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Targeted stakeholder consultation relating to the Review of the EU recommendation on the definition of the term "nanomaterial"

Fields marked with * are mandatory.

Introduction

In 2011, the European Commission adopted the Recommendation 2011/696/EU on the definition of nanomaterial (hereafter: the Recommendation). A common definition of the term "nanomaterial" across EU regulation supports a harmonised approach, facilitates implementation and enforcement, and can serve as the technical and scientific basis for EU legislation and policies that set provisions specific to nanomaterials. Member States are also invited to consider the definition in the Recommendation in their national legislation.
The Recommendation foresees a review of the definition by the Commission. The aim of the review is to reassess the definition in light of experience and scientific and technological developments since the adoption of the Recommendation. The review should address the objective, scope, clarity, usefulness, relevance, effectiveness, completeness and implementation.
To prepare the review, the Commission performed a number of consultations (targeted stakeholder survey, a comprehensive assessment and a workshop), and the Commission's Joint Research Centre (JRC) published three technical reports. The first JRC report compiles the collected experiences (EUR 26567 EN), the second report evaluates these experiences (EUR 26744 EN) and the third report presents a scientific-technical evaluation of options to clarify the definition and to facilitate its implementation (EUR 27240 EN).
The consultations and the JRC reports highlighted the following interim findings:

a) The definition is fit for purpose, its main elements are generally accepted;
b) Uptake of the definition in EU regulation to date has not been as comprehensive as anticipated. While some delay in the uptake can be attributed to the anticipation of the results of the review of the definition, direct uptake has been hindered by the lack of clarity of some of the definition's elements in particular in relation to the term particle and to particle properties
c) Limiting the default inclusion of a number of materials to only carbon-based materials (fullerenes, graphene flakes and single wall carbon nanotubes) may be outdated;
d) Implementation of the definition remains challenging. Because of the high diversity among nanomaterials, a single universally applicable and affordable particle size measurement method is unlikely to become available.

As a consequence of the above interim findings, the Commission services considered that the issues identified might be addressed through minor changes of the current definition in the Recommendation 2011/696/EU, and through implementation support with guidance that keeps abreast with development in methods. The JRC reports had been completed already in 2015. Meanwhile, in the absence of an actual

revision of the Recommendation, the existing definition has been applied in further EU regulations (i.e., REACH and the Medical Devices Regulation). Further implementation support was provided by an additional JRC report (EUR 29647 EN), through sectoral guidance (e.g. by ECHA and EFSA) and the development of analytical measurement methods (EUR 29876 EN, EUR 29942 EN).

The review of the Recommendation was recently reaffirmed as one of the actions under the 2020 Commission Chemicals Strategy for Sustainability. As a result, the Commission organises this second targeted stakeholder consultation, seeking stakeholders' views on the Commission's interim findings and considerations for potential changes. As the definition is horizontal in its application, the 'target' stakeholder group remains wide: economic operators implementing all relevant EU sectoral regulation and their federations, Member States competent authorities and other regulatory stakeholders, research organisations supporting implementation, academia and NGOs.
It should be noted that other or more specific nanomaterial definitions in individual legislation, where the definition from the Recommendation has not yet been taken up (e.g., the definition of 'engineered nanomaterial' in the Novel Foods Regulation (EU) 2015/2283 or the nanomaterial as "insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm" under Regulation of cosmetic products (EC) No 1223/2009) are outside the remit of this consultation.

Instructions for the respondents

Attached: ***Privacy statement***

The questionnaire features three distinct parts. While all the parts are open to all respondents:

- the first part is of more general nature and is aimed toward all stakeholders; it includes questions about the definition, the general expectations of the measure and the interim findings of the review;
- the second part lists elements of the definition considered for change, followed by detailed questions focusing on the technical aspects of the considered changes to the definition; respondents can choose to skip the detailed technical questions;
- the last part of the consultation includes questions to a specific group of stakeholders, i.e., the manufacturers, importers or downstream users of materials that could become included or excluded by changes considered. Only those stakeholders should reply to this set of questions.

A "final comment" field is available for all at the end of the questionnaire.

Answers to the "Multiple choice" questions can be further substantiated in a free text field at the end of the chapter. Respondents should note that most issues are elaborated in the follow-up questions and may not require immediate detailed response in the introductory general open question.
Answers to most of the questions are compulsory: open questions can however be left empty, and the multiple choice questions always include a 'no opinion' answer.

