if the material has a specific surface area lower than 60 m^2/cm^3."

In the same Recommendation (2011/696/EU), the EC announced that the proposed definition would be reviewed in 2014: "...Technological development and scientific progress continue with great speed. The definition including descriptors should therefore be subject to a review by December 2014 to ensure that it corresponds to the needs."[1]

In 2013, the Joint Research Centre of the European Commission (JRC) started working on a series of three scientific and technical reports supporting the review of the EC Recommendation for a definition of the term "nanomaterial", based on a list of specific questions and tasks addressing certain points of the Recommendation, which were agreed between policy DGs and the JRC. Based on this list the JRC started collecting feedback from stakeholders and users of the EC nanomaterial definition, and in March 2014 JRC released a first report, with a compilation of the collected feedback and data.[2] In a second report[3] released in August 2014 JRC provided an assessment of the information collected in the first JRC report, complemented, where necessary, with new or additional input.

The previously mentioned JRC reports[2,3] include a wide range of opinions and experiences from stakeholders and users from the European Union and other parts of the world, including the United States of America and Japan. The current report also refers to two earlier JRC reports which provided considerations on a definition of nanomaterial for regulatory purposes[4] and an analysis of requirements on measurements for the implementation of the European Commission definition of the term "nanomaterial".[5]

1.2. Purposes of the document

In the third report of the series, presented here, JRC provides scientific-technical recommendations on possible ways to clarify the definition and to facilitate its implementation. These recommendations are expressed as options to be considered by the EC policy services in the review of the definition. It will help them take into account the experience gained during the use of the EC definition of nanomaterial since its adoption in October 2011, which has resulted in various suggestions of stakeholders for possible amendments or changes.

While many of these suggestions are very valuable, some are mutually incompatible and others have not been supported by valid arguments. JRC pointed out in the second report (EUR 26744[3]) that a number of core aspects and characteristics of the current EC definition should be maintained. There are other elements in the current definition, for which difficulties – either conceptual or practical – have been identified. In this report, for every issue, the option to maintain a specific element has always been considered, and there may be strong arguments in favour of this.

The options presented here are intended to allow policy-makers an informed choice of their preferred approach towards the issues presented in the previous JRC reports. The detailed arguments concerning the points addressed and the conclusions and options of this report are provided in the four JRC reports mentioned above,[2,3,4,5] and will not be repeated here. Considerations related to implementation in specific policy areas in which the definition may be used will be necessary when the definition is implemented in those sectors. Such considerations are, however, beyond the scope of the EC Recommendation, and of this JRC report.

2. Considerations on specific elements of the EC Recommendation for a definition of nanomaterial (2011/696/EU) – Article 2

Article 2 of the definition[1] contains the core defining elements of the current Recommendation. Those elements will be addressed in this section.

2.1. Scope in terms of origin of the materials

Current situation

The current definition refers to natural, incidental and manufactured materials. Hence, it has a broad scope in terms of the origin of the materials, and applies to all materials regardless of their origin. As a consequence, it covers a potentially very large number of materials, regardless of (for example) whether these are new and man-made for a specific purpose, or have been in the environment for a long time.

Possible adjustments

Option 1: no change

Discussion

The current scope is in line with the call of the European Parliament of 24 April 2009 on regulatory aspects of nanomaterials[6] for the introduction of a comprehensive definition of nanomaterials, and with the suggestion of JRC[4] that such a definition should be broadly applicable in EU legislation. While one of the reasons for the EP to call for a nanomaterial definition was the health and safety issue, it has to be acknowledged that the definition itself is not based on hazard or risk assessment, nor does it prejudge or reflect the scope of application of any EU legislation or provisions establishing additional requirements for those materials. Instead, the definition should purely classify a certain group of materials according to well-defined criteria, which might deserve specific considerations in regulatory provisions. When the definition is applied in specific EU legislation, the scope can at this point be adapted according to the requirements of specific legislative provisions.[7]

Option 2: narrow the scope in terms of origin of the materials

Discussion

Narrowing the scope in terms of origin of the materials in any manner would not be in line with the current comprehensiveness of the definition. A narrower scope might no longer be adaptable to specific regulations if that regulation applies to materials, the origin of which might not be covered by the EC definition with a restricted scope. Furthermore, a priori there is no difference between the properties of a material of natural origin and those of the same material when it is manufactured.

2.2. Particulate matter and nanostructured materials

Current situation

The current definition is explicitly limited to particulate matter and its provisions are designed and tailor-made to specifically address this type of material. This approach was inspired by earlier reports from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[8] and JRC[4] which stated that human and environmental exposure is more likely for particulate materials than for "embedded" nanomaterials, and hence the former are more relevant in the regulatory context. As a consequence, some materials defined as nanomaterials by other organisations or standardisation bodies are not covered by the EC definition.[3] For example, ISO[9] includes in its definition of nanomaterial also materials with larger external dimensions, if they have internal structures or surface structures in the nanoscale. Note that certain types of nanostructured materials (according to the ISO definition) are also covered by the EC definition of nanomaterial. These are materials consisting of aggregates and/or agglomerates of particles, at least half of which have an external dimension between 1 nm and 100 nm.

Possible adjustments

Option 1: no change

Discussion

The option "no change" would preserve the focus on particles. As a result, the regulatory debate will likely be directed to those materials that are specifically relevant in a regulatory context, namely the materials with an enhanced mobility and increased number of exposure routes due to their external nanoscale dimensions. There may also be new interaction mechanisms with biological entities, resulting e. g. from the smaller radius of curvature of the particle surface, and the change in surface reactivity. It is worthwhile here to emphasize again that a material shall not be considered unsafe because it is a nanomaterial according to the EC nanomaterial definition, and vice versa, i. e. it does not imply that a material is safe just because it is not a nanomaterial.

If this "no change" option would be the preferred one, then it will become even more important to develop a clear and commonly shared interpretation of the term "particle", which is discussed in section 2.7. In this context the question has to be answered whether, for example, suspensions of nanomaterials (colloidal systems) should be regarded as nanomaterials in their own right or whether only the particulate fraction is the nanomaterial. The latter interpretation, i.e. that the liquid is not part of the nanomaterial, seems to be a more supported position at present. On the other hand, in specific contexts, such as that of REACH, a liquid may be seen as essential element of the colloid. In that case REACH requires that the liquid be included in the substance identification for registration purposes.

Option 2: specific consideration of colloidal systems

Another possibility is to consider such neat suspensions, mixtures and formulations as nanomaterials as a whole if one or more ingredients are a nanomaterial and (potentially) if the content of these ingredients exceeds a certain mass or volume threshold.[10] This issue will be discussed in more detail in several of the following sections. In any case, it would be helpful to develop guidance on the issue of neat suspensions of particles.

