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COMMISSION STAFF WORKING DOCUMENT

Review of the Commission Recommendation 2011/696/EU on the definition of nanomaterial

Accompanying the document

Commission Recommendation

on the definition of nanomaterial

{C(2022) 3689 final}

Executive summary

Regulatory context, Recommendation 2011/696/EU

In 2011, the European Commission published Recommendation 2011/696/EU on the definition of nanomaterial. The publication of this Recommendation reflected the increased societal concerns and the resulting regulatory attention for a growing class of materials with one particular common aspect, having structural features at a very small, 'nanoscale' size.

The 2011/696/EU definition (commonly referred to also as EU nanomaterial definition, or the EU definition, though strictly speaking should better be labelled as 'EC definition' for European Commission, notation used in this document) was not the first nanomaterial definition. A number of different nanomaterial definitions had been developed or were being developed in parallel. The EC definition aligned itself with the emerging consensus that the size range relevant for nanomaterials, and nanotechnology in general, was the range between 1 nm and 100 nm. However, the EC definition was (one of) the first definition(s) to include a threshold value, limiting itself to particulate materials of which a sufficiently important fraction of the particles has a size in the nanoscale range. This threshold value was needed to meet the explicit intention to make the definition enforceable in the regulatory sense.

Given the many developments in the nanotechnology area, the Commission indicated in its 2011 Recommendation its intention to review the definition in 2014. This review was initiated in 2013. This staff working document summarises the substantial efforts spent on the review process, as well as the outcome of the resulting revision.

Steps in the review process (reports, consultation) and parallel developments

The initial phase of the review process included a targeted stakeholder consultation and a stakeholders' workshop. The Commission's Joint Research Centre (JRC) performed the consultation, analysed the outcome, combined that with its own experiences in the domain and findings published in literature, and documented this in three JRC reports. In 2015, the last JRC report in this series presented a number of options for changes, addressing the main issues in the 2011 EC definition that were identified by users.

Parallel to the review efforts, the use of the 2011 EC definition expanded. It was taken up in several pieces of EU legislation including REACH and inspired other definitions (regulatory and other). To enable its regulatory implementation, particle size analysis methods were improved and validated, and guidance was prepared by the JRC and the NanoDefine research project. On the one hand, the increased use of the 2011 EC definition provided it with broad acceptability allowing to draw conclusions on its utility and 'fitness for purpose'. On the other hand, an increasing volume of measurements and data also confirmed some of the weaker points, mainly on clarity of certain terms and on the measurability for certain groups of materials. These weaker points and the prospects of its potential review slowed down further uptake in other pieces of legislation.

Based on the initial JRC findings, as well as on a growing and ever more solid evidence base, the Commission services prepared proposals for a series of minor amendments to the 2011 EC definition. These changes were subjected to a targeted stakeholder consultation in the second quarter of 2021. The entire set of received comments was published in August 2021 on the review website of DG ENV. A detailed analysis of the feedback is presented in Annex 1 to this staff working document. Some of the proposed changes were contested by particular stakeholder groups, but most of them were supported by a majority of the stakeholders. All comments were individually analysed. Summary responses to the observations, with indications where they resulted in the change of the proposal, are presented next to statistical analysis of answers to structured questions.

Elements of the definition – rationale and changes, guidance

This staff working document accompanies the revised Commission Recommendation on the definition of nanomaterial. The revised definition remains focused on particulate materials and based on the fraction of particles in the 1 nm to 100 nm nanoscale range in the number-based particle size distribution. The following are the main differences compared to the 2011 definition:

- The term 'contains' is replaced by 'consists of', to emphasise that the definition is that of a substance or material on its own, not as an ingredient or part of another material.

- The term 'solid' is added to the definition, incorporating the clarification[1] that the definition is limited to materials that consist of solid particles, as opposed to liquid particles encountered in emulsions or even gaseous particles (e.g. bubbles).

- The new definition explicitly specifies that, when establishing the number-based particle size distribution, particles sticking together with other particles (only) have to be taken into account if they are identifiable as constituent particles of these bigger agglomerates and aggregates. This does not constitute a reason for not applying appropriate measurement procedures, with ample relevant information now to be provided also in a dedicated guidance, but is a recognition of the enforceability ambition of the definition.