To facilitate an understanding of how the modifications, if applied, would work as part of the definition, they have been compiled in a single text (attached: ***Modification elements***). In the Recommendation 2011/696/EU, elements of the definition are preceded by short paragraphs that motivate the individual elements of the definition. In analogous fashion, draft motivation paragraphs to the considered changes were also prepared for the survey and are referenced with each question (attached: ***Modification motivation paragraphs***). The motivation paragraphs or the short rationale provided with each considered revision

element are not mandatory reading in order to respond to the associated questions, but they help avoid misinterpretation.

We strongly recommend to first download the PDF version of the questionnaire [click "**Download PDF**"], the Recommendation 2011/696/EU, the document with compiled modification elements under consideration and the associated motivation, in order to examine the questions and elaborate the replies before starting an on-line session.

Please note that all documents have been prepared only for the purpose of this targeted stakeholder consultation and do not prejudice any decisions by the Commission. We would like to thank all respondents for taking the time to reply to the questionnaire.

General information about the respondent

* **Important notice on the publication of contributions**
Replies to this targeted stakeholder consultation will be published on the European Commission's website (for further information, please consult the privacy statement).
Please note: regardless of the option chosen below, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.
Respondents should not include personal data in any information submitted in the context of consultation if they opt for anonymous publication.

* Please indicate whether your reply:

- (●) Can be published, including personal data (name and email, country of residence, profession, self-declared area of competence and information about the represented organization). I consent to publication of all information in my contribution and I declare that none of it is under copyright restrictions that prevent publication.
- ( ) Can be published in an anonymous way. I consent to publication of all information in my contribution except explicitly requested personal data, and I declare that none of it is under copyright restrictions that prevent publication.

* Are you a citizen or replying on behalf of an organisation (trade group, industry, SME, public body, interest group, industrial or consumer association, trade union, academic/research institution, etc.)?

- ( ) Citizen
- ( ) Company
- (●) Stakeholder/Organisation
- ( ) EU or Member State authority (national or regional)

Transparency Register Number

Text of 1 to 15 characters will be accepted

905394213999-33

* Please indicate the name of your organisation:

1 character(s) minimum

AVICENN

The organisation's head office is in

France

* Please briefly describe your organisation, including geographiccoverage of its services, affiliation and if relevant turnover:

AVICENN is a French NGO which undertakes strategic watch on nanomaterials (available from http://veillenanos.fr) and promotes greater transparency and vigilance on nano-related risks

* What is the size of your organisation?

- (●) 1 - 10 members/employees
- ( ) 11 - 50 members/employees
- ( ) 51 - 250 members/employees
- ( ) 251 - 1000 members/employees
- ( ) Over 1000 members/employees

* Please specify the type(s) of organisation you represent (1 answer possible)

- ( ) SME (Small or medium-sized enterprise)
- ( ) Non-SME or group
- ( ) Law firm or consultancy
- ( ) Non-EU authority
- ( ) International organisation
- ( ) Trade or business association
- ( ) Academic/research institution
- ( ) Trade union or professional association
- ( ) Consumer association
- (●) Other non-governmental organisation, platform or network
- ( ) Other (please specify)

Self-declared area of competence (Please select up to three)

at most 19 answered row(s)

	Most relevant	Relevant	Least relevant
Standardisation	○	○	○
Research (e.g. nanosafety/general)	○	○	○
Nanotechnology (general)	○	○	○
Products safety, workers and/or consumer protection (general)	◉	○	○
Trade (general)	○	○	○
Industrial chemicals (manufacturing/import/downstream use)	○	○	○
Cosmetic products	○	○	○
Food/food packaging/feed	○	○	○
Biocides and plant protection products	○	○	○
Medical devices	○	○	○
Pharmaceuticals	○	○	○
Environment (air, water, waste etc., including life cycle aspects)	○	◉	○
Energy	○	○	○
Transport	○	○	○
ICT	○	○	○
Construction or decoration materials (including paints)	○	○	○
Sports materials (including finishing materials such as waxes or surface coatings)	○	○	○
Defense	○	○	○
Other (if chosen please specify)	○	○	○

* Interest and intended use of the definition by the respondent (multiple answers possible)

between 1 and 9 choices

- ☑ Regulatory implementation
- ☑ Risk assessment and risk management
- ☑ Regulatory development
- ☐ Trade
- ☑ Communication
- ☐ Innovation

- [ ] Purely scientific
- [ ] No direct intended use
- [ ] Other (If selected please specify)

Please indicate a contact person and an email address for correspondence

* Contact Name

Text of 1 to 128 characters will be accepted

Mathilde DETCHEVERRY

* Email

detcheverry.avicenn@gmail.com

Part 1. General observations

* **Regulatory approach to nanomaterials**:

The general format and fitness for purpose of the Recommendation on the definition of nanomaterial under review is associated with the general regulatory approach to nanomaterials taken in the EU. To help interpret responses further in the survey, please indicate which of the answers below correspond best with your general position regarding the approach to nanomaterials in the EU. **Choose maximum three**.