Option 3: extension to non-particulate matter/inclusion of nanostructured materials

Discussion

An extension to non-particulate matter and the inclusion of other types of nanostructured materials not yet covered by the current definition would significantly change and enlarge the scope of the definition as compared to the current situation. On the one hand it would bring the EC definition more in line with the ISO definition of nanomaterial.[9] Furthermore, it would probably include materials such as "nanoporous" materials (also known as mesoporous and microporous materials, according to definitions which predate the nano-terminology area), and also next generation nanomaterials which have been developed only recently. Examples for the latter are hybrid polymeric/multifunctional molecular systems purposely designed for medical applications. On the other hand, this would require a very different approach and a re-design of the EC definition and its criteria for nanomaterials. For example, a criterion based on the size distribution by particle numbers, which is the core element of the current definition, would not be applicable anymore to nanoporous and dense nanostructured materials. Other or additional criteria, for example based on surface or interface structure, or on the volume fraction of the particulate component of the material, would have to be introduced.

In addition, the vagueness of the term "nanostructured" may have the consequence that a plethora of traditional materials would fall under such an extended scope. If it would become necessary to address non-particulate or nanostructured materials in certain regulatory fields, specific legislation could always be developed.

2.3. Size as the only defining property and the selected size range

Current situation

Size is the primary defining property of a nanomaterial in the current definition. The fact that a size at the nanoscale is the only common property of all nanomaterials was highlighted in an earlier report by JRC.[4] Likewise, SCENIHR concluded that size is universally applicable to nanomaterials and the most suitable defining metric.[8]

Furthermore, the size range of 1 nm to 100 nm, as used in the current definition, is well defined with clear boundaries. Such clear boundaries were primarily introduced with the regulatory purpose of the definition in mind rather than for scientific reasons.

Some materials have intrinsic properties that change pronouncedly (e.g. due to quantum effects) when their external dimensions are reduced to a particular size, somewhere in the range from 1 nm to 100 nm. This holds true as well for extrinsic properties (e. g. interference with biological pathways), although these often change less abruptly than the former. Other materials exhibit less sudden effects but will still have some property changes due for example to increased specific surface area. Furthermore, which properties change significantly and which do not is material dependent. Although the size range from 1 nm to 100 nm, with fixed boundaries, may not capture all relevant "nanoscale" properties, the majority of such phenomena are observed in this size range.[11] The definition of the nanoscale as ranging from 1 nm to 100 nm is therefore in line with the primarily regulatory purpose of the definition. It is also in agreement with international use.[2,3,4]

Possible adjustments

Option 1: no change

Discussion

Keeping size as the only defining property with the size range from 1 nm to 100 nm is in line with the current purpose of the EC definition of nanomaterial, namely its use in a regulatory context. On the other hand, guidance on which size (distributions) to measure and how to do that at the nanoscale, is needed.

Option 2: include other properties

Discussion

Including properties other than the size as identifier of nanomaterials in the definition would require a decision on the reasoning for choosing such properties. Physicochemical properties that change pronouncedly below a certain external particle size depend on the material, and the size at which they change also depends on the property itself. Hence precise considerations on which properties to select would be necessary. In addition, usually there is no well-defined transition point at which a property or its value becomes characteristic for the nanoscale,[4] and not all materials exhibit the same phenomena. Therefore it would be necessary to define, in quantitative terms, for each material and property, when a property value is sufficiently different from its non-nanoscale value to regard it as nanoscale phenomenon. Furthermore, some nanomaterials do not have corresponding non-nanomaterials.

Should it be possible in the future to clearly link a certain nanoscale property to, for example, hazard, that property could be considered as identifying criterion, but as a consequence this would significantly change the concept of the definition, and it would also require more testing of the materials. It is therefore clear that including properties other than size as identifying criteria for nanomaterials requires careful and extensive considerations and also guidance on how to apply such criteria.

As discussed above, nanoscale properties other than the size depend on the material and the specific property, and it would be difficult to consider them for a broad definition. Therefore, if deemed necessary, it would be more advantageous to address this in specific legislation.

Option 3: extend or reduce the size range

Discussion

There has been no request to narrow down the 1 nm to 100 nm size range, but there have been suggestions for an extended size range, i.e. a larger upper size limit. However, unless one has the intention to change the character of the definition and strengthen the conceptual link either to phenomena at the nanoscale or to possible nanospecific hazards, it is difficult to conceive objective reasons for doing so. (See also option 3 in section 3.3.)

One can therefore question the tendency in the area of nanomedicines to use 1000 nm as an upper limit instead of the 100 nm upper size limit adopted in all other domains. In this context it would indeed be useful to clarify the need for an explicit reference to pharmaceuticals and medical devices in the current EC Recommendation. It is noted here that the size range from 1 nm to 100 nm is used for the definition of nanomaterial in the Proposal for a Regulation of the

European Parliament and of the Council on medical devices (COM(2012) 542 final).

2.4. A fraction of the number of particles as defining threshold

Current situation

A material is considered a nanomaterial if 50 % or more of the particles have one or more external dimensions in the size range between 1 nm and 100 nm.

Possible adjustments

Option 1: no change

Discussion

Particles are the fundamental units that constitute the basis of the EC's nanomaterial definition. A threshold referring to the relative number of particles in a material as defining criterion is in line with this choice, and in agreement with earlier reports by JRC[4] and SCENIHR.[8] Nanomaterial definitions included in recent EU and Member States regulatory provisions are also using a metric based on particle number fractions.

Activities aimed at implementing this metric are ongoing,[12] because a number based threshold results in some challenges for its implementation. First of all, number-based size distributions are often not easy to measure, especially when there are particles with size in the 1 nm to 100 nm range. Indeed, the measurement range of many instruments is not appropriate for a rigorous assessment of a material against the definition. Secondly, in practice, particle size distributions are often measured based on mass or volume, and they cannot be easily transformed into a number based distribution, even if the shapes of the particles are known. Most volume- or mass-weighted mean particle diameters are also equivalent diameters, relying on assumptions of e.g. the shape of the particles. The particle number estimates derived from these mass- or volume-based mean diameters require even more assumptions. Furthermore, mass or volume based particle size distributions, as measured in practice, generally do not refer to the constituent particles that need to be measured according to the definition, but more often to particle aggregates or agglomerates.

Available measurement techniques cover the requirements resulting from the EC definition to a varying degree and generally agreed technical standards on how to measure particle size distributions in order to determine whether a material is a nanomaterial according to the EC definition are not yet available.[3,5] Therefore guidance on how to measure the number based particle size distribution of different materials is needed. As currently the instrument developments and method validations in the nanoparticle size analysis area are a continuous effort, and because the choice of methods is very dependent on the material under investigation, any guidance will likely be formulated in a generic way or address specific materials or individual groups of materials.

Another important consequence of using a number based size distribution as the sole defining criterion for the classification of a nanomaterial is that materials having a very low mass fraction of nanoparticles may also fall under the definition. Due to measurement uncertainties this may lead to different classifications between laboratories.