- The carbon-centric explicit inclusion of fullerenes, graphene and carbon nanotubes in the 2011 definition is eliminated. It is replaced by a generic, chemical element-neutral inclusion of all elongated particles (e.g. rods, fibres, tubes) with a diameter smaller than 1 nm and length above 100 nm and of plate-shaped particles with a thickness below 1 nm and lateral dimensions above 100 nm, in the relevant size fraction.

- For practical measurability reasons, it is allowed to not count particles with at least two orthogonal external dimensions larger than 100 µm.

- All references to possible uses of a material's specific surface area in the assessment whether a material is a nanomaterial or not, are replaced by a general and evidence-

[1] Such clarification was provided already in the Q&A accompanying the existing Recommendation 2011/696/EU.

based statement that materials with a specific surface area by volume of < 6 m^2/cm^3 shall not be considered a nanomaterial.

- The definition, now explicitly states that single molecules are not considered 'particles'[1].

- The flexibility provision in the 2011 definition that "*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 %*" has been deleted. To obtain maximal consistency between different pieces of legislation, the threshold value is now fixed at 50 %.

In the results of the 2021 stakeholder consultation, the proposed change receiving the most outspoken resistance, in particular from non-governmental organisations, is the latter, fixing the value of the threshold fraction to 50 %.

This default percentage defines the nanomaterial based on its majority component, in accordance with the general naming convention. While fixing the value makes the definition simpler and more transparent, facilitates implementation and ensures consistency across legislation applying this definition, the value itself reflects the convention and was set in the absence of a systemic reason or scientific rationale for another (lower) limit. It is important to underline that fixing the threshold fraction at 50 % only implies that materials containing less particles in the nanorange should not be called nanomaterials. The fixed value does not prevent that, where necessary, regulatory or other action is taken for materials that contain smaller fractions of particles in the nanoscale range or perhaps particles that would be marginally exceeding 100 nm size, another convention employed. An example already in place, is provided in the document.

Implementation

Effective use of a revised definition requires further clarification of some of the terms applied, also through examples, as well as application guidance that sets out applicable methods, best practices, etc. This will be provided in an associated Guidance, developed by the Joint Research Centre, using the scientific-technical reports supporting the 2011 definition as the basis. This horizontal guidance is expected to be complemented by guidance at sectoral level as the revised EC definition is worked into new or revised legislation[2], for example also in the food sector and in the cosmetic products sector.

[2] The exact approach and timing is determined by the sector. The EC definition may even be used in another act providing a definition of nanomaterial for horizontal policy and legislative use adopted by the Commission or Union legislator, in which case such an act would replace the revised Commission Recommendation as a reference.

CONTENTS

1. INTRODUCTION

In 2011, the European Commission (EC) published the Recommendation 2011/696/EU on the definition of nanomaterial[3], here subsequently referred to as the Recommendation. The purpose of the Recommendation is to provide a coherent overarching definition of the term nanomaterial (NM) for use across policies in the European Union.

The scope and application of the Recommendation and its definition have been subject to a review by the Commission between 2013 and 2021. Based on the findings of the review, the Commission decided to revise the definition of nanomaterial, replacing the Recommendation 2011/696/EU and adopting a new Recommendation C(2022) 3689. This Commission staff working document explains the review process, its findings and the changes to the definition.

[3] COMMISSION RECOMMENDATION of 18 October 2011 on the definition of nanomaterial (2011/696/EU); OJ L 275, p.38-40

1.1. Background and the Commission Recommendation 2011/696/EU

What is a nanomaterial?

In the most common use of the word, nanomaterials are chemical substances, materials or products with internal features or consisting of particles having external dimensions at the 'nanoscale' (size range of 1 nm to 100 nm, where 1 nm = 10^{-9} m). The nanomaterial form of a given material may exhibit novel or different characteristics compared to the conventional form of the same material, where one exists, and may differ from its other nanomaterial forms (also called nanoforms). Often, such materials are deliberately manufactured and used in order to deliver/exhibit those characteristics, which include increased strength, chemical reactivity or electrical or thermal conductivity. There are also many nanomaterials that are natural by origin or may be an incidental by-product of human activity (e.g., welding fumes).

The ability to manipulate materials at the nanoscale and exploit their new properties and functionalities is already significantly influencing society and helping to address important societal challenges (e.g., healthcare and medicine, energy, electronics and computing, food and feed). They can be used to create lighter, stronger, and more durable packaging materials, helping to keep our food longer fresh and reduce waste; help deliver a medicine; reduce fuel consumption through lighter composites; support water remediation; increase battery capacity, etc.

Why nanomaterial-specific provisions?

The properties that result from the new or modified features at the nanoscale may influence the materials' behaviour and fate in biological systems and environmental compartments thereby impacting their inherent hazard properties and exposure routes, possibly resulting in a modified risk profile for human health and the environment as compared to their conventional forms or other nanoforms.

The assessment of hazards and risks of materials and their subsequent risk management is one of the frequent features of regulation on chemicals, materials and products made of these materials and their uses. The effectiveness of such assessments is determined by:

a) The ability to differentiate between substances/materials/products, which might differ in properties that would influence the outcome and are therefore not assessed as one.
b) Having adequate knowledge of their characteristics, inherent hazard properties and potential routes of biological and environmental exposure, to enable reproducibility of assessment.
c) The ability to apply assessment methods suitable to the substance/material/product assessed.

For nanomaterials, the legislator recognised separate or additional provisions that may be appropriate to ensure sufficient appreciation of the potential differences due to their features at nanoscale, even when materials may otherwise share identical chemical composition (a). This specific class of materials may require further characterisation, additional hazard and exposure information, and specific or adapted methods to achieve adequate results (b and c). Knowing when to trigger these requirements requires criteria, set by the nanomaterial definition.

Why a common definition of nanomaterial for regulatory purposes?

A material identified as nanomaterial under one legislation should be also considered as nanomaterial under another piece of legislation, as this will minimise the effort of identification, support consistency in application and, facilitate communication and exchange of information relevant in regulatory processes.

Is a material, not identified as nanomaterial according to the definition, still adequately assessed and managed by legislation?

Applying specific provisions for explicitly identified nanomaterials does not invalidate general provisions or perhaps further specific provisions for other (classes of) materials in legislation and supporting guidance.

While many conventional materials can be very different from nanomaterials and may not even contain particles, some materials, not fulfilling the nanomaterial definition, may still contain a fraction of nanoparticles or other features at the nanoscale or close to it, and may require specific considerations during their safety assessment.

This can be exemplified in the regulated food and feed product areas, where this situation is covered by setting specific information requirements and guidance. Following a mandate from the European Commission, the European Food Safety Authority (EFSA) has developed guidance on the information that applicants and other interested parties should submit for assessing if a conventional material, not covered by the legal definition of engineered nanomaterials under the Novel Food Regulation, consists of or contains a fraction of nanoparticles that requires nanoscale considerations during the risk assessment process. Somewhat similar consideration was followed by the European trade unions (ETUC) when they proposed a nanomaterial definition. The ETUC definition required a nanomaterial to consist for at least 80 % of particles with a diameter of 100 nm or below. In the case of a particle size fraction below 100 nm between 10 % and 80 %, ETUC speaks of a multi-constituent substance composed of the nanoform and the bulk material.

In addition, legislations across different sectors have provisions, normally triggered by indication of concern, that enable specific scrutiny of individual substances/materials/products (see for example substance evaluation under REACH).

How to define a nanomaterial? Commission Recommendation 2011/696/EU

There are several approaches worldwide that aim to identify a nanomaterial. The International Organization for Standardization (ISO) defines the term ‘nanoscale’ as the length range approximately from 1 nm to 100 nm and introduces the concept of a ‘nano-object’ as a characteristic feature of nanomaterials having one, two or three external dimensions at the nanoscale (ISO/TS 80004-1:2015).

To best cater the regulatory purposes in the EU, the 2011 EC definition was designed pursuing the following main objectives:

- To follow as closely as possible international conventions and norms established in the field.
- To reflect state-of-the-art technical and scientific knowledge and developments.
- To be broadly applicable in different EU legislative contexts.

- To be directly applicable to the substance/material/product that is subject to EU law, rather than describing its particular element (i.e. particle as nano-object) or property.
- To provide clear and unambiguous regulatory criteria that provide a yes-or-no answer to whether a material is a nanomaterial and that can subsequently be utilised in triggering the specific provisions of the legislation.
- To be straightforward and avoid reliance on concepts that might be difficult to enforce, be material-specific or change through time (e.g., 'novel property').
- To avoid any link to pre-determined notion of hazards[4].

The main text from Recommendation 2011/696/EU is provided in the box below. It was developed by the Commission services, based on comprehensive scientific input by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report *'Scientific basis for the definition of the term "Nanomaterial"*[5] and the European Commission's Joint Research Centre (JRC) report '*Considerations on a Definition of Nanomaterial for Regulatory Purposes*[6].

Main text (excluding recitals) of the Recommendation 2011/696/EU on the definition of nanomaterial

1. Member States, the Union agencies and economic operators are invited to use the following definition of the term 'nanomaterial' in the adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies.

2. 'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

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.

4. For the purposes of point 2, 'particle', 'agglomerate' and 'aggregate' are defined as follows:

(a) 'particle' means a minute piece of matter with defined physical boundaries;

[4] In addition to the lack of scientific basis for such generic position, approach would also be self-defeating as the principal objective of nanomaterial-specific provisions in EU legislation is to ensure adequate assessment of risk of the individual materials addressed.

[5] https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf

[6] EUR 24403 EN, doi 10.2788/98686

(b) 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

(c) 'aggregate' means a particle comprising of strongly bound or fused particles.

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 m^2/cm^3. However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with the definition in point 2 even if the material has a specific surface area lower than 60 m^2/cm^3.

6. By December 2014, the definition set out in points 1 to 5 will be reviewed in the light of experience and of scientific and technological developments. The review should particularly focus on whether the number size distribution threshold of 50 % should be increased or decreased.

7. This Recommendation is addressed to the Member States, Union agencies and economic operators.

The definition applies to any particulate material, regardless of its origin: natural, incidental or manufactured. Features of manufactured materials at the nanoscale may be deliberately engineered or just an 'incidental' result of the manufacturing process. Also the term 'material' used in the definition is generic. It should be recalled that the 'material' will however be restricted by the scope of any specific piece of binding legislation using or referring to this definition.

The definition is based on the only feature common to all nanomaterials, the nanoscale of the external particle dimensions. Unlike in the ISO definition, the size interval is however set precisely at 1 nm to 100 nm to enable unambiguous regulatory outcome. The definition also recognises that sizes of particles in the material will always form a distribution thereby requiring a threshold on the fraction of particles meeting the defined size range. To ensure adequate focus to the nanoscale features that may be alternatively obscured by the presence of large particles, for example, when a particle mass metric would be employed[7] the threshold in the definition is also set with regard to a particle number-based size distribution. As a convention, a default threshold of 50 % was adopted, defining a nanomaterial based on the majority of its particles having external dimensions in the nanoscale. To accommodate specificities of certain materials with features in the nanoscale, and where warranted by concerns for the environment, health, safety or competitiveness, the threshold of 50 % can be lowered to 1 % to 50 %.

The choice to restrict the definition to particulate materials, including particles in aggregates and agglomerates, is deliberate, and knowingly excludes from the definition nanostructured materials that do not consist of particles. This is based on known regulatory interest and takes into account identified challenges in regulatory

[7] A single 1 mm particle weighs as much as 10^{12} 100 nm particles of the material with the same composition.

implementation, in particular the inability to identify methods that would allow for the definitive exclusion of materials with absence of nanoscale features.

Further elements are, however, added to the definition to address the internationally accepted but rigid lower limit of 1 nm, thereby excluding several carbon allotropes generally recognised as nanomaterials (single wall carbon nanotubes with length over 100 nm, the smallest fullerenes and thin graphene flakes). These materials are included by derogation. To facilitate implementation, a secondary definition based on volume specific surface area is included.

The Commission Recommendation 2011/696/EU, as all Commission Recommendations, is not legally binding but has been either incorporated or referenced in the following regulations:

- Biocidal Products Regulation (BPR)[8]
- Medical Devices[9]
- REACH Regulation[10]

In 2012, in the Second Regulatory Review on Nanomaterials[11], the Commission confirmed its plans to use this definition in all its new legislative proposals where nanomaterial-specific provisions would be considered necessary and adapt accordingly regulations with existing nanomaterial definitions. This has been achieved to a varying degree.

The Commission invited also the Member States, the Union agencies and European economic operators to consider the application of the definition in their own work. Several Member States developing national registries of nanomaterials have used, or referenced, the definition of Recommendation 2011/696/EU.

Chapter 2.1 reviews the uptake and application of the Recommendation in more detail.

1.2. Review of the definition in the Recommendation 2011/696/EU - procedural aspects

Point 6 of the Recommendation indicates that "*By December 2014, the definition set out in points 1 to 5 will be reviewed in the light of experience and of scientific and technological developments. The review should particularly focus on whether the number size distribution threshold of 50 % should be increased or decreased.* ".

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8 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products; OJ L 167, 27.6.2012, p.1

9 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; OJ L 117,5.5.2017, p.1

10 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; OJ L 396, 30.12.2006, p.1

11 COM(2012) 572 final

The Commission launched the review in 2014, based on preparatory work completed already in 2013. It performed a targeted stakeholder survey, organised a workshop and performed a comprehensive assessment and analysis of the availability and quality of data on nanomaterials. The Commission's Joint Research Centre (JRC) published three Science for Policy reports (see main review chapter below).

Publication of the roadmap[12] in 2017 identified that the final stage before concluding the review should be a consultation regarding the review's interim findings and the elements of the definition considered for change.

As part of simplification and consolidation of the legal framework objective, the review of the EC definition was one of the actions incorporated in the 2020 Commission's Chemicals Strategy for Sustainability[13]. The final targeted stakeholder consultation took place between May and June 2021. The extensive feedback received was reviewed and analysed by the Commission services and is presented in chapter 2.10. As presented below, internal consensus has been reached to revise the definition. The publication of this staff working document and the new Commission Recommendation [C(2022) 3689] replacing Recommendation 2011/696/EU is concluding the review.

2. REVIEW

This chapter summarises the main activities and outcomes of the review. Specific details and background can be found in the reports published by JRC. These reports form the basis of the conducted review and of this staff working document.

The first JRC report "*Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Part 1: Compilation of information concerning the experience with the definition*"[14] (below: Review-1) compiles the experience with the definition and its implementation, collected both from stakeholders and from JRC scientists. Stakeholder input identified a perceived lack of clarity of scope, wording, and terms of the definition as key issues. Some stakeholders also provided results of size distribution measurements of specific particulate materials and estimates of the resources required to implement the definition. The JRC report includes sections on: the identification of other international definitions; uptake of the Recommendation in EU legislation and national activities in the Member States; a compilation of significant related activities; a review of applicable measurement procedures; methods/algorithms to convert measurement data from other metrics to the metric relevant for the nanomaterial definition; information on the manufacturing of nanomaterials; differences in particle shapes; materials of natural and incidental origin; and the nanostructured materials not covered by the definition, that is limited only to particulate materials.

The second JRC report "*Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Part 2: Assessment of collected information concerning the experience with the definition*"[15] (below: Review-2) evaluates the experiences, collected

[12] Review and potential revisions of the EU Recommendation on the definition of nanomaterial (No 2011/696), Roadmap , published on the Commission Better Regulation Portal, Ares(2017)4513169 - 15/09/2017

[13] COM(2020) 667 final

[14] EUR 26567 EN; doi:10.2788/36237

[15] EUR 26744 EN; doi: 10.2787/97286

between August 2013 and April 2014 from scientists, research institutes, regulatory bodies, NGOs, and industry, regarding the implementation of the definition. While a number of assessments from the report is summarised in the subchapters below, readers are still invited to read the full report.

The third JRC report "*Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Part 3: Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation*"[16] (below: Review-3) presents a scientific-technical evaluation of options to clarify the definition and to facilitate its implementation. These options represent the basis for the elements of change presented in the targeted stakeholder consultation in 2021, and subsequently taken up in the revised definition in the new Recommendation C(2022) 3689 replacing the Recommendation 2011/696/EU, as presented also in chapter 3. Rationale for changes, per element, is discussed in the corresponding chapters below and in the sections addressing the targeted stakeholder consultation (Chapter 2.10). Still, the third JRC report in combination with the assessment in the Review -2 report includes the main scientific-technical rationale for all the changes eventually applied in Recommendation C(2022) 3689.

The three JRC Review reports refer to the definition in the Recommendation 2011/696/EU as the "EC definition", which is also the term sometimes chosen in the chapters below.

The JRC Review reports were published in 2014 and 2015. Additional relevant information was generated in the implementation years 2014-2021 and is, where appropriate, reflected in the subchapters below. In particular, additional guidance on the use of particle size analysis methods has been provided in the subsequent JRC reports from 2019 "*An overview of concepts and terms used in the European Commission's definition of nanomaterial*"[17], and "*Identification of nanomaterials through measurements*"[18], and from "*The NanoDefine Methods Manual*"[19] from 2020 substantially from the work and results obtained from the EU FP7 research project[20].

Significant feedback has been received in the targeted stakeholder consultation that was performed between May and June 2021. The aim and main outcome of the consultation is briefly summarised in chapter 2.10, with a comprehensive presentation (Annex A) of all the feedback received together with the Commission services' responses, complementing where necessary the general arguments already made in the preceding chapters.

The subchapters (0-2.10) first summarise the general experience with the uptake of the Recommendation 2011/696/EU, followed by the reflection on the chosen scope and main attributes of the EC definition, also from the perspective of comparison with other definitions and stakeholder perception and assessment of clarity of the terms employed, and finalise by the presentation of the implementation and measurement challenges.

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16 EUR 27240 EN; doi:10.2788/678452

17 EUR 29647 EN; doi:10.2760/459136

18 EUR 29942 EN; doi:10.2760/053982 , doi:10.2760/7644

19 EUR 29876 EN; doi:10.2760/79490, doi:10.2760/58586

20 http://www.nanodefine.eu/

2.1. Application of the Recommendation 2011/696/EU

The Commission Recommendation on the definition of nanomaterial can be considered an appropriate legislative tool for the intended purpose, providing a single definition for use within the individual sectoral legislation.

The uptake may, however, be hampered by external factors unrelated to the Recommendation (e.g., legislative review cycles), and by potential challenges related to the EC definition's implementation, indicating that the definition in the Recommendation might not always be fit for its intended purpose.

2.2. Examples of legislation that adopted the EC definition

As indicated in the introductory chapter 1.1, three EU regulations have made use of the definition of Recommendation 2011/696/EU either as a whole or its core parts (Biocidal Products Regulation[6], Medical devices[7], REACH[8]). The main feature of the definition, the 50 % threshold of constituent particles within the size interval 1 nm – 100 nm, based on the number-based particle size distribution as well as the specific derogation for carbon-based materials with features smaller than 1 nm are always taken up. Text is modified, by replacing 'material' in the EC definition by the desired object within the regulation to which the definition should be applied, e.g.:

- Biocidal Products Regulation: "'nanomaterial' means a natural or manufactured **active substance or non-active substance** containing particles …"
- REACH: "a nanoform is a form of a **natural or manufactured substance** containing particles …"

Further supporting definitions of particles, aggregates and agglomerates were also copied directly in the regulations.

The EU Ecolabel Regulation[21] does not in its main text include a definition or reference to nanomaterials, but several of the criteria for specific products include conditions related to nanomaterials, which indirectly reflect the evolution of the EC definition of nanomaterial: Commission Decision 2011/382/EU[22] establishing the ecological criteria for the award of the EU Ecolabel to hand dishwashing detergents introduced provisions in absence of a definition introduced reference to 'nanoform', with description in the guidance. Following the introduction of the Recommendation 2011/696/EU, criteria would copy the EC definition text (e.g., Commission Decision (EU) 2017/1217 on hard surface cleaning products[23]), unless the definition would be in direct conflict with sector regulation, such as in the case of cosmetic products, where the sectoral definition was employed (Commission Decision (EU) 2021/1870 on criteria for cosmetic products and animal care products[24]).

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21 Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel; OJ L 27, 30.1.2010, p. 1–19

22 Commission decision 2011/382/EU of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to hand dishwashing detergents, OJ L 169, 29.6.2011, p.40

23 Commission Decision (EU) 2017/1217 of 23 June 2017 establishing the EU Ecolabel criteria for hard surface cleaning products, OJ L 180, 12.7.2017, p. 45–62

24 Commission Decision (EU) 2021/1870 of 22 October 2021 establishing the EU Ecolabel criteria for cosmetic products and animal care products, OJ L 379, 26.10.2021, p.8

2.3. Examples of legislation that did not or not yet adopt the EC definition

There are EU regulations with already existing nanomaterial definitions that did not make use of it most notably Novel Foods (Regulation (EU) 2015/2283)[19] and Cosmetics (Regulation (EC) 1223/2009)[20] where the definitions of 'engineered nanomaterial' [25] and 'insoluble or bio persistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm', are used[26].

In the first years after the adoption of the Recommendation 2011/696/EU, the EU food and cosmetic sectors investigