

The Director General

Maisons-Alfort, 14th January 2022

**Scientific and technical support
NOTE**

**of the French Agency for Food, Environmental and
Occupational Health & Safety**

**on "preparing a proposal for an updated definition of the term 'nanomaterial'
based on Recommendation 2011/696/EU"**

On 10 July 2018, the Directorate General for Health (DGS), Directorate General for Risk Prevention (DGPR), Directorate General for Food (DGAL), Directorate General for Labour (DGT) and Directorate General for Consumer Affairs, Competition and Fraud Control (DGCCRF) made a formal request to ANSES for support in preparing a proposal for an updated definition of the term "nanomaterial" based on European Commission Recommendation 2011/696/EU.

1. BACKGROUND AND PURPOSE OF THE REQUEST

The growing use of nanoparticle substances in a wide variety of sectors has led the public authorities to adapt national and European regulations to take account of their specific features.

The dimensional characteristics of these substances, which may give the materials particular properties or behaviours, also suggest probable differences in how they interact with living organisms (toxicity – ecotoxicity and environmental fate). However, often developed for their specific properties and regarded as vectors of innovation, the state of knowledge on the potential effects of these substances on the environment and health is generally inadequate to assess the risks.

In the absence of a fully agreed definition that would enable the scope of the objects concerned to be identified, the first step towards a better understanding consisted in harmonising the vocabulary used (nano-objects, aggregates, agglomerates, engineered nanomaterials, etc.),

initially via standardisation, and then establishing a definition and criteria enabling these substances to be characterised, with regard to their size, distribution, specific surface area, etc.

At European level, Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU) has several times served as a reference for various legislative texts in Europe. It was based on work by the Scientific Committee on Emerging and Newly Identified Health Risks (Scenihp), published in 2010.

The European Commission (EC) had proposed using this recommendation as a basis for adapting the definition of nanomaterial in Regulation (EU) No 1169/2011 on the provision of food information to consumers, mainly by introducing a 50% threshold for the number-size distribution. This proposal was rejected by the European Parliament in 2014 on the grounds that there was no justification for the introduction of such a threshold, which was inappropriate here for responding to consumer demand for information.

At present, the various European regulations that take account of nanomaterials use different definitions (regulations on biocidal products, cosmetic products, novel foods, food information to consumers, medical devices).

Work to revise the annexes of Regulation (EC) No 1907/2006 ("REACH") in order to adapt it to substances in nanoparticle form was published in 2018 (Regulation (EU) 2018/1881). The draft text of these annexes was voted by the EC in committee on 26 April 2018 and came into force on 1 January 2020. The text refers to the European recommendation on the definition.

The current definitions proposed in the EC's 2011 recommendation and in the different regulations contain differences and imprecisions (50% threshold in particle number or size, notions of insolubility or biopersistence in the cosmetics regulation, etc.). These are regularly highlighted by stakeholders, who would like a clearer and harmonised definition. In several communications relating to this recommendation, the EC had announced its intention to revise it before December 2014, in order to better take into account the specificities of these substances and advances in knowledge, and to clarify certain points of the definition.

The Joint Research Centre (JRC), a research service of the European Commission, published a first report in 2014 with proposals for criteria that could be considered to define nanomaterials (JRC 2015). More recently, in preparation for the EC's proposal for a definition, the JRC published in early 2019 a supporting document defining useful terms and concepts related to the definition (JRC 2019b), followed by another report, this time on analytical techniques for identifying nanomaterials (JRC 2019a).

With a view to a public consultation on a proposed change to the 2011 European definition, the Directorate General for Health (DGS), Directorate General for Risk Prevention (DGPR), Directorate General for Food (DGAL), Directorate General for Labour (DGT) and Directorate General for Consumer Affairs, Competition and Fraud Control (DGCCRF) made a formal request to ANSES on 10 July 2018 in order to draft a contribution to this public consultation. After several rounds of discussion since 2012, the Commission opened a short phase of public consultation (from 6 May 2021 to 30 June 2021) in order to gather opinions on the proposed changes to the 2011 European definition.

In order to carry out this work, ANSES planned its activities in several phases:

- 1) initially (before the public consultation) conducting a review of knowledge on existing analytical methods, in order to determine the main parameters for characterising nanomaterials (general principles, advantages and limitations, particularly from a metrological perspective);
- 2) without waiting for the final wording, examining the consequences of the parameters and thresholds of the definition (e.g. size, particle number proportion, etc.) on the assessment and management of the health risks associated with nanomaterials;
- 3) in a second step (during the public consultation), determining the existence of measurement methods compatible with the European Commission's proposed definition and presenting the adaptations it considers necessary, particularly with regard to the health aspects. These insights will be detailed in the response to the public consultation.

The work of the first phase was the subject of a report published in February 2020¹. This scientific and technical support note brings together the main insights available in June 2021 and provided by ANSES to the parties behind the formal request to support them in their response to the European Commission (Annex 1), and a background analysis proposed by the Agency.

2. ORGANISATION OF THE WORK

In order to prepare, within a very tight timeframe, the scientific and technical information needed for drafting the French response to the public consultation launched by the European Commission, ANSES entrusted examination of this request to the Working Group on "Definition of nanomaterials". This WG was set up without a call for applications and reporting to the Expert Committee (CES) on "Assessment of the risks related to physical agents and new technologies".

This WG, which was set up on 27 May 2021, met four times² in order to produce a supporting document for the response to the public consultation, whose full text can be found in Annex 1. This work was presented to the CES on Physical Agents on 17 May 2021, then transmitted electronically and presented to the parties behind the formal request on 22 June 2021. ANSES also contributed to the public consultation on 25 June 2021 in its own name, based on the same work³.

The working group is currently continuing its work in order to examine the matter in greater depth and provide useful insights for the upcoming discussions in the next step of the European process to regulate nanomaterials. A report compiling all these elements will be published in 2022. In the meantime, and in view of the request from its supervisory ministries, the Agency

¹ "Review of analytical methods available for characterising nano-objects and their aggregates and agglomerates, in order to meet regulatory requirements", ANSES 2020 <https://www.anses.fr/fr/system/files/AP2018SA0168Ra.pdf>

² 27/05/2021, 31/05/2021, 16/06/2021 and 18/06/2021 by videoconference

³ <https://www.anses.fr/en/content/seeking-more-protective-european-definition-nanomaterials>

is providing a review of the working group's thoughts, together with its own background analysis, in this interim response.

3. ANALYSIS AND CONCLUSIONS

General points on changing usage and regulation of nanomaterials with regard to the health risks associated with their use

Engineered nanomaterials are used in a wide variety of everyday products (sunscreens, textiles, food, paints, etc.) and concern many industrial sectors such as construction, automotive, packaging, chemicals, the environment, agri-food, energy, cosmetics and health products. The large number of existing substances and the lack of knowledge on the characterisation of their hazards for both humans (toxicological effects) and the environment (ecotoxicological effects), or on the exposure associated with their use, constitute major difficulties in assessing the risks they pose to the environment and/or human health.

In this context, in accordance with Articles L. 523-1 to L. 523-8 of the French Environmental Code, pursuant to the Grenelle II Act of 12 July 2010, the mandatory declaration of manufactured, imported or distributed nanomaterials has been in place since 1 January 2013 in order to gain a better understanding of the nanomaterials on the French market, their volumes and their uses. This approach has been followed according to specific conditions in other countries such as Belgium, Norway, Sweden and Denmark. For its part, the European Union Observatory for Nanomaterials (EUON), launched by the EC after it had ruled out the idea of a European register, provides only limited information. At the European level, the EC has adopted specific declaration obligations for chemicals liable to contain nanomaterials. They have been in force since 1 January 2020 within the framework of the REACH Regulation on chemicals.

Eight years after its R-nano scheme came into force, the Agency assessed² the contribution of the data from mandatory reporting and formulated recommendations to improve the scheme's effectiveness with regard to the objectives defined when it was set up. Over this same period of around a decade, ANSES identified uneven developments in the information needed for understanding the risks associated with the presence of engineered nanomaterials in different fields of use:

- Significant developments in analytical methods for characterising the presence of nanomaterials;
- Very few and much-debated developments in hazard characterisation of substances in nanoparticle form. To ANSES's knowledge, it is still the only agency to have proposed a toxicity reference value for a chemical in nanoparticle form (ANSES opinion of 30 January 2019 for nanometric TiO₂ by the respiratory route); the Category 2 classification for carcinogenicity, proposed by ECHA's Risk Assessment Committee for this same respiratory route, has not been translated into a regulatory framework; on TiO₂ by ingestion, EFSA has updated its assessment of the risk of the use of the additive E171 in nano form, believing that it could no longer exclude genotoxicity concerns, after an analysis mainly of the academic literature;

² [ANSES Opinion and Report on the quality, use and sharing of data declared in the R-Nano register, 2020](#)

- Methodological work to clarify the specific characteristics of risk assessment methods when substances contain a fraction of engineered nanomaterials that cannot be neglected ([ANSES opinion on nanomaterials in food products](#), 2021), which continues to call for more toxicity data;
- Lastly, with regard to uses and exposure, the deployment of several national registers and the adoption of declaration requirements for the REACH Regulation mentioned above.

Regarding the change to the definition or a recommendation on a definition intended to replace that of 2011, **the Agency stresses that the current situation enables marketing stakeholders to avoid taking action with regard to the various regulatory obligations in terms of providing characterisation data, whether on the hazard or exposure:** this is the challenge that a new proposed definition will have to address, with regard to the control of health or environmental risks.

Points prepared by the working group based on the response to the European consultation on the recommendation on the definition

The note sent to the ministries in June 2021 to support their response to the public consultation is reproduced in full in Annex 1. The main findings of this work and the points warranting attention raised by the working group are reiterated here:

- Most of the modifications proposed lead to exclude objects by reducing the scope of the definition without clear explanation nor risk assessment justification (coarse particles, micelles, single molecule, fullerenes).
- The definition must constitute a common base to rely on and must be based only on clearly defined physico-chemical parameters. Following this definition, sectoral regulation could specify the criteria of interest, and of management (declaration, additional data requirement, etc.).
- Besides the logical application of this definition within REACH, the link with other regulations dealing with specific substances (PPP, BP, cosmetics ...) needs to be clearly assessed. This definition needs to be established as the basis for any other regulation with sectorial adaptation when needed as REACH is managing these substances when not specifically covered by sectorial applications (article treated and managed in BPR, additives in PPP, etc.). There is a lack of clarity on the adaptation of this definition to sectorial regulation, and how harmonisation will be performed. Materials identified as nanomaterials need to keep this status even in downstream regulations.
- The issue of the particle number threshold is very important and must be lowered for an effective risk assessment for human and environmental health purpose. This is directly linked to the principle of precaution set out in REACH regulation. Different groups of experts expressed recommendations in this direction (decreasing the threshold, mixing thresholds differentiated by dimension intervals, etc.)
- The nanoscale (1-100 nm) is not open to discussion in the public consultation, although very much awaited. Different groups of experts expressed recommendations in this direction.
- The implicit exclusion of very large but thin (1-100 nm) platelets is not appropriate: The proposed revision of the definition should address the entire particle size distribution

and not only a pre-filtered fraction of it to avoid unacceptable biases. Exclusion of very large but thin (1-100 nm) objects would exclude many 2D materials from the definition.

- The metrological criteria must not appear in the definition since they evolve at a faster pace than (pre)regulatory aspects. However, availability and cost are important issues to consider for the implementation of the revised recommendation.
- The definition explicitly relies on technical guidelines. They must not appear directly in the text of the definition. In annexes or in notes, these TG or reference documents (ISO, JRC, etc.) must be clearly detailed with exact reference and wording, possibly with additional explicative notes.
- A more detailed explanation of the terms used in this definition should be provided as many inconsistencies in interpretations and lack of clarity remain, especially with the new terms proposed during this public consultation (solid, identifiable constituents, single molecules ...).
- Many points for which we are consulted are linked to related points and should not be considered separately.

Insights for an overall approach to the risks, developed by the Agency

In light of the analysis of the declaration scheme set up in France under the Grenelle acts for the environment, different recommendations have been made to improve this scheme and ensure it more fully meets the objectives set by these texts in terms of traceability, information and risk assessment. The completeness and quality of the data collected today are still insufficient to allow their full exploitation in quantitative studies, to assess exposure of the public, workers or the environment to substances containing nanomaterials, or to dynamically feed into an interconnected national environmental health data scheme, as defined in the objectives of the PNSE4.

In addition, the Agency draws attention to the fact that progress is needed on understanding the risks of nanomaterials, by pushing stakeholders to improve all the components that contribute to its assessment:

- An updated regulatory framework, which underlines the importance of revising the proposed definition dating from 2011: ANSES believes it essential to create such a definition, integrating health and safety issues and cutting across all the different sectors of use, and submit it to prior consultation, in line with the new European situation with regard to chemicals (Green Deal, Chemicals Strategy for Sustainability);
- Precise characterisation of the nanomaterials used; its analytical feasibility is now clearly established and the costs may require clear identification of the actors responsible for establishing it, the reporting requirements and the methods for communicating the results;
- More explicit requirements for the data to be produced by economic actors on the hazards of these substances for both humans and the environment;

- Appropriate assessment methodologies that can, where relevant, take account of nanomaterials found in products or released into the environment, including identifying situations where such assessments are not required.

Indeed, it is only if progress is made on all the aspects that contribute to risk assessment that the efforts made by the various risk governance stakeholders will be fully effective in terms of information and protection of humans and the environment.

Dr Roger Genet

ANNEX 1: ELEMENTS PROVIDED TO THE MINISTRIES IN RESPONSE TO THE EUROPEAN COMMISSION'S PUBLIC CONSULTATION ON THE DEFINITION OF NANOMATERIALS

Response to the European Commission's public consultation on the definition of nanomaterial

ANSES's proposed response

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To help with its response to Request No 2018-SA-0168 entitled "Request for support in preparing a proposal for an updated definition of the term 'nanomaterial' based on Recommendation 2011/696/EU on the definition of nanomaterial", ANSES called on a multidisciplinary working group of 10 experts that was appointed on 27 May 2021.

This document follows the same format as the response form for the public consultation organised by the European Commission. Each question is followed by:

- a summary of the main reasons behind the response to the Commission's question;
- the proposed formal response to the question.

Formal responses are either presented as form items to be ticked or written text.

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., 2 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.

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.

PART 1. GENERAL OBSERVATIONS

QUESTION 1 (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.

OPTION 1 : Nanomaterials are materials/chemicals like any other and do not require special legislation or special provisions.

OPTION 2 : 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.

OPTION 3 : 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.

OPTION 4 : Triggering specific provisions does not require a common definition for this subgroup of materials between sectors; triggers should be tailored to each individual situation.

OPTION 5 : A common definition of nanomaterial used across legislation and sectors increases efficiency and consistency of implementation.

None of the above.

I have no view.

❖ Main reasons behind the response provided

Option 1 corresponds to the position that has long been adopted in the context of REACH and that is supported by most of the industrial companies concerned. When the Regulation was adopted in 2006, the idea of adopting specific standards for nanoparticles and nanomaterials was considered and rejected. This cannot be France's position under any circumstances, in view of the provisions of the *Grenelle* acts for the environment.

Option 2 seems to be the one that the Commission has long defended – and continues to defend today – for legal reasons: adopting a specific regulation for nanomaterials would be highly complicated (since it would be necessary to consider all their applications) and certainly counterproductive (because it would generate a movement towards technical specialisation of texts based on raw materials where the choice has rather been made to manage this issue through a broad common text (REACH) relayed through sector-specific policies and regulations (for cosmetics, food, biocides, etc.)). The two communications published by the Commission on the regulatory review on nanomaterials support this view, indicating that its policy does not appear to have changed in this respect.

By elimination, these first two options are not desirable because from a strictly health perspective, as soon as specificities distinguish nanomaterials from classical chemical substances, it becomes necessary to consider them differently from these substances and call for an adaptation of the regulations concerning them.

Option 4 (tailoring to each individual situation without any common definition) is rather ambiguous about the precise functioning proposed. The case-by-case approach may appear attractive from a health perspective (regulatory adaptation to each situation), but firstly it does not seem compatible with the current regulatory system (REACH in particular), which would require a complete overhaul, and secondly this way of functioning would not allow binding decisions to be taken quickly. Moreover, this option would lead to a substantially higher workload and cost for assessing authorities and agencies, by decreasing their ability to process dossiers, thereby leading to a potential risk to human health and the environment through a lack of data assessment.

Combining Option 5 (a common definition for the different application sectors) with Option 3 (standalone regulation of nanomaterials) seems to be the best choice, by default, provided that its implementation is made explicit (ascertaining that the definitions developed are in line with the regulatory objectives and the targeted use cases): for this, the ANSES working group suggests an approach aimed at having a broad definition of nanomaterials (based solely on physico-chemical parameters), on which sector-specific regulations (cosmetics, food, etc.) would be based, while allowing the management of nanomaterials to be adapted to sectoral specificities (intervention of relevance criteria such as, for example, consideration of the solubility of nanomaterials in the field of cosmetics, to determine whether or not specific regulatory requirements are needed).

With this in mind, the harmonised definition should be considered as the common foundation (across all application sectors) for objects regarded as nanomaterials, because they have potentially different properties conferred by their dimensions. In this context, such a definition should have a regulatory (not only technical) scope that overrides sector-specific regulations and is therefore directly applicable in REACH, and to which the sector-specific regulations must refer (a definition to which management rules specific to these sectors would apply).

This definition should at least define the scope within which toxicological and ecotoxicological issues arise so that potentially problematic cases are systematically examined.

It should be noted that there is considerable controversy about whether the term "nanomaterial" should be defined or not at all. This topic will be addressed in the second part of the expert appraisal.

❖ Proposed response to the European Commission's public consultation

	Working Group
Option 1	
Option 2	
Option 3	X
Option 4	
Option 5	X
None of the above	
I have no view	

QUESTION 2 (CONSISTENCY OF NANOMATERIAL DEFINITION IN REGULATORY CONTEXT - A)

Which of the answers below corresponds best with your position regarding the (harmonized) approach to nanomaterials in EU regulation? at least 1 choice(s)

OPTION 1 : A directly applicable and legally binding EU definition in place of the Recommendation would increase efficiency and consistency of implementation across sectors.

OPTION 2 : 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.

OPTION 3 : The present approach is adequate.

OPTION 4 : 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.

❖ Main reasons behind the response provided

The current approach cannot be considered adequate (Option 3): the multiplicity of definitions without any defined hierarchy undermines legal certainty in the interpretation of texts.

It is not currently used to compile or assess dossiers.

Option 2 is the same, except that it suggests only a token change that cannot be regarded as satisfactory.

The purpose of the proposed harmonisation is rather unclear (harmonisation of the definition or of the management rules?). It is not an end in itself: it is rather a question of making the European texts work well so that they can cover (and provide relevant management rules for) problematic substances.

Along the lines of the WG's proposal presented above, Option 1 could be interesting provided that the definition is sufficiently flexible or broad, to ensure that problematic substances are not excluded. Nevertheless, the question is poorly formulated since the preamble to the consultation states from the outset its intention not to intervene in sectors where nanomaterials are already specifically regulated (pharmaceuticals, cosmetics, food, etc.). In order to answer positively, it should be possible to remove these sectoral definitions (a scenario that is not really being considered in principle).

❖ Proposed response to the European Commission's public consultation

	Working Group
Option 1	X
Option 2	
Option 3	
Option 4	
None of the above	
I have no view	

QUESTION 3 (CONSISTENCY OF NANOMATERIAL DEFINITION IN REGULATORY CONTEXT – B)

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?

Reminder of points (a) to (d):

- 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. ...
- 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....

❖ **Main reasons behind the response provided**

While (b) to (d) seem acceptable, the first statement does not seem correct as it stands. The ambiguities of the definition have been discussed in an extensive body of literature (JRC reports, etc.), leading to different interpretations in different European regulations. Major points such as the value of thresholds are the subject of disagreement and complex discussions, hence this long overdue revision. All in all, this definition has rarely been used in practice, and particularly in France it has mostly been used as a basis for the definition used in the mandatory declaration.

Concerning point (b), it should be stressed that the lack of clarity is certainly one of the reasons – but not the only one – for the limited use of the definition. The preference for a case-by-case approach, which avoids overly disrupting the regulatory categories and provides time for analysis (but at the risk of always delaying binding decisions), plays a central role.

Point (c) is the only one that is acceptable without discussion.

Point (d) underlines the fact that the definition should include a certain degree of flexibility and be clear on the objectives: the definition designates the substances or objects that are potentially of interest and that should therefore be looked at more closely (the Commission has always been reluctant to make this explicit, preferring to say that the definition was only "technical" and independent of any regulatory consideration, which moreover could be considered contradictory with the possibility of adapting the threshold).

❖ **Proposed response to the European Commission's public consultation**

	Working Group
Fully disagree	
Mostly disagree	
Mostly agree	X
Fully agree	
Don't know / No opinion	

Please substantiate your answers (1000 character(s) maximum)

Conclusion (a) is not valid as proposed but some agreement can be found with conclusions (b) to (d). The definition recommended in 2011 is not adapted to the various scopes of regulatory issues that we are facing. Many reports (including JRC's reports) underline the limits and ambiguities of this definition, leading to various interpretations in many application sectors. Major points such as the threshold are still debated, and are a source of disagreements between stakeholders, hence the importance of revising this definition. The current recommendation has rarely been applied as it is, mainly due to the fact that the definition is not legally binding.

QUESTION 4 (CONSISTENCY OF NANOMATERIAL DEFINITION IN REGULATORY CONTEXT – C)

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

❖ **Proposed response to the European Commission's public consultation**

	Working Group
Fully disagree	
Mostly disagree	X
Mostly agree	
Fully agree	
Don't know / No opinion	

Please substantiate your answers (1000 character(s) maximum)

Many important details regarding the regulatory context in which this definition would operate, are not addressed or remain unclear despite of their relevance.

Technically, the thresholds defining the nanoscale (currently 1-100 nm) were expected to be discussed. Within the proposed definition in 2011, the inclusion or exclusion of nanostructured materials was clearly indicated as a point of revision and is not explicitly addressed there. Many terms suggested to be included in the definition are ambiguous and lead to the exclusion of objects that are nanomaterials according other mainstream definitions (e.g. ISO).

The process and format of this consultation significantly restrict the scope of the consultation (short consultation period, narrow formulation of questions,...). The overall objective of the future definition remains unclear.

PART 2. REVISION CONSIDERATIONS (INDIVIDUAL TECHNICAL ELEMENTS)

QUESTION 5 (E1 WORDING : CONTAINING / CONSISTING OF)

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?

❖ Main reasons behind the response provided

One of the main points highlighted by the working group is that introducing the term "consisting of" could clarify that we are talking about the substance at the nanoscale and not a product containing it as an ingredient (i.e. differentiating a nanoscale ingredient from a sunscreen product containing it). In general, the target object should be the ingredient and not what it is incorporated into (e.g. a finished product or a mixture such as a sunscreen is not a nanomaterial).

The WG however noted several points that warrant attention:

- this change seems to result in a more restrictive definition and could therefore exclude certain objects (e.g. nano-objects grafted onto larger objects). If it excludes hybrid materials (e.g. core-shell or other nanocomposites such as candurin for which the nano aspect of TiO_2 could be ignored) in practice, then it is not desirable;
- the very term "consisting" seems to introduce the idea of intentionality. This idea is a source of multiple interpretations because it depends on an assessment by stakeholders, whoever they may be. Certainty is one of the qualities expected from the drafting of a legal text, in the sense that it must produce effects that everyone can foresee in advance so that they can refer to it appropriately;
- the working group stresses that this change should in no way exclude unintentionally created materials; intentionally or unintentionally created materials still seem to be present in the introduction of the definition.

❖ Proposed response to the European Commission's public consultation

	Working Group
Fully disagree	
Mostly disagree	X
Mostly agree	
Fully agree	
Don't know / No opinion	

QUESTION 6 (E2 PARTICLE - CHANGE 1 : SOLID)

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 nonsolid objects does not prevent the use of external size as the defining property.

Do you agree with the restriction to solid particles only?

❖ Main reasons behind the response provided

Introducing the term "solid" has the effect of excluding certain "objects" (micelles, emulsions, etc.). These objects are increasingly being developed in several sectors.

From a health perspective, some of them are used as micellar nanovectors for medical applications and clearly have an increased ability to cross certain biological barriers, particularly cell barriers. For this reason in particular, they should not be excluded. If solely the dimensional criterion is adopted to define nanomaterials, there is no reason to exclude them at this level.

The purpose of this change, explicitly designed to exclude micelles, emulsions, etc., is not justified. Why should these objects be excluded?

Lastly, from a semantic perspective, introducing the adjective "solid" does not provide any clarification because its meaning at the nanoscale is a matter of debate depending on the disciplinary fields. More consensual criteria should be provided (at the very least refer to technical guides in the definition). Consequently, in practice, as it stands, this change would not enable the objects concerned (mainly micelles) to be excluded, and therefore does not meet the EC's stated objective.

❖ Proposed response to the European Commission's public consultation

	Working Group
Fully disagree	X
Mostly disagree	
Mostly agree	
Fully agree	
Don't know / No opinion	

QUESTION 7 (E2 PARTICLE - CHANGE 2 : UNBOUND)

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'?

❖ **Main reasons behind the response provided**

The entire working group agrees that this change clarifies matters and avoids discussions on bound and unbound states, which were very difficult to objectively determine.

❖ **Proposed response to the European Commission's public consultation**

	Working Group
Fully disagree	
Mostly disagree	
Mostly agree	
Fully agree	X
Don't know / No opinion	

QUESTION 8 (E2 PARTICLE - CHANGE 2 : IDENTIFIABLE CONSTITUENT PARTICLES)

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

❖ Main reasons behind the response provided

The working group underlines that this is ultimately a metrological exclusion criterion and points out that metrological criteria should not be used at this stage in a definition, as it should not be the difficulty in characterisation that guides a definition.

Legally, this change would clearly open up the possibility of excluding what cannot be identified.

Moreover, the term "identifiable" is vague and raises several questions:

- if the object is not identified, will it therefore be considered unidentifiable? if so, this will not encourage characterisation but will rather limit it to the obvious;
- are micelles and nano-objects vectored in micelles "identifiable"?

Determination of this criterion is highly dependent on the analytical techniques used to identify the objects (depending on the analytical techniques and methods, it may or may not be possible to distinguish these objects). This raises the underlying question of the metrological method used to answer it. Therefore, if this term were to be retained, it seems necessary to accompany it with details of the analytical methods used to identify these objects (technical guidelines clearly referred to in the definition), as recalled in the general comments at the end of the form.

❖ Proposed response to the European Commission's public consultation

	Working Group
Fully disagree	X
Mostly disagree	
Mostly agree	
Fully agree	
Don't know / No opinion	

QUESTION 9 (E2 PARTICLE - CHANGE 3 : 100 MICRON PLATELETS)

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?

❖ Main reasons behind the response provided

For the working group, this proposal corresponds to the search for a technical simplification that should not appear in a definition.

This change would result in certain objects being excluded and this exclusion is not justified: sheet-like objects are indeed nanomaterials as long as their thickness falls within the range considered. Many 2D nanomaterials are beginning to find new applications (MoS₂, h-BN, graphene and derivatives, etc.). What is the logic behind distinguishing a part of a material rather than considering it as a whole?

From a health perspective, there is no reason to exclude them (in ecotoxicology, such 2D objects can be considered as vectors).

There is also no scientific basis for the proposed threshold of 100 microns.

If this change were to be maintained, the question arises as to the feasibility of excluding the targeted particles: how can this be achieved in practice? Making the distinction is possible with some tools but not with others. Otherwise, it would be necessary to filter the measurements beforehand, but with results that are not guaranteed. This metrological subject should be clarified in an *ad hoc* technical guideline.

Consequences of this change: depending on how the particle size distribution is determined, this will have the effect of decreasing the percentage of objects regarded as nanomaterials (by eliminating the largest particles) or conversely increasing it (if these objects are indeed considered to be nano-objects due to their thickness being between 1 and 100 nm, as determined by electron microscopy).

❖ Proposed response to the European Commission's public consultation

	Working Group
Fully disagree	X
Mostly disagree	
Mostly agree	
Fully agree	
Don't know / No opinion	

QUESTION 10 (E2 PARTICLE - CHANGE 3 : PLATELETS CLASSIFICATION)

As you do not fully agree please provide further clarification below. Choose one or more answers. (between 1 and 5 choices)

Option 1 The implicit exclusion of very large but thin (1-100 nm) platelets is not appropriate

Option 2 An upper limit is useful but the proposed value or constraint regarding at least two orthogonal dimensions is not appropriate.

Option 3 The upper limit should apply only to specific types of particles.

Option 4 The definition should explicitly allow flexibility in whether particles larger than the upper limit are included or excluded in the tally.

Other

❖ **Main reasons behind the response provided**

As stated above, it is not desirable for platelets corresponding to the definition of nanomaterials to be rendered “invisible”. Option 1 therefore seems preferable.

❖ **Proposed response to the European Commission's public consultation**

	Working Group
Option 1	X
Option 2	
Option 3	
Option 4	
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 proposed revision of the definition should address the entire particle size distribution and not only a pre-filtered fraction of it to avoid unacceptable biases. Exclusion of very large but thin (1-100 nm) objects would exclude many 2D materials from the definition.

QUESTION 11 (E2 PARTICLE - CHANGE 4 : SINGLE MOLECULES)

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?

❖ Main reasons behind the response provided

Adding the term "single molecule", which is supposed to clarify understanding, is described by the Commission itself as "open to interpretation". This being contradictory, this addition seems unnecessary.

Differences in interpretation of the term "single molecule" are to be expected by stakeholders. For example, logically, nanoplastics should not be excluded from the scope of the definition, as they are composed of polymers and additives. However, viewed solely from the perspective of the polymer, some might consider these nanoplastics to be outside the scope of the definition. Another example is amorphous silicas, in which the Si atoms are all covalently bonded via oxygen atoms. In this case, should silica be considered as a molecule?

This change excludes certain objects from the scope of the definition and is related to question 6. While this was initially motivated by the desire to exclude natural macromolecules (e.g. proteins, which some WG members pointed out were of little interest in the scope of the definition of nanomaterials), this change could also lead to the exclusion of other nanomaterials (several of which would be of interest):

- possibly (see previous paragraph) nanoplastics (the interaction with the plan to restrict micro- and nanoplastics should be studied);
- other polymers, in particular those of natural origin and transformed for specific applications (e.g. celluloses, starches, lactates, etc.), which are the focus of research and industrial applications;
- fullerenes, certainly;
- nanomicelles and lipid structures used as vectors (also extensive research and applications). In the case of substances vectored in this way, the question arises as to the relevance of the impact of the vector itself on living organisms.

As mentioned in question 6 on the introduction of the term "solid", there is no evidence to justify the exclusion of these objects. If the dimensional criterion is indeed adopted to define nanomaterials, there is no reason to exclude these objects at this level.

❖ Proposed response to the European Commission's public consultation

	Working Group
Fully disagree	
Mostly disagree	X
Mostly agree	
Fully agree	
Don't know / No opinion	

QUESTION 12 (E2 PARTICLE - CHANGE 5 : CARBON BASED NM EXCEPTION)

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.

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:

Option 1 No need for any additional inclusion of materials through criteria or specific derogation

Option 2 Maintain current derogation

Option 3 Update the derogation list

Option 4 Partially agree with the replacement of derogation but conditions need to be modified

Option 5 Agree with the replacement of derogation with the inclusion of fibre- and plate-like materials as proposed

None of the proposed or no opinion

❖ **Main reasons behind the response provided**

Option 5 extends the scope of the definition to similar existing or future materials. However, it excludes the iconic C₆₀ fullerene. From C₇₀ onwards, fullerenes no longer necessarily have a completely spherical shape and may have a form factor (length/diameter) > 1, but should it then be necessary to say precisely from which form factor a nanomaterial is considered to be "elongated"? Even if these objects are quite rarely encountered, some applications do already exist and it is quite possible that they could be developed in the near or distant future. From a health perspective, there is no justification for their exclusion.

The working group stresses that not a lot is missing from this proposal (Option 5) for it to be satisfactory. However, the change should not exclude fullerenes.

In this sense, the WG proposes retaining this Option 5 but supplementing it with a non-restrictive list (modified Option 3), which would ensure and reinforce the consideration of notable exceptions (fullerenes, etc.).

❖ **Proposed response to the European Commission's public consultation**

	Working Group
Option 1	
Option 2	
Option 3	
Option 4	
Option 5	
None of the proposed or no opinion	X

If you prefer to keep the derogation in form of list of specific materials, please provide the list: (1000 character(s) maximum)

(no response provided)

If you agree with the replacement of the list, using the additional conditions for constituent particles, please individually comment conditions to include plate-like and fibre-like particles as presented above, or add your own:

(1000 character(s) maximum)

Additional suggested specifications should be included in the definition along with a non-exhaustive derogation list that includes materials such as fullerenes. Besides not excluding known relevant materials as fullerenes, this solution clarifies the situation regarding flagship plate-like and fibre-like particles (already present in this list) and also extends the definition to similar materials, which already exist or will be developed in the future.

QUESTION 13 (E2 PARTICLE - CHANGE 5 : CARBON BASED NM EXCEPTION)

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

❖ **Main reasons behind the response provided**

- Ambiguity/interpretations: changes that introduce ambiguous terms and/or open the door to various interpretations that should, if retained, explicitly call for technical guidelines (JRC document?) in order to precisely characterise these criteria;
- Unjustified/unjustifiable exclusion criteria: changes introduce exclusion criteria implicitly based on hazard/risk assessments, which should not play a part at this level, used to exclude certain types of materials, some of which are nevertheless of interest;
- Marginal clarifications: a few changes (mainly the removal of terms) that help clarify the definition;
- Change options that could usefully extend the scope of the definition in the context of a broader basic definition, established on dimensional criteria, for sectorally differentiated applications (e.g. the concept of insoluble nanomaterials for a sector).
- Changes to the definition that should necessarily be thought through and decided in light of the exact regulatory context in which the definition is set (see below).

❖ **Proposed response to the European Commission's public consultation**

	Working Group
Fully disagree	
Mostly disagree	X
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)

Ill-defined terms are used (mainly: solid, identifiable constituent and single molecule), leading to confusion and misinterpretation.

Only dimensional criteria (not solid state, single molecule, etc.) must be used. Additional criteria (and motivation) are not clearly defined. There is no obvious scientific argument supporting exclusion of NM for some categories, leading to exclude some relevant NMs (polymer, nanoplastics, fullerenes, etc.). Moreover, a natural origin does not ensure safety (e.g. toxins)!

The ability to identify or not an object is a metrological criterion and should not be used to legally exclude a NM with various components. This raises objectivity, energy and

willingness questions in terms of characterization. Is a non-identified object considered unidentifiable?

The definition should address the whole particle size distribution and not a pre-filtered fraction to avoid unacceptable biases.

QUESTION 14 (E3 : SIZE DISTRIBUTION THRESHOLD FLEXIBILITY)

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?

❖ Main reasons behind the response provided

This question is closely linked to that of the threshold value and the answers given cannot be viewed in isolation (options: keep the threshold at 50% provided that the possibility of lowering the threshold is authorised, option of a very low fixed threshold, no threshold, etc.).

It should be noted that determining the methods for characterising particle size distribution used to verify this inclusion/exclusion criterion for a material is particularly crucial.

- Concerning the flexibility of the threshold:
 - The flexibility option is not widely used in practice;
 - It is often seen as an obstacle to harmonising the definition;
 - It avoids arbitrarily setting a threshold intended to be applicable to any chemical substance and covers differences between application sectors (no mixture threshold for the Novel Food Regulation, for example).

- Specifically concerning the threshold value considered:
 - The 50% threshold has no justification or absolute scientific validity;
 - Several studies show that this 50% threshold is too high for health criteria. For example, the Scenihr proposed much lower threshold;
 - On this basis, it appears necessary to lower the value of this threshold.

This particularly complex issue raises the more general question of the precise utility of the definition, and calls for a clear explanation of the idea of harmonisation being discussed. To this end, the working group believes it necessary to have a basic definition, a common core for all the regulations concerned, but one that can allow for differentiated management by sector in light of their respective specificities.

This definition should be understood as a means of identifying materials that warrant special attention on the basis of a dimensional criterion alone. It is then up to the sector-specific regulations to stipulate the nanomaterials of interest among these and determine the necessary risk management actions.

In a highly sectorised regulatory environment, each sector-specific regulation could then build on this definition and adapt the criteria for identification (determining which nanomaterials warrant special attention in that sector) and management (declaration, additional data required for authorisation, etc.) to the specificities of the sector.

With this in mind, the working group proposes:

- Setting a low threshold, establishing a common scope for all regulations, which would encompass all the materials requiring particular attention (with regard to the "nano" problem) by the legislator when drafting the regulatory texts relating to management;
- The issue of flexibility should then come into play in determining how to target nanomaterials that will be subject to sector-specific regulatory constraints. It is therefore up to the legislator to stipulate for each sector which nanomaterials, among those falling within the scope of the definition, should be subject to management measures, taking the particularities of each sector into account (possibility of considering higher threshold values if it can be demonstrated that there is no risk below the chosen threshold, reversal of the burden of proof).

The WG is aware that a low threshold leads to a significant increase in the number of cases in which questions might arise. Questions on the unintentional generation of nanomaterials through wear/friction between non-nano particles have not been ignored. Similarly, the technical difficulties (impossibility) of demonstrating the complete absence of a nanomaterial in a material are well known. However, these disadvantages still seem minor compared to the disadvantages of in principle excluding too many substances from the scope of the definition.

❖ Proposed response to the European Commission's public consultation

	Working Group
Fully disagree	
Mostly disagree	X
Mostly agree	
Fully agree	
Don't know / No opinion	

QUESTION 15 (E3 : SIZE DISTRIBUTION THRESHOLD)

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

❖ **Main reasons behind the response provided**

See previous paragraph.

❖ **Proposed response to the European Commission's public consultation**

	Working Group
Fully disagree	X
Mostly disagree	
Mostly agree	
Fully agree	
Don't know / No opinion	

You may substantiate your answer. (1000 character(s) maximum)

No scientific based justification supporting a unique threshold value fitting all existing substances can be found. Many reports underline that current value of 50% is too high for risk management purposes. For instance, many organizations such as Scenihir have suggested very low values to cope with these objectives. Then, lowering this value appears necessary. Flexibility of this threshold should only take place for determining which nanomaterials should be subjected to regulatory conditions into sector specific regulations.

QUESTION 16 (E4 VSSA – CHANGE 1: INCLUSION CRITERION)

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.

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.

❖ **Main reasons behind the response provided**

- An additional confusing criterion: the volume-specific surface area (VSSA) criterion is added to the dimensional one. In practice, this can lead to contradictory results (if the results differ according to these two criteria), and therefore potentially to confusion;
- Meaning of this criterion in the definition: this VSSA criterion can be interpreted in two ways:
 - A simple proxy: it is often considered a proxy for the dimensional criteria discussed above (i.e. a practical indirect approach enabling the dimensional criterion to be verified);
 - Nanostructured objects: it could however also be a way to include nanostructured objects (objects that do not correspond to NOAAs but have a nanostructure on the surface or internally) in the scope of the definition of nanomaterials. It should be stressed that the question of whether or not these nanostructured objects should be included in the nanomaterials category is not clarified;

Regardless of the meaning, this criterion does not seem very appropriate here. Firstly, it is not desirable to include such a measurand, which refers to specific techniques for such measurements, in a definition, and secondly, the threshold value considered in the VSSA requires adjustments and cannot therefore be set to meet the objectives (see below);

- Threshold value: the threshold value is precisely calculated from two thresholds (dimensional: 100 nm and mixture: 50%) for non-porous spherical objects. This value should therefore be reviewed according to the thresholds that will be considered but also adjusted to the morphology of the objects studied (NanoDefine results);

- **Operability:** the various sources (NanoDefine in particular and very recently Claire Dazon's thesis³) indicate that although this criterion can be useful for screening (rapid review), there are problems associated with its implementation and the methods used to characterise it:
 - Difficulties in implementation: the density of materials (especially porous ones), which is a key factor in this type of measurement (see review of methods), is not easy to obtain or determine. These measurements are not feasible for all materials;
 - The existence of false positives and false negatives, even when performed correctly, especially in the case of powders with high polydispersity or strong particle aggregation (Wohlleben *et al.* for the NanoDefine work).

Nevertheless, considering that:

- measurement of specific surface area is a particularly useful screening tool;
- in general, the nanoscale state of a material should be determined by comparing different analytical methods (and therefore the VSSA cannot be regarded as an exclusive criterion, i.e. materials that do not fulfil this single criterion cannot be excluded from the scope of nanomaterials on the basis of this single result);

the WG believes that this measurand, together with the analytical techniques and methods for measuring it, should necessarily be included in the JRC technical guidelines that will accompany the definition.

❖ **Proposed response to the European Commission's public consultation**

	Working Group
Fully disagree	
Mostly disagree	
Mostly agree	
Fully agree	X
Don't know / No opinion	

³ "Occupational exposure to nanomaterials during powder handling: relationships between physical-chemical properties, and characteristics of released aerosols" defended on 31/1/2019

QUESTION 17 (E4 VSSA – CHANGE 1: EXCLUSION CRITERION)

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?

❖ Main reasons behind the response provided

For the same reasons as given in the previous paragraph, this change is not considered useful or relevant.

❖ Proposed response to the European Commission's public consultation

	Working Group
Fully disagree	X
Mostly disagree	
Mostly agree	
Fully agree	
Don't know / No opinion	

You may substantiate your answer. (1000 character(s) maximum)

VSSA is used as proxy for 1-100 nm dimensional criterion. Unfortunately, there is no non-controversial conversion chart between these two metrics available. Therefore the relevance of discussing of specific thresholds of a problematic metric appears as questionable (existence of known exceptions).

FREE TEXT TO COMPLETE QUESTIONNAIRE

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?

(4 000 car. Max)

- Most of the modifications proposed lead to exclude objects by reducing the scope of the definition without clear explanation nor risk assessment justification (coarse particles, micelles, single molecule, fullerenes).
- The definition must constitute a common base to rely on and must be based only on clearly defined physico-chemical parameters. Following this definition, sectoral regulation could specify the criteria of interest, and of management (declaration, additional data requirement, etc.).
- Besides the logical application of this definition within REACH, the link with other regulations dealing with specific substances (PPP, BP, cosmetics ...) needs to be clearly assessed. This definition needs to be established as the basis for any other regulation with sectorial adaptation when needed as REACH is managing these substances when not specifically covered by sectorial applications (article treated and managed in BPR, additives in PPP, ...). There is a lack of clarity on the adaptation of this definition to sectorial regulation, and how harmonisation will be performed. Materials identified as nanomaterials need to keep this status even in downstream regulations.
- The issue of the particle number threshold is very important and must be lowered for an effective risk assessment for human and environmental health purpose. This is directly linked to the principle of precaution set out in REACH regulation. Different groups of experts expressed recommendations in this direction (decreasing the threshold, mixing thresholds differentiated by dimension intervals, etc.)
- The nanoscale (1-100 nm) is not open to discussion in the public consultation, although very much awaited. Different groups of experts expressed recommendations in this direction.
- The implicit exclusion of very large but thin (1-100 nm) platelets is not appropriate: The proposed revision of the definition should address the entire particle size distribution and not only a pre-filtered fraction of it to avoid unacceptable biases. Exclusion of very large but thin (1-100 nm) objects would exclude many 2D materials from the definition.
- The metrological criteria must not appear in the definition since they evolve at a faster pace than (pre)regulatory aspects. However, availability and cost are important issues to consider for the implementation of the revised recommendation.
- The definition explicitly relies on technical guidelines. They must not appear directly in the text of the definition. In annexes or in notes, these TG or reference documents (ISO, JRC, etc.) must be clearly detailed with exact reference and wording, possibly with additional explicative notes.
- A more detailed explanation of the terms used in this definition should be provided as many inconsistencies in interpretations and lack of clarity remain, especially with the new terms proposed during this public consultation (solid, identifiable constituents, single molecules ...).
- Many points for which we are consulted are linked to related points and should not be considered separately.