Option 2: change the threshold

Discussion

Any fixed quantitative threshold will lead to borderline cases, regardless of its numerical value. For such borderline cases, it is expected that different measurements could lead to different conclusions about the nanomaterial status of the investigated material. These differences may come from sampling or measurement uncertainties, which generally increase with a lower threshold value.[5]

The analysis in the previous two JRC reports in this series did not reveal compelling reasons to change the current threshold of 50 %. This regards materials commonly called nanomaterials in scientific literature but excluded from the definition as well as materials not commonly called nanomaterials but included in the definition.[3] Borderline cases would exist for any fixed threshold. Since the EC definition of nanomaterial should not be related to hazard or risk considerations, the selection of a threshold is essentially a policy choice and should be justified as such. However, it is noted that choosing a threshold lower than 50 % would lead to naming a material after one of its minority components which is questionable from a technical and common sense point of view. Moreover, decreasing the threshold and thus including more and more materials in the definition is also undesirable because it may deflect the attention from the materials which are more relevant for further consideration.

2.5. What are constituent particles and how to measure their size?

Current situation

Recital (4) of the current Recommendation specifies that the definition of the term "nanomaterial" in EU legislation "should be based solely on the size of the constituent particles of a material". A substantial number of the comments and criticisms to the EC definition refer to the analytical challenge of identifying the constituent particles and measuring their size inside aggregates. This issue was raised in a JRC Reference Report[5] and confirmed as a challenge in the implementation of the EC definition.[2,3]

Possible adjustments

Option 1: no change

Discussion

Several projects have already been started to tackle the challenges of identifying and quantifying the constituent particles of a material in order to decide whether or not it is a nanomaterial according to the EC definition. This includes large investments such as the collaborative FP7 project NanoDefine[12] as well as activities by other stakeholders, consisting of method developments and/or assessments as well as the preparation of specific guidance documents. Furthermore, stakeholders have become familiar with concepts and terminology of the definition since its adoption, and some practice and guidance is already available or is currently being developed.

On the other hand, the requirement to identify and quantify "constituent particles" still poses conceptual and technological challenges, and currently only a limited number of experimental methods are available to address them in a satisfactory way for a number of materials. Scientific considerations also indicate that some of these challenges will be difficult to solve as the definition includes all agglomerates and aggregates. Clearly, guidance on the practical implementation of this concept is needed.

Option 2: Adjustment of the definition – inclusion of the term "constituent particles"

It could be helpful to include the term "constituent particles" explicitly in the definition, i.e. referring to "*…particles, in an unbound state or as constituent particles of…*" in addition to referring to it in the Recitals of the definition. This would eliminate remaining doubts on the type of the particles to which the definition refers.

A more specific clarification of the term "constituent particles" could then explain the latter term as *an identifiable, integral* component *of a larger particle which existed as a separate particle prior to its* incorporation *into the larger entity.* The specification "identifiable, integral part of a larger particle" is in line with a proposal from ISO/TC 229.[13]

Discussion

Choosing this option clarifies the meaning of the term "constituent particle" which now is used in Recital (4) of the Recommendation. It eliminates a number of the concerns raised during the JRC survey.[2] However, identifying the constituent particles in strongly bound ensembles would still be a challenge. Additional guidance on the term "constituent particle" including methods how constituent particles can be identified would be necessary. If measuring the size of constituent particles within ensembles is too difficult, the size distribution as measured for example during the manufacturing process, before the constituent particles are incorporated into larger entities, may be used alternatively. Such implementation issues could be addressed in the Recitals or Technical Annexes.

Option 3: Adjustment of the definition – specification of the term "constituent particles"

In order to counteract the experimental difficulties of identifying and measuring constituent particles in aggregates while addressing the main reasoning for inclusion of agglomerates/aggregates (i.e. the possibility that ensembles may release particles), an option would be to address this issue in the definition, by specifying a more pragmatic approach on what to consider as the constituent particles in aggregates and agglomerates and to add a specific definition of the term "constituent particles" for the purposes of the EC Recommendation.

Referring to "*constituent particles are particles separable from larger particles*" in the definition could pave the way for such a pragmatic approach, but it would also make it necessary to specify certain experimental conditions which need to be met in order to separate (de-aggregate or de-agglomerate) the entities into their constituents to be counted as individual particles for the purposes of the definition.

Further clarification could be given by specifying that "A particle *which cannot be dissociated (de-agglomerated or de-aggregated) into smaller constituent particles under the dispersion conditions defined in the Technical Annex shall be counted as one single particle."*

Discussion

Option 3 is an approach to facilitate the implementation of the definition of nanomaterial through measurements. It solves the challenge of identifying the constituent particles and measuring their size inside aggregates. If only particles are taken into account that are unbound or which can be brought in an unbound state through dispersion methods, then the number of techniques that are potentially suitable for implementation of the EC nanomaterial definition increases considerably.[3,5] Having a definition for regulatory purposes that can more readily be implemented through measurements would be an advantage.

This option also contributes to the clarification of the term "constituent particle" and eliminates a number of the concerns raised during the JRC survey,[2] specifically addressing aggregates.

It eliminates materials mainly consisting of larger (>100 nm) aggregates of small particles from the nanomaterial definition. As a justification for doing so one could consider the choice of 1 nm to 100 nm as defining nanoscale size range, because this is the range in which the majority of specific nanoscale phenomena occur.[11] In addition, particles with an external size below 100 nm are on average more mobile than particles larger than 100 nm.

The concept "particles in an unbound state or constituent particles separable from larger particles" corresponds with the existing term "smallest dispersible unit" used by ISO.[14] Hence the use of this concept would be in line with an international convention.

On the other hand, such an approach would deviate from the principle of identifying a constituent particle by its distinguishability from other particles by morphological features. It is also possible that certain materials, which are clearly considered nanomaterials under the current EC definition, would be excluded.

In many cases the nanoscale properties of small particles will not be preserved when they are aggregated. For example, nano-effects are often related to an enhanced surface reactivity of small particles. Since aggregation reduces the material's surface area, the surface-reactivity related nano-specific properties of particles not separable from larger aggregates are at least less pronounced. Furthermore, the properties and phenomena related to the mobility of particles smaller than 100 nm are no longer relevant if the particles occur in the form of large aggregates that cannot be disaggregated. In other cases the nanospecificity will be preserved when particles are aggregated. For example, the photocatalytic properties and the UV-absorption characteristics of TiO_2 persist when the nanoparticles are aggregated. Similarly, the increased mechanical strength of nanoparticles can be preserved when they are rapidly sintered together and transformed into solid materials without significantly changing their size.

In any case, the proposed approach would need very clear definition of the dispersion conditions to be applied when aiming at dissociating larger entities with the goal to quantitatively identify their constituents. Clarification would also be needed on how strong the constituent particles should be bound within a larger entity. This could be done in a Technical Annex to the Recommendation (see also section 4). The complexity of this task should not be underestimated.

2.6. Flexibility of the threshold value in the particle number based size distribution

Current situation

The definition allows lowering the default 50 % value of the threshold in the particle number based particle size to any value between 1 % and 50 % in sector specific legislation. This introduces a level of flexibility that however conflicts with regulatory consistency and may create confusion among business operators, consumers and regulators. Situations may arise where a specific material is considered a nanomaterial under one regulatory framework whereas the same material is not considered a nanomaterial in another regulatory framework covering a different sector.