- [ ] Nanomaterials are materials/chemicals like any other and do not require special legislation or special provisions.
- [x] Nanomaterials do not require legislation as a separate category of materials /chemicals, but specific nanomaterial provisions within legislation may be required in some sectors to ensure efficiency and effectiveness. A definition, triggering such provisions, is thus required.
- [x] Special, stand alone legislation for nanomaterials may be a more effective way to address at least some EU objectives, like for example high protection of human health and the environment. A definition, determining the scope of this legislation, is thus required.
- [ ] Triggering specific provisions does not require a common definition for this subgroup of materials between sectors; triggers should be tailored to each individual situation.
- [x] A common definition of nanomaterial used across legislation and sectors increases efficiency and consistency of implementation.

- [ ] None of the above.
- [ ] I have no view.

* **Consistency of nanomaterial definition in regulatory context**: Which of the answers below corresponds best with your position regarding the (harmonized) approach to nanomaterials in EU regulation?

at least 1 choice(s)

- [x] A directly applicable and legally binding EU definition in place of the Recommendation would increase efficiency and consistency of implementation across sectors.
- [x] The present approach (definition from the Recommendation is made legally binding as it is taken up in sectoral legislation) is adequate, but direct reference to the Recommendation rather than copying of the text of the definition, should be made possible.
- [ ] The present approach is adequate.
- [ ] There is no inherent need for harmonisation – any definition needed for triggering specific provisions should be determined within the individual sector.
- [ ] None of the above.
- [ ] I have no view.

* Do you agree with the interim review findings regarding the present Recommendation 2011/696 /EU, as presented in **the bullets a) to d) in the introduction**?

- ( ) Fully disagree
- (•) Mostly disagree
- ( ) Mostly agree
- ( ) Fully agree
- ( ) Don't know / No opinion

Please substantiate your answers

1000 character(s) maximum

a) The definition is not fit for purpose, since it only takes into account the size of the nanomaterials, not its other physical-chemical parameters that are important.
b) Delay in the uptake can be attributed to other factors
c) Limiting the default inclusion of a number of materials to only carbon-based materials may be outdated;
d) Granted, implementation of the definition remains partially challenging & expensive for many nanomaterials but electron microscopy, coupled with an additional ad hoc technique if needed, can provide reliable classification. Manufacturers who want to produce and sell nanomaterials, and their clients who want to use them in their products, must pay for these costs - otherwise, this would only be privatizing benefit and socializing costs, which is not fair from a citizen's perspective. Proper characterization and risk assessment must be made before commercialization, to avoir pollution and health problems (too often seen a "negative externalities").

* Overall, as compiled in the attached document, are the considered **modifications** of the Recommendation sufficiently comprehensive and clear?

- (●) Fully disagree
- ( ) Mostly disagree
- ( ) Mostly agree
- ( ) Fully agree
- ( ) Don't know / No opinion

Please substantiate your answer

1000 character(s) maximum

Cf. Andrew Maynard's comment published in Nature in 2011 (cf. https://www.nature.com/articles/475031a) : "Many parameters other than size modulate risk, including particle shape, porosity, surface area and chemistry. (...) The transition from 'conventional' to 'unconventional' behaviour, when it does occur, depends critically on the particular material and the context.
A 'one size fits all' definition of nanomaterials will fail to capture what is important for addressing risk. (...) regulators should work with a list of nine or ten attributes (including size and surface area) for which certain values trigger action. (...) Attributes other than size and surface area would be included; cut-off values would be compound-specific and based on current science; and the criteria would allow for changes in a given material over time. Such regulatory sophistication will obviously take a lot of work. (...) These trigger points must be flexible, so that they can be modified as evidence grows"

* **Navigation**

- (●) Continue to Part 2 (questions on the individual elements considered for revision)
- ( ) Proceed directly to Part 3 (replacement of current derogation: identification of affected materials and impact)
- ( ) Proceed directly to the Final Question

Part 2. Revision considerations (individual technical elements)

In order to efficiently respond to the questions, we recommend to have the following documents at hand:

- The Commission Recommendation 2011/696/EU,
- Modification elements (note labels E1-E4 in the document),
- Modification motivation paragraphs.