Possible adjustments

Option 1: no change

Discussion

The flexibility of the threshold allows regulators to address particular concerns for the environment, health, safety or competitiveness in specific regulatory areas by regarding a material as nanomaterial even if it contains less than 50 % particles with external dimensions between 1 nm and 100 nm.

The current paradigm for risk assessment is considered to be applicable also to nanomaterials.[15] However, in addition to the safety assessment of non-nanomaterials the risk assessment of nanomaterials requires further considerations in terms of testing requirements and procedures.[16,17,18,19] Those considerations should cover the additional risk assessment information needs for the physicochemical characterisation that may arise due to the specific characteristics and properties of nanomaterials. Depending on the specific threshold this could be the case for materials containing less than 50 % nanoparticles.

Lowering the threshold for specific sectors, applications or materials may on the other hand create confusion among consumers and business operators. EU Member States, using the EC definition of nanomaterial, could come to the conclusion to apply a lowered threshold and the value might be different in individual Member States.

One should also bear in mind that the definition of nanomaterial is intended to be without regard to hazard or risk, as specified in Recital (4).[1] Possible concerns as listed in Article 4 of the definition, could also be addressed by restricting the use of the materials in question in certain sectors, applications or products, rather than lowering the threshold in the definition, e.g. by limiting the content of certain materials at the product level.

Option 2: change in the definition

The possibility of lowering the threshold could be removed from the definition.

Discussion

On the one hand, with a fixed threshold possible concerns regarding the safety of certain materials or uses cannot be met by decreasing the threshold, as is currently the case, which could trigger additional actions, as discussed in option 1. However, if there are particular concerns for the environment, health, safety or competitiveness, which may necessitate a threshold of less than 50 %, these concerns could be met by introducing appropriate restrictions on those materials, e.g. by limiting their content in products. Material-specific concerns will be taken into account in risk assessment and addressed by specific risk management measures, regardless of the definition of nanomaterial.

On the other hand, in section 3.3 of JRC report EUR 26744,[3] an extensive analysis is given on different aspects of the flexible threshold value. The report concludes that "the flexible approach impacts negatively on the transparency of the legislation addressing nanomaterials due to the fact that materials may be regarded as nanomaterials or not, depending on the legislation. It counteracts the intention that the EC definition should guarantee that a material which would be regarded as nanomaterial in one sector will be given the same classification if used in another one." In addition, the JRC report notes that "...current methods would not allow reproducible and valid measurements at the lower end of the flexible threshold range."

2.7. The term "particle"

Current situation

The current EC definition of nanomaterials refers to particles. A particle is defined as a minute piece of matter with defined physical boundaries, in line with the ISO definition.[9] Experience shows that this can be interpreted in different ways,[2,3] and a discussion is ongoing about including or excluding, for example, single molecules, micelles and non-solid materials.

Possible adjustments

Option 1: no change to the Recommendation

In case of no change it would be necessary to provide guidance on how the term "particle" should be interpreted for the purpose of the nanomaterial definition, because the scope of the definition depends very much on the interpretation of this core term.

Option 2: amend the definition of the term "particle" in the Recommendation (1)

The definition of the term "particle", currently specified in Article 4(a) of the EC Recommendation, could be amended as follows:

> *"Particle": minute piece of matter with defined physical boundaries characterized by a discontinuity in one or more physicochemical properties, i.e., a phase boundary, and which is mobile in its immediate environment under appropriate conditions. Single molecules and gas bubbles are not considered particles.*

Discussion

This option would specify better what physical boundaries are and how the term could be applied for the purposes of the definition. Physical boundaries would be specified more from a physicochemical point of view with the concept of phase boundary. The latter is clearly defined as a jump of the chemical potential.[3] The explicit exclusion of single molecules is in line with the current interpretation of the Commission as laid down in a Staff Working Paper (SWP)[7] and the related Q&A section[20] on its website. With this option the definition would include not only solid particles but also softer materials such as micelles or liquid droplets, and hence it would result in a widened scope of the definition. It may be necessary to clarify the difference between a single molecule and a particle in specific cases for the purposes of the definition of nanomaterial.

Option 3: amend the definition of the term "particle" in the Recommendation (2)

The definition of the term "particle", currently specified in Article 4(a) of the EC Recommendation, could be amended as follows:

"Particle": minute piece of solid matter with defined physical boundaries characterized by a discontinuity in one or more physicochemical properties, i.e., a phase boundary, and which is mobile in its immediate environment. Single molecules are not considered particles.

Discussion

Compared to Option 2, this third option would be more restrictive as it focuses on solid particles. "Solid" is one of the four fundamental states of matter (the others being liquid, gas, and plasma). It is characterized by structural rigidity and resistance to changes of shape or volume. This excludes emulsions (liquid particles in liquid media) and micelles. A rationale for this is the fact that for these materials the external dimensions generally depend more on chemical and physical (mechanical) forces from their surroundings than those of solid particles. For micelles, also the high frequency of molecules leaving and entering the structure makes their structure highly dynamic.

Hence guidance on how to interpret the term "particle" would be helpful regardless of which option would be chosen here.

2.8. The terms "one or more external dimensions"

Current situation

The definition refers to "one or more external dimensions" of the particles. It was noted in a previous JRC report[3] that the term "external dimension is not unambiguously defined". For example, a non-symmetric particle is characterised by a large number of external dimensions, as pointed out in an earlier JRC report.[5] Also, the comment has been made repeatedly that flat, flake- or platelet-like particles with only one external dimension in the nanoscale, but two larger, lateral dimensions (well) outside the nanoscale, are not to be considered as nanomaterials.

Possible adjustments

Option 1: no change

Discussion

Without further explanation on what the term "one or more external dimensions" means the current ambiguity will persist, but it may be addressed by precise guidance on what are considered external dimensions of particles for the purpose of the definition and by providing examples for the users of the definition.

Option 2: change to minimum external dimension in the definition

The term "one or more external dimensions" could be substituted by "*minimum external dimension*".

Discussion

If this option is chosen to remove the ambiguity noted above, it may be helpful to additionally provide a clarification of the term "minimum external dimension". For example, a Technical Annex to the Recommendation or a note to the definition could specify one or a limited number of physically defined measurands, such as the minimum Feret diameter, or the diameter of the largest inscribed circle, or (e.g.) the average thickness of platelets/flakes. A section discussing the minimum external dimension may also be helpful in guidance documentation on the implementation of the current definition.

Option 3: change the definition to require at least two external dimensions in the nanoscale

The term "one or more external dimensions" could be substituted by "*two or more external dimensions*".

Discussion

Using this option, plate-like particles with large lateral dimensions are not considered as nanomaterials. If this option is chosen, similar issues as mentioned under Option 1 need to be considered. Also, it could be considered to have a larger threshold value for the maximum lateral sizes than for the minimum external dimension (100 nm).

2.9. The word "containing"

Current situation

The definition uses the term "containing particles", which seems to suggest that a nanomaterial can also contain other and even large fractions of matter that is not "particulate", e.g. a continuous solid matrix.

Possible adjustments

Option 1: no change

Discussion

Maintaining the word "containing" in the current context would mean that the current ambiguity as pointed out above would persist. In this case it would be advantageous to develop clear guidance on the meaning of the term for the purposes of the definition. One possibility to address this was already pointed out in section 2.2, i.e. to consider suspensions, mixtures and formulations as nanomaterials as a whole if one or more ingredients are nanomaterials and if these ingredients constitute more than a certain percentage of the overall mass or volume.[10] In other words, there should be some minimum limit for the non-particulate fraction of a material "containing" nanoparticles to be a nanomaterial.

Option 2: change the wording by using the term "mainly consisting of" instead of "containing"

Discussion

Calling a material a nanomaterial is making a statement about the material as a whole. When judging whether a material is a nanomaterial, it is therefore not sufficient that the material "contains" a fraction or phase that has significant nanoscale aspects. Instead, the material should be evaluated based on what it mainly "consists of". For example, if vitamins are added to milk, the (now "fortified") milk should clearly not be called a vitamin. The same argument can be made about colourants or other additives.

It is recognised that the identification of materials "containing" a relevant fraction of particles with nanoscale external dimensions will also have to be addressed for regulatory purposes, possibly in new, additional or more specific legislation. However, it is helpful to separate this challenge from the discussion of the definition of nanomaterial. In this context, a nanomaterial definition using the term "containing" may create confusion.[3] Using the term "mainly consisting of" is an immediate and effective remedy to address this.

2.10. The term "unbound"

Current situation

The current definition refers to the "unbound state" of particles which is perceived by some as a term that is not precise enough as it has triggered a number of requests for clarification.[3]

Possible adjustments

Option 1: no change

Discussion

In order to clarify what is meant with particles in an unbound state, guidance documentation should be developed, possibly also with the term used in option 2 below. In this context this could also clarify the issue whether or not the definition covers materials or products in which nanoparticles are embedded and bound to a solid matrix. (See also the discussion on the term "containing", section 2.9).

Option 2: change in the definition by using the term "individual entity" instead of "unbound state"

Discussion

The alternative wording "individual entity" would not change the contents of the definition. According to ISO 26824:2013[21] a particle can move as a unit, and this statement applies to both "individual entity" and "unbound state" when referring to particles.

3. Considerations on specific elements of the EC Recommendation for a definition of nanomaterial (2011/696/EU) – other articles

3.1. The volume-specific surface area

Current situation

According to the current definition of "nanomaterial", where technically feasible and requested in specific legislation the volume-specific surface area (VSSA) can be used to determine compliance with the definition of nanomaterial, but the VSSA cannot be used to classify a material as a non-nanomaterial. As noted in the previous two JRC reports,[2,3] there is some confusion about when VSSA can be used as a proxy method. There is also concern that porous materials are not being given appropriate consideration, there are differing opinions about the utility of a VSSA criterion, and there is clear evidence that particle shape and size polydispersity can strongly influence the equivalence of the thresholds in number based size distribution and in VSSA used in the current Recommendation.

A simple analysis of the text of the Recommendation suggests that:

(1) a material cannot be determined to be a non-nanomaterial through the use of VSSA measurement. Therefore particulate materials with a VSSA of less than 60 m^2/cm^3 should in general have their number size distributions (or their median particle size) determined by other methods to decide whether they are covered by the EC definition of nanomaterial or not;

(2) unless it is clearly requested in specific legislation that VSSA should (must) or may (by choice) be used, VSSA cannot be used to demonstrate that a material is in compliance with the definition of nanomaterial;

(3) it is not clear from the text whether specific legislation should impose that VSSA must be used, or whether specific legislation could allow the use of VSSA as an option but not a requirement;

(4) if it is stated in specific legislation that VSSA must be used, then it would appear that a material with a VSSA value above 60 m^2/cm^3 "should be considered as falling under the definition" regardless of its number size distribution (the Q&A text appears to reinforce this interpretation) – i.e. there is no provision that if a material does not meet the size distribution criterion but has a VSSA higher than 60 m^2/cm^3 then it should not be considered a nanomaterial;

(5) if it is stated in specific legislation that VSSA can be used but is not "compulsory", then this opens up the possibility for different laboratories to interpret the nanomaterial-status of the same material differently;

(6) if it is technically feasible to measure VSSA, but only requested in some legislation and not in other legislation, then this opens up the possibility that the same material may have different nanomaterial-status under different legislation.

Point (4) indicates the possibility that a material consisting of porous particles (or particles that are coated with porous or rough coatings) with a median size of greater than 100 nm, or even of particles with "special" shapes, which does not meet the number size criterion, would fall under the definition purely on the basis of its VSSA value if the latter is higher than 60 m^2/cm^3.

It should be remembered (as presented in the second JRC report[3]) that for most "real" materials the threshold of 60 m^2/cm^3 does not equate to a median value of the smallest dimension of the constituent particles of 100 nm. The most notable cases are for needle/rod-shaped and platelet/flake-shaped particles where (for monodisperse and well-dispersed constituent particles) threshold values of 40 m^2/cm^3 and 20 m^2/cm^3, respectively, would be appropriate, and for porous particles where the VSSA is higher than would be the case for non-porous particles. Polydispersity and other particle shapes can also have a major influence on the equivalence of the VSSA and size-based thresholds.

Possible adjustments

Option 1: no change

Discussion

The BET method is a simple and inexpensive technique for a positive identification of a material as nanomaterial. Given that "high aspect ratio" particle shapes, aggregation of constituent particles, and polydispersity will all tend to reduce VSSA for any particular median constituent particle size, the threshold of 60 m^2/cm^3 is a rather "safe" threshold for non-porous materials, so for positive identification of such materials as nanomaterials, this threshold is unlikely to result in false classification. A measured VSSA value smaller than 60 m^2/cm^3 will in any case trigger the need for particle size distribution measurement for most materials.

A problem with the current situation is that it has been claimed that particulates consisting of very large particles with fine pores, or large particles with micro- or mesoporous or high surface area coatings, would "incorrectly" fall under the definition. Unless a provision is introduced that a VSSA of greater than 60 m^2/cm^3 can be "over-ruled" by the number-based size criterion, then a sample of such particles with a median size of greater than 100 nm may need to be regarded as a nanomaterial (if so stipulated by legislation).

Without some adjustments of the text, confusion about when and how VSSA can be used will persist. In addition, having VSSA as an additional compulsory or optional criterion (strongly associated to the recommended size-based definition) in some legislation, but not in other legislation, will add to inconsistency in nanomaterial labelling within and between sectors.

Option 2: remove VSSA as defining criterion and clarify its role as screening criterion

Discussion

Removal of VSSA as defining criterion would have the advantage of simplifying the definition and focussing only on size as a defining metric. It would remove the current confusion about when VSSA can be used, and whether or not a VSSA higher than 60 m^2/cm^3 always means that a material should be classified as a nanomaterial. It would also reduce potential inconsistencies in material classification within and between sectors.