I want to specifically comment on the following individual element(s) (**tick all that apply to be guided to them in the survey**):

- [x] E1 Change from 'contain' to 'consist'
- [x] E2 Different particle aspects, including consideration of particles with dimensions outside 1-100 nm and generalization from current derogation of fullerens, single wall carbon nanotubes and graphene flakes
- [x] E3 Flexibility of the particle number concentration threshold
- [x] E4 Application of VSSA (Volume Specific Surface Area)

Note: Answers to multiple-choice questions can be complemented in an optional free-text field at the end of each chapter. Any remaining general technical observations, identifying omissions and further suggestions can be provided in the answer to the final open question of the questionnaire.

E1 Element considered for revision: contain/consist

Change: *'Nanomaterial' means a … material ~~containing~~ consisting of solid particles…'*

Rationale in the attached motivation: Paragraph 5.

Main rationale:

Increased clarity. Material" is a generic term for what is evaluated in specific legislation: chemical substance, cosmetic ingredient etc. The material should be evaluated based on what it mainly "consists of", or in other words on what it is made of and without taking into account other components that may be present such as impurities, additives or stabilisers. Application of the definition still allows for the existence of another fraction or phase beside the particles in the material under assessment.

* Does the change from 'containing' to 'consisting of' clarify the scope of the definition?

- ( ) Fully disagree
- ( ) Mostly disagree
- ( ) Mostly agree
- ( ) Fully agree
- (•) Don't know / No opinion

E2 Element considered for revision: particles

Note: a free-text answer option is available at the end of the chapter on particles to substantiate any of the answers given.

Change 1. *'…material consisting of solid particles…'*

Rationale in the attached motivation: Paragraph 8.

Main rationale:

Increased clarity. The definition in the current Recommendation 2011/696/EU is interpreted in the existing Questions&Answers prepared by the European Commission and the JRC Report EUR 29647 EN "An overview of concepts and terms used in the European Commission's definition of nanomaterial" to cover only solid particles. The term "Solid" is here used in its meaning as one of the four fundamental states of matter, characterized by structural rigidity and resistance to changes of shape or volume, considered in this context under normal conditions. This excludes emulsions (liquid particles dispersed in liquid media) and micelles (agglomerates of dispersed surfactant molecules in a liquid). Restriction to solid particles is considered to ensure that the highly dynamic nature of the external dimensions of such non-solid objects does not prevent the use of external size as the defining property.

* Do you agree with the restriction to solid particles only?

- ○ Fully disagree
- ◉ Mostly disagree
- ○ Mostly agree
- ○ Fully agree
- ○ Don't know / No opinion

Note: a free-text answer option is available at the end of the chapter on particles to substantiate any of the answers given.

Change 2. *'particles~~, in an unbound state or as an~~ that are either present on their own or as identifiable constituent particles in aggregates…'*

Rationale in the attached motivation: Paragraphs 7 and 9.

Main rationale:

Increased clarity and ease of implementation. The term 'unbound' has been identified in the JRC survey as potentially ambiguous. Understanding that the definition applies to the material itself and not to its interaction with the environment (which might as well literally 'bind' the particle), the reference to 'unbound' is not strictly necessary and is replaced by 'present on their own', as identifying a particle itself is sufficient to implement the definition.

The qualifying term 'constituent' for particles in aggregates and agglomerates should eliminate doubts to which particles the definition refers (i.e. regarding sizing, counting).

The additional qualifier 'identifiable' in the definition proper makes it explicit that the application of the concept of constituent particle is bound by the practical consideration of properly identifying and measuring the constituent particles. Guidance on the implementation of the definition will include the specific situations where the identification of constituent particles as part of larger structures, in particular in strongly bound aggregates, is challenging.

* Do you agree with the replacement of the reference to the 'unbound state'?

- ○ Fully disagree
- ○ Mostly disagree
- ○ Mostly agree
- ○ Fully agree
- ◉ Don't know / No opinion

* Do you agree with the reference to the 'identifiable constituent' particles?

- ○ Fully disagree
- ◉ Mostly disagree
- ○ Mostly agree
- ○ Fully agree
- ○ Don't know / No opinion

Note: a free-text answer option is available at the end of the chapter on particles to substantiate any of the answers given.

Change 3. Restriction of the particles to be considered in point 2): *Particles with at least two orthogonal external dimensions larger than 100 micrometre shall not be counted for the purpose of the number size distribution.*

Rationale in the attached motivation: Paragraph 14.

Main rationale:

Increased clarity and ease of implementation. Excluding from counting the particles with at least two orthogonal external dimensions above 100 micrometre that are themselves not aggregates or agglomerates of smaller constituent particles can address some of the practical measurement issues. It can also help to avoid in practice any potential ambiguity in differentiating between a particle and a larger solid product such as a large material sheet that should not be covered by the definition. The limit of 100 micrometres is based on the total suspended particle size as the largest particle size explicitly set by any regulation in the EU, i.e. air emission regulation[1]. In reasonably foreseeable practical cases, the relative contribution of particles in the size range 1 nm to 100 nm to the total number of particles would not be significantly influenced by either counting or excluding these large particles. Such upper limit means that a material with a majority of such particles, even if the third dimension of these particles is within 1-100 nm, is not considered a nanomaterial.

[1] For example, Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (Text with EEA relevance), OJ L 344, 17.12.2016, p. 1

* Do you agree that particles with at least two orthogonal external dimensions larger than 100 micrometres should not be counted for the number based size distribution?

- ( ) Fully disagree
- ( ) Mostly disagree
- ( ) Mostly agree
- ( ) Fully agree
- (•) Don't know / No opinion

As you do not fully agree please provide further clarification below. Choose one or more answers.

between 1 and 5 choices

- [x] The implicit exclusion of very large but thin (1-100 nm) platelets is not appropriate
- [ ] An upper limit is useful but the proposed value or constraint regarding at least two orthogonal dimensions is not appropriate.
- [ ] The upper limit should apply only to specific types of particles
- [x] The definition should explicitly allow flexibility in whether particles larger than the upper limit are included or excluded in the tally
- [ ] Other

Please substantiate your answer and provide an alternative upper limit value or particle type(s) as appropriate

Text of 1 to 128 characters will be accepted

> The modifications would need to be clarified & illustrated, so that we can see what materials would fall off this new definition

Note: a free-text answer option is available at the end of the chapter on particles to substantiate any of the answers given.

Change 4. Subdefinition of a particle in point 2a): '*Single molecules are not considered particles.*'

Rationale in the attached motivation: Paragraph 12.

Main rationale:

Increased clarity. The explicit exclusion of single molecules is in line with the current interpretation of the Recommendation 2011/696/EU as laid down in the European Commission's Questions&Answers and the JRC Report EUR 29647 EN “An overview of concepts and terms used in the European Commission’s definition of nanomaterial”. A single molecule, including macromolecules such as proteins or polymers that may be larger than 1 nm, should not be considered a particle for the purpose of the definition. As there are different interpretations of the term ‘molecule’, a case-by-case consideration may be required in such very specific situations. This aspect will therefore be picked up in the Guidance and would include discussion of concrete cases (e.g. fullerenes, proteins, polymers).

* Do you agree not to consider single molecules as “particles” in the definition?

- ○ Fully disagree
- ◉ Mostly disagree
- ○ Mostly agree
- ○ Fully agree
- ○ Don't know / No opinion

Note: a free-text answer option is available at the end of the chapter on particles to substantiate any of the answers given.

Change 5: Delete derogation for specific carbon-based materials '~~*3. By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.*~~', and include additional conditions b) and c) in the definition under point 2:

‘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.

Rationale in the attached motivation: Paragraph 13.

Main rationale:
Generalization of an existing derogation. Ideally, a definition would cover all materials using one straightforward rule, without the need for derogations. However, avoiding exceptions by extending or narrowing the basic criteria may result in unwanted inclusion or exclusion of other materials.
Complementing the core definition with lists of explicitly included or excluded materials can be a pragmatic way to tackle the problem; the existing derogation was based on the knowledge of materials at the time (in 2011), making sure that some flagship nanomaterials (e.g. carbon nanotubes, graphene) with particles which may be thinner or smaller than 1 nm, are included.
This approach could be maintained. The review has however identified that it is not only carbon from which such particles can be manufactured and the list should be updated. The weakness of a list is a need for periodic update of the definition and the probable constant gap in the list compared to materials development.

Removing the list altogether would revise the present scope and leave some flagship materials out of the definition.
A more generic treatment of cases as presented above should potentially resolve this issue, increasing at the same time also the internal consistency of the definition by relying solely on counting the particles.
But such replacement would identify as nanomaterials beside the single wall carbon nanotubes and single-layer graphene flakes also certain other forms of substances or ingredients placed on the market (e.g. some specifically tailored forms of silicate minerals, oxides, nitrides or halides) that will extend the present scope of the definition, while excluding the presently included single-molecule fullerenes.
The questions below address the appropriateness of the technical solution considered. The questions in Part 3 explore the potential consequences of applying this change.

* Indicate your preferred solution in relation to the potential revision of existing derogation that specifically includes fullerenes, single wall carbon nanotube and graphene flakes as nanomaterials:

- ○ No need for any additional inclusion of materials through criteria or specific derogation
- ○ Maintain current derogation
- ○ Update the derogation list
- ○ Partially agree with the replacement of derogation but conditions need to be modified
- ◉ Agree with the replacement of derogation with the inclusion of fibre- and plate-like materials as proposed
- ○ None of the proposed or no opinion

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* Do you agree that with these five changes particles are clearly and adequately defined for the purpose of the definition?

- ○ Fully disagree
- ○ Mostly disagree
- ○ Mostly agree
- ○ Fully agree
- ◉ Don't know / No opinion

You may substantiate your answers on any revised element regarding particles (changes 1-5).

1000 character(s) maximum

What about fullerenes? polymers? others?

E3 Element considered for revision: flexibility of the threshold

Change: Removal of flexibility clause '~~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 %.~~', leaving only default threshold of 50%.

Rationale in the attached motivation: Paragraph 7.

Main rationale:

In Recommendation 2011/696/EU, a certain flexibility was introduced as a safeguard in the light of the uncertainties and lack of knowledge on nanomaterials at the time. However, it may create confusion among business operators, consumers and regulators. Depending on the thresholds used in specific legislation, the same specific material could be considered as a nanomaterial under one regulatory framework but not under another. It has also been the main reason why direct reference to the nanomaterial definition in Recommendation 2011/696/EU was not possible in some instances.
The current review has not found evidence that the existing default threshold of 50% (i.e. more than half of all particles in the material are in the nano-size range) should be increased or decreased to address a particular concern or to cover or exclude specific materials. With a reduction of the threshold, from 50% to a lower value, the challenges associated with the measurement of particle size distribution would also be further increased (point elaborated in the JRC report EUR 26744 EN).

* Do you agree with removing the flexibility of the threshold?

- (•) Fully disagree
- ( ) Mostly disagree
- ( ) Mostly agree
- ( ) Fully agree
- ( ) Don't know / No opinion

* Do you agree with maintaining the default threshold value of 50%?

- (•) Fully disagree
- ( ) Mostly disagree
- ( ) Mostly agree
- ( ) Fully agree
- ( ) Don't know / No opinion

You may substantiate your answer.

1000 character(s) maximum

We understand that, from a metrologist or manufacturer's point of view, a threshold is needed to be able to determine if a material falls in the scope of the definition and must be labelled, registered, limited to specific uses only for example. But labelling, registration or restriction of nanomaterials are not a goal in itself. They do exist because of the potential risks of nanomaterials, linked to their high reactivity. This 50% threshold is too high to ensure that human health and the environment are protected. Highly respectable institutions have recommended a 10% threshold (not only in food or cosmetics, as stated by EFSA in 2012 and French ministry of Ecology in 2017 and French ministry of Economy in its control of [nano] labelling implementation

since 2017) but also more generally (cf. French High Council of Public Health - HSCP in 2018). ANSES has also taken position in favor of a lower threshold for the French nano-database r-nano.

E4 Element considered for revision: VSSA (Volume Specific Surface Area)

Change 1: Remove existing reference to VSSA '5. Where technically feasible and requested in specific legislation, compliance with the definition in point 2 may be determined on the basis of the specific surface area by volume. 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 m2/cm3 . However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with the definition in point 2 even if the material has a specific surface area lower than 60 m2/cm3.' Rationale in the attached motivation: Paragraph 15.

Rationale in the attached motivation: Paragraph 15.

Main rationale:

In the Recommendation 2011/696/EU, the identification of a nanomaterial through its VSSA value is possible but the number size distribution would prevail in case of conflicting results. The VSSA value may be subject to interpretation, as high surface area may be due to the internal nanostructure, not attributable to aggregates or agglomerates of constituent particles. Moreover, particle shape and size polydispersity can strongly influence the relation between thresholds in number-based size distribution and in VSSA. The NanoDefine project concluded that such an identification was not appropriate.
This is without prejudice to the continued use of VSSA as a screening method for selection/identification of materials that might fulfil the definition as outlined also in the JRC Report EUR 29942 EN “Identification of nanomaterials through measurements”. Relevant support in the Guidance is being planned.

* Do you agree with deleting the use of VSSA as a surrogate for particle size distribution measurement for classifying materials as nanomaterials?

- ○ Fully disagree
- ◉ Mostly disagree
- ○ Mostly agree
- ○ Fully agree
- ○ Don't know / No opinion

Change 2: Insert the following VSSA reference: *a material with a specific surface area by volume of 5 m2 /cm3 or less shall not be considered a nanomaterial.*

Rationale in the attached motivation: Paragraph 16.

Main rationale:

VSSA measurements can be considered as a tool for the exclusion of a material as a nanomaterial and thus to avoid additional costly measurements. The NanoDefine project demonstrated with a large set of different materials that the materials with a volume specific surface area of 5 m2/cm3 or less with great

certainty do not have the number- based particle size distribution of a nanomaterial. Therefore, those materials should not be considered as a nanomaterial.

* Do you agree with adding a possibility to use a VSSA threshold value of 5 m2/cm3 as a threshold value to exclude materials from the definition of a nanomaterial

- (●) Fully disagree
- ( ) Mostly disagree
- ( ) Mostly agree
- ( ) Fully agree
- ( ) Don't know / No opinion

You may substantiate your answer.

1000 character(s) maximum

As a screening method it can be helpful in certain cases, but false positives or false negatives can not be excluded, thus this can not be used to exclude materials.

* **Navigation**

- (●) Continue to Part 3 (replacement of current derogation: identification of affected materials and impact)
- ( ) Proceed directly to the Final Question

Part 3. Consequences of the replacement of the derogation for fullerenes, single wall carbon nanotubes and graphene flakes for the economic operators in different sectors

The Recommendation has no direct legal impact. But when a particular piece of legislation takes up the definition, with some elements potentially modified compared to the existing definition in the Recommendation 2011/696/EU, this change may affect business activities (innovation, manufacture, import or use of those materials) and even implementation of safety measures at the workplace, as (additional) materials might consequently fall under specific regulatory requirements designed for nanomaterials.

Most of the changes considered do not intend to change the scope of the existing definition in the Recommendation (which materials are covered, which not) but aim at clarification and implementation addressing the scope of the existing definition. Replacement of the derogation on fullerenes, single-wall carbon nanotubes and graphene flakes with criteria under Points 2 b) and c), elaborated in Part 2 of this questionnaire, brings a more generic inclusion of materials with elongated (tubes, wires, ribbons, rods) and platelet-like particles with dimensions below 1 nm and other above 100 nm, even if these cases remain an exception. The questions below aim to identify its impact as well as potential impact of any other change considered. Note that while the questions are generic, they demand identification of the legislation under which such impacts would take place, to support also legislation-specific analysis of the feedback to this

questionnaire.

The respondents are reminded that the scope of this review is concluding on the definition of the term nanomaterial in the Recommendation 2011/696/EU. The answers should therefore reflect the estimated impact of its potential change and not e.g. the full anticipated impact in the legislation where the alignment with the horizontal definition is yet to take place. As appropriate, consultation on those impacts may be part of the associated regulatory action in the sector concerned.

Additional comments may still be provided answering an open question at the end.

* Do you produce or import materials that are not nanomaterials under the current Recommendation 2011 /696/EU, but would be nanomaterials if the changes considered are implemented, in particular the replacement of the derogation with criteria b) and c) (see elements considered for modification)?

Note: few further more detailed questions follow if answered Yes or Probably.

(•) No ( ) Possibly ( ) Probably ( ) Yes

* Do you plan to produce such materials in the near future?

Note: few further more detailed questions follow if answered Yes or Probably.

(•) No ( ) Possibly ( ) Probably ( ) Yes

Impact of categorization of the material(s) as nanomaterial on the placement on the market and innovation. Please tick all that would apply.

Categorization would

	Never	Rarely	Occasionaly	Frequently	Very frequently	Do not know
Be the leading (50%) cause to withdraw from the market	○	○	○	○	○	○
Likely be a contributing factor to withdraw from the market	○	○	○	○	○	○
Would not be a significant factor in considering position on the market	○	○	○	○	○	○
Would negatively affect our innovation and competitiveness	○	○	○	○	○	○
Would not affect our innovation and competitiveness	○	○	○	○	○	○
Is likely to boost innovation and/or competitiveness	○	○	○	○	○	○
Other(please specify)	○	○	○	○	○	○

Final comment

Do you have any further comment, proposal for additional change to be considered or general observation regarding the objective of a consistent regulatory approach to nanomaterials?

4000 character(s) maximum

AVICENN welcomes the European Commission's consultation on its proposal for a revised definition of the term "nanomaterial". However, the proposed rewording and motivations are not very readable and will likely lead to new problems of interpretation – an unfortunate paradox, since the objective was to clarify the definition. Given the considerable stakes involved, a more open and sequenced approach would be appropriate, including Q&As public sessions, with contradictory insights from independent experts of various disciplines (physical chemistry, toxicology, metrology, law, etc.), which would help elected officials and stakeholders to make an informed opinion and relevant contributions.

The proposed definition is intended to be science-based, unconnected with risk management aspects. But the 50% and 100 nm thresholds have no solid scientific basis. While metrologists or manufacturers legitimately ask for quantifiable elements to determine whether a substance is a nanomaterial (for registration or labelling purposes for example), the specific properties of nanomaterials - and the toxicity that may result from them - do not "magically" disappear below 50% or above 100 nm. Their toxicity is linked not only to the size of the particles but also to other physico-chemical parameters that are at least as important – but are ignored in the proposed definition.

More generally, the technical considerations proposed for consultation should not overshadow the most important thing to keep in mind, i.e that the regulatory framework and the institutions must ensure that only nanomaterials with a favourable benefit/risk ratio shall be authorised - for well-defined uses - and that these nanomaterials can be (re)used and recycled in a safe circular economy, with minimum adverse effects on human health and ecosystems.

The revision of REACH annexes has certainly been a step in the right direction, but there is still a long way to go: ECHA's resources are too limited to check the proper registration of nanoforms within the current scope of REACH; and nanoforms produced or imported in less than one tonne per year are not covered by REACH, even though their lower tonnage is no guarantee of lower toxicity (quite the contrary actually, since some nanoforms may be more recent and therefore even less controlled than more common nanoforms).

Many opinions from the SCCS highlight the lack or limitations of data submitted by many suppliers; it is thus urgent is to take action. First, by requesting a thorough & mandatory characterization of materials on the market and, second, by assessing their specific properties and toxicity. (Re)authorisations shall be granted on the basis of a robust assessment of the benefit/risk ratio. Until then, a precautionary approach should lead nanoforms for which environmental or health concerns exist to be withdrawn from consumer products. At the very least, an informative approach should lead to extend labelling obligation (which currently exists only for biocides, cosmetics & food) to all sectors, in order to minimise the exposure of the most exposed (workers) and vulnerable people (children, women of childbearing age, immuno-compromised people, the elderly, etc.).

If not, the misadventure that IKEA recently experienced* could happen again and again, with all that this implies in terms of increased mistrust and defiance of consumers towards industries, and citizens towards public institutions.

* IKEA recently took out of the range its GUNRID "air purifying" curtains, one of the flagship products of their 2020/21 paper catalogue. Tests made by the French national metrology laboratory (LNE), on AVICENN's request, have revealed many nanoparticles of titanium dioxide (TiO2 – a suspected carcinogen by inhalation) on their surface. 100% are below the 100 nm threshold. IKEA acknowledged that they did not purify the air to the extent that was expected. Cf. http://veillenanos.fr/wakka.php?wiki=NpTiO2RideauxIkea

We would like to thank you for having taken the time to reply to the questionnaire.

Useful links

Recommendation 2011/696/EU (https://eur-lex.europa.eu/eli/reco/2011/696/oj)

Review information (https://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm)

JRC report EUR 26567 EN (http://publications.jrc.ec.europa.eu/repository/bitstream/JRC89369/lbna26567enn.pd

JRC Report EUR 26744 EN (http://publications.jrc.ec.europa.eu/repository/bitstream/JRC91377/jrc_nm-def_report2_eur26744.pdf)

JRC Report EUR 27240 EN (http://publications.jrc.ec.europa.eu/repository/bitstream/JRC95675/towards%20review%20ec%20rec%20def%20nanomaterial%20-%20part%203_report_online%20id.pdf)

JRC Report EUR 29647 EN (http://publications.jrc.ec.europa.eu/repository/handle/JRC113469)

JRC Report EUR 29876 EN (http://publications.jrc.ec.europa.eu/repository/handle/JRC117501)

JRC Report EUR 29942 EN (http://publications.jrc.ec.europa.eu/repository/handle/JRC118158)

Chemicals Strategy for Sustainability (https://ec.europa.eu/environment/strategy/chemicals-strategy_en)

Background Documents

Privacy statement

draft_Modification_elements

draft_Modification_motivation_paragraphs

Contact

Contact Form