As has been argued in Report 2, there are some cases where the use of VSSA with appropriately chosen thresholds may be as reliable as (or possibly more reliable than) ensemble particle size distribution methods both for positive and for negative classification with respect to the definition. VSSA should therefore, together with the other screening methods, be included in guidance documentation on the implementation of the definition by measurements.

3.2. How to prove that a material is not a nanomaterial and how to avoid unintended inclusion of materials in the definition?

Current situation

For a large number of materials it is possible to demonstrate that they meet the nanomaterial criteria of the current Recommendation. However, it can be extremely difficult to prove that a material is not a nanomaterial. The simple reason for this is that most measurement methods do not detect particles in the lower size range of the definition. This problem is even more severe in the presence of larger (non-nano) particles, also for methods such as TEM with the required spatial resolution. Therefore, for many materials the available methods cannot be used to demonstrate that a material is not a nanomaterial, while for other materials this will be very difficult. If it is important to be able to confirm that a material does not fulfil the EC definition of nanomaterial, then this observation should be duly considered.

This section also addresses a second issue, namely that also materials with a very small mass fraction of small particles are included in the definition. This may lead to problematic cases as pointed out in a previous report,[3] for example when a material consists of a mixture of particles with external dimensions in the centimetre range and particles with external dimensions of a few nanometres. The ability to judge the relevance of the small fraction not only in terms of number of particles but also in terms of their mass, could be an additional and useful tool in the assessment-tool kit. Furthermore, a definition based only on a number based criterion classifies many materials as nanomaterials only because of contamination or surface wear and tear. To avoid this, it could be specified what level of contamination by nanoparticles is acceptable for a material to not be a nanomaterial.

This second issue (inclusion of materials in the definition even for very small mass fractions of nanomaterials) is conceptually different to the first mentioned issue (how to prove a material is not a nanomaterial). However, both issues stem from the use of a threshold in the particle number based particle size distribution as the defining criterion. Therefore, in terms of possible practical solutions they are related, and this is why they are discussed together in the following paragraphs.

Possible adjustments

Option 1: no change

The difficulties pointed out above would persist, but could be mitigated by guidance specifying what to do in case the measurement results classify a material as non-nanomaterial, but without ruling out the opposite classification. This is the case if the measurement range of the method(s) used to assess the material, possibly both in terms of particle size as well as in particle concentration or number, is not sufficiently wide (particularly at the lower end of the measurement range) to reliably classify a material as nanomaterial or non-nanomaterial.

Option 2: introduce an additional criterion based on mass fraction

An additional criterion based on a minimum mass fraction for particles with external dimensions between 1 nm and 100 nm could be introduced. In that case it could be specified that a material in which the mass fraction of the particles with a minimum external dimension in the size range between 1 nm and 100 nm is less than a certain percentage ("X %") of the total mass of particulate matter is not a nanomaterial.

Discussion

The use of a particle number based threshold in the EC nanomaterial definition has been thoroughly discussed, and it is not necessarily questioned by the additional criterion. The option presented here would have the sole purpose to mend the first issue mentioned above, by providing a means of demonstrating that a material is not a nanomaterial. In this case the number based size distribution would not have to be measured if the mass based size distribution indicates that the material is not a nanomaterial.

A decision of a specific value for "X" would require extensive considerations on its consequences for the implementability. It should be carefully chosen so as not to undermine the number-based threshold as the actual criterion to decide whether a material is a nanomaterial. A debate of the exact level of a mass (or volume) threshold "X" would distract attention from the discussion of whether having a second threshold is acceptable in principle or not. Only if that decision is made, a discussion of defining a value for "X" becomes meaningful.

Depending on the value chosen for "X", this modification of the definition can also amend the second of the issues mentioned above, by directly eliminating the materials with a very low mass fraction of nanoparticles.

Adding a criterion based on mass replaces the general idea that the definition of nanomaterial should be based solely on the size distribution based on particle numbers, as specified in Recitals 8 and 10 of the EC Definition of nanomaterial,[1] as well as in a scientific opinion by SCENIHR.[8] On the other hand, this option solves many of the implementation problems, as it does not require precise quantification of the number of particles in very small fractions of the investigated material, but rather requires that the mass fraction of the particles with external dimensions between 1 nm and 100 nm is below an appropriate limit.

Option 3: use VSSA as independent defining criterion

Discussion

VSSA as an independent criterion would mean that a material that meets the size distribution criterion OR an appropriately chosen VSSA criterion should be classified as a nanomaterial (removing the “if requested by specific legislation” condition in the current Recommendation). Promoting VSSA to an independent defining criterion would also imply using VSSA for identification of non-nanomaterials, as well as accepting the fact that analysis versus the two criteria could give contradictory results. Therefore a resolution mechanism would need to be included with the two independent criteria. The advantage of VSSA as an independent criterion is that for many materials it is technically simple, measurement results are rather reproducible, and it is relatively cheap. Due to the clear "reducing influence" of particle shape, aggregation/agglomeration, and polydispersity on VSSA values, a VSSA threshold considerably less than 60 m^2/cm^3 would be prudent. A value closer to 20 m^2/cm^3 or even less would be more likely to capture materials that meet the size-based criterion.

However, a low VSSA threshold might then capture materials that would not have fallen under the size-based criterion. This might be resolved by the use of a “transition” zone with an upper (U) and a lower (L) threshold for VSSA. The upper and lower threshold could have values of e.g. $U = 60\ m^2/cm^3$ and $L = 5\ m^2/cm^3$, or $L = 1\ m^2/cm^3$ or possibly even less. The lower threshold (L) should be chosen to minimise inconsistency with the number based criterion but obviously must be in the range where VSSA can be reliably measured. If the measured VSSA value is in the transition zone between U and L, i.e. $L < \text{VSSA} < U$, then only the size-based criterion can be used because VSSA is not reliable enough. If the VSSA value is below the lower threshold L then it is indicative of a non-nanomaterial (independently of the size-based criterion), and if it is above the upper threshold U then the material should be classified as a nanomaterial unless the size based criterion indicates otherwise (see the following table).

VSSA < *L*	***L* < VSSA < *U* "transition zone"**	**VSSA > *U***
Based on the VSSA the material is a non-nanomaterial	Classification only according to the size-based criterion	Based on the VSSA the material is a nanomaterial – unless the size-based criterion indicates otherwise

This offers the advantage of being able to classify a large number of materials as non-nanomaterials, or nanomaterials, at a relatively low cost (acknowledging the fact that the classification may not in every case be compatible with the size-based criterion).

Another advantage is that this approach would efficiently "filter out" materials that consist mainly of very large particles that are only "contaminated" with tiny mass fractions of nano-sized particles (e.g. coming from air pollution or extremely low levels of contamination by commonly used nanomaterials like TiO_2). It should however be noted that allowing VSSA to be used to classify a material as a non-nanomaterial will almost certainly lead to some situations where samples can be classified as non-nanomaterials despite that fact that the majority of the particles present are less than 100 nm in size (the mass contribution of the nanoparticles being very small).

One disadvantage in using VSSA as an independent criterion "in parallel" to the size-based criterion is the increased complexity of the definition itself (in contrast to the implementation, which could be more easy). Secondly, if the “transition zone” approach is not used then if a material is classified only against one criterion due for example to simplicity or cost, and then subsequently classified against the other, it opens up the probability of common reclassifications. Thirdly, and importantly, having VSSA as an equal criterion would demote the size-based criterion. This however is in line with industrial practice and an increasing number of toxicological findings that use surface area as the metric that best predicts many of the nanomaterial's nano-specific properties.[22] If no transition zone is used then clearly the size-based criterion would take priority and the situation would be similar to the current one. If however, the transition zone approach is used then the VSSA criterion should take priority below the lower VSSA threshold. In any case if a low VSSA threshold is used this corresponds to a very low mass fraction of sub-100 nm particles.

If this option of using the VSSA as additional criterion for determining whether a material is a nanomaterial is chosen, it may be expressed in the following way (here using U = 60 m^2/cm^3 and without quantitative value for *L)*:

Compliance or non-compliance with the definition in point 2 may be determined on the basis of the specific surface area by volume. 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 m^2/cm^3 unless a valid measurement of the number-based size distribution indicates otherwise. A material should be considered as not falling under the definition in point 2 where the *specific surface area by volume of the material is less than L m²/cm³. A material with a VSSA between L m²/cm³ and 60 m²/cm³ should be classified only on the basis of the median value of the number-based size distribution determined using an appropriately justified method.*

Option 4: introduce an additional criterion combining the median minimum dimension with the average minimum dimension

The 50 % threshold based on particle size distribution by number may be substituted by a criterion based on a combination of this median minimum dimension and an average minimum dimension. This would specifically address cases where part of the material consists of very large particles in addition to particles at the nanoscale. The average and median are different if the size distribution is skewed, i. e. if the size values are clustered toward one end of the size range and/or if there are a few extreme values. In those cases, the average can be significantly influenced by those few values, e. g. if the material contains a few large particles. Using an average minimum dimension instead of a median makes the classification more susceptible to the influence of a few large particles. Choosing a higher upper size limit (e.g. 500 nm) would take this into account, but it would allow at the same time to limit this influence by choosing an appropriate upper limit. A material consisting of particles that have a median minimum dimension of between 1 nm and 100 nm, and an average minimum dimension of, for example, between 1 nm and 500 nm, could then be regarded as nanomaterial.

Discussion

This modification of the definition addresses the problem of how to exclude materials not usually considered as nanomaterial by requiring a low average minimum dimension. Particles are taken into account with equal statistical weight for determining the average minimum dimension, regardless of their size (and mass). The definition would still be based on the number of particles at the nanoscale, but a certain number of large particles would shift the average minimum dimension out of the range specified for nanomaterials. The median minimum dimension as well as the average minimum dimension are, on the other hand not easier to measure than the number based particle size distribution. In addition, the combination of average and median external dimensions makes the definition less understandable and more complex.

3.3. Materials explicitly included in the definition

Current situation

Ideally a definition would cover all materials that should be regarded as nanomaterials, in simple and straightforward words, without the need for exceptions (inclusions or derogations). Avoiding such exceptions by extending or narrowing the basic definition may result in unwanted inclusion or extension of other materials. In this case, complementing the core definition with lists of explicitly included or excluded materials can be an alternative, pragmatic way to tackle the problem. Such lists may be regularly reviewed in the light of technological and policy developments.

Article 3 of the current definition lists some materials that are considered as nanomaterials, even if their minimum external dimension is smaller than 1 nm. These materials are single-walled carbon nanotubes, fullerenes and graphene flakes. Graphene flakes have a thickness of one or a few graphene layers whereas the lateral dimensions are much bigger. For these materials it is not clear whether the 50 % threshold in the number based particle size distribution also needs to be met. It has also been questioned why only carbon-based 2D (graphene) and tubular (single-walled carbon nanotubes) materials are listed.[2,3]

Possible adjustments

Option 1: no change

Certain fullerenes (e.g. C_{60}), monolayers of graphene and in specific cases also SWCNTs can have external dimensions close to or below 1 nm. They are normally considered to be nanomaterials but are borderline cases with respect to the size criterion of the definition. The explicit inclusion of those materials eliminates the resulting uncertainty. The current provision in the definition is relatively easy to implement since it eliminates the need to measure the size distribution of those materials and requires only their chemical identification. Depending on how the definition should be interpreted, one may also have to count the fullerenes, tubes and flakes as other particles, if they are present in a material containing also other (larger) particles.

However, also other materials that have a tubular or flake structure have been produced,[2] and other forms of graphene exist.[3] Such materials are not covered by the derogation and would not be considered as nanomaterials if their external dimensions are below 1 nm. If the external dimensions of these materials are larger than 1 nm they would have to be tested against the 50 % criterion, just as any other particulate material.

Option 2: extension of the list of materials explicitly included in the definition

This option consists of including (similar) materials which should be generally regarded as nanomaterials, e.g. materials that consist of flake-like, tubular or needle-shaped particles as well as other forms of graphene-like 2D materials, but not limited to carbon-based materials. Many of the early nanomaterials were carbon based materials, but the evolution of nanotechnology has resulted in a diversification of the elements used to construct the cage-like or tubular or 2D materials typical for nanotechnology. At this point, it is difficult to justify why these explicitly mentioned materials should be carbon-based materials only.

The explicit inclusion of materials often considered as nanomaterials for other reasons than size is more questionable. Quantum dots have been mentioned in this context[2] because they have properties clearly attributable to their size. The criterion, which may justify their inclusion in a list of explicitly included materials, would however not be their size but specific electronic and optical properties, which are the defining criteria of quantum dots. The introduction of such a criterion could be seen as problematic, because the core definition is based only on the external size of the particles.

Option 3: modify the derogation

Option 3, which can be combined with Option 2, is a modification of the derogation to make it clear that particles with an external dimension below 1 nm and other external dimensions above 1 nm (platelets, needles, but also more spherical particles) should be addressed in the same way as particles with minimum external dimensions in the range 1 nm to 100 nm when assessing whether a material is a nanomaterial or not. This would be equivalent to removing the 1 nm limit, so that one could just as well modify the definition to say “minimum external dimension below 100 nm” instead of “from 1 nm to 100 nm”. Removing the lower limit of 1 nm would, at this point in time, not add to the implementation challenges, because those challenges are already present at external dimensions larger than 1 nm. However, it could delay the resolution of these challenges.

This option effectively eliminates any doubt about whether the explicitly mentioned particles are subject to the 50 % threshold value in the number-based particle size distribution. At the same time, this also clarifies that the presence of a limited number of graphene flakes or carbon nanotubes in a material does not necessarily make the material a nanomaterial.

Option 4: remove derogations

Avoiding derogations for specific materials without any other modification of the definition may lead to uncertainties as discussed above. In order to clearly include or exclude the materials in question it may then be necessary to modify, i.e., to extend or to narrow other criteria (size and number based concentration). In turn, this may result in unwanted inclusion or exclusion of certain other materials.

4. Guidance

The sections above have indicated at several instances the need for further guidance. Guidance can provide additional information that helps to understand and implement the definition, thereby keeping the actual definition lean and placing detailed explanations and interpretations elsewhere. It also allows quick adaptation to changed circumstances, as guidance documents do not require the same decision process as formal pieces of legislation.

Based on the recent two JRC reports, guidance on the following issues could be envisaged.

4.1. Good measurement practice

A number of stakeholders request that the EC puts forward a reference method or a list of approved measurement methods that can be used to assess whether a material is a nanomaterial or not.

This may be done by updating the Q&A document currently available on the DG ENV website[20] with a section or multiple sections on analytical aspects, including measurement uncertainty, the method-defined nature of particle size measurements, alternative methods (including conversion of data and read-across), with the common message that emphasises the responsibility of the analyst to judge the reliability of the method(s) he/she chooses to apply. It will also be helpful to systematically and periodically add the results of currently ongoing projects on the implementation of the EC definition to the guidance.

4.2. Minimum external dimension

For the purpose of this definition, the "minimum external dimension" of a particle can be understood as the minimum Feret (or caliper) diameter in many cases, as defined in ISO 26824:2013: "*Feret diameter is the distance between two parallel tangents on opposite sides of the image of a particle.*"

Where this is not applicable or where it is contrary to expert opinion, alternative measures can be used and should be explained in specific guidance. Examples of materials for which the minimum external dimension is not easily measured as a Feret diameter are double-curved nanotubes or curved platelets.

4.3. Sample preparation – dispersion

Proper sampling and sample preparation is a fundamental prerequisite for reliable and reproducible characterisation of particles and to produce correct particle size distributions. Many methods currently used to characterise the size of small particles require additional treatment after sampling, before the sample is fit for analysis. This has been recognised and discussed in detail in a number of publications, including reports by OECD[23] and the JRC.[5,24] It is advisable that guidance related to the implementation of the EC definition of nanomaterial takes those findings into account.

If Option 3 under section 2.5 is chosen, then the constituent particles would in principle have to be defined via a certain dispersion protocol, specifying exactly which dispersants to use, the nature and amount of external energy input etc. Such a dispersion protocol could be either included in the respective legislation itself or in an international standard.

Experience shows that a fixed dispersion protocol is applicable only to the material for which it was developed, or at most to very similar materials. An alternative to one specific dispersion protocol would be to require testing under a limited number of conditions. The classification could then be based on the conditions that yield the highest number of dispersed particles. Such an approach offers the flexibility to deal with different kinds of nanoparticles, at the same time avoiding that a large number of conditions must be tested. While it would be premature to define dispersion conditions here, a potential approach could be as follows:

- Dispersants to be tested: Dispersions should be prepared in three different dispersants, one non-polar (e.g. ethanol), one polar-aprotic (e.g. acetone) and one polar-protic liquid, to cover the three large solvent classes. Water seems a natural choice for the polar-protic liquid, due to its prominence in environmental and physiological settings.

- Energy input: The energy input could be related to the binding energy of the material to avoid creation of nanoparticles by breaking up of constituent particles. Possible levels could be in the range between 30 % and 50 % of the average bulk binding energy. Determining the latter may require still more guidance.

Difficulties will arise when selecting the dispersants and the level of energy input.

5. Internationally harmonised terminology

In a multidisciplinary and cross-cutting field such as that of nanotechnology, it is desirable to harmonise the related terminology at international level. That is why the previous JRC Reports in this series[2,3] provided a detailed comparison of the EC nanomaterial definition with a number of other international definitions.

Of all other nanomaterial definitions, the EC definition is most often compared to the definition developed in ISO. ISO has developed terminology for the field of nanotechnology, including definitions for basic terms such as nanomaterial, as well as for the main nanomaterial sub-categories. In 2010, ISO defined the term "nanomaterial" (in ISO/TS 80004-1:2010) as "material with any external dimension in the nanoscale [...] or having internal structure or surface structure in the nanoscale". This term includes the term "nano-objects", defined as "materials with one, two or three external dimensions in the nanoscale", which is a generic term for all discrete nanoscale objects.

The ISO definition is developed for broad use across all possible areas, sectors, disciplines, in industry and academia alike. The EC definition, on the other hand, is developed very specifically for use in a regulatory context. Therefore it needs to be sufficiently specific and quantitative to enable its practical implementation and for this reason the EC could not simply adopt the ISO definition of the term nanomaterial: the ISO definition, not bound by concerns of regulatory implementation, is less quantitative, and thereby it is easier to include also materials that are not so easily defined in a quantitative manner, such as e.g. nanostructured materials.

Nevertheless, there were requests to use, where possible and without changing the meaning of the EC definition, other related supporting terms defined in ISO, including the term "nano-objects", in the EC definition of nanomaterial. This may appear attractive in view of international harmonisation of terminology, but it would require a more precise ISO vocabulary, because the ISO terms rely on the ISO definition of nanoscale: "size range from approximately 1 nm to 100 nm" (ISO/TS 27687:2008). In this definition, it is the term "approximately" that poses a problem for regulatory applications. Hence, building an EC definition of nanomaterial using ISO terms such as nano-object, would have the consequence of giving up the fixed size range established in the EC definition,[1] which was considered essential for the regulatory purpose of the EC definition.[4]

With respect to the other existing national or international nanomaterial definitions for regulatory use, there is no clear inspiring tendency to which the EC definition can or should be aligned. Rather, the EC definition seems to be a source of inspiration for the developers of nanomaterial definitions in more specific regulatory frameworks.

6. Conclusions

Since its adoption in October 2011, the European Commission's Recommendation of a definition of the term "nanomaterial" has been used as basis for legally binding definitions of nanomaterials in European Union legislation adopted thereafter (Biocidal Products Regulation) or for proposals of such legislation (Medical Devices Regulation), as well as in EU Member States' country-specific regulatory provisions. Likewise, ongoing amendments of nanomaterial definitions in legislation adopted in 2011 or earlier use the EC Recommendation as basis for harmonisation of the term nanomaterial across sectors. Furthermore, it is used in guidelines relating to legal provisions that address nanomaterials without having a specific definition (REACH).

In those three years the practical experience gained by applying it to real materials has led to a discussion on whether and how the definition should and could be further clarified and/or amended. Scientific and technical aspects of these discussions were collected and analysed in two previous JRC reports. The options provided in this third report offer possibilities for resolving issues identified in the past three years. It seems that most of the scientific-technical issues discussed so far could be dealt with through a carefully balanced set of modifications to the definition and of new or additional guidelines on the implementation of the definition.

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Authors: Hubert Rauscher, Gert Roebben, Ana Boix Sanfeliu, Hendrik Emons, Neil Gibson, Robert Koeber, Thomas Linsinger, Kirsten Rasmussen, Juan Riego Sintes, Birgit Sokull-Klüttgen, Hermann Stamm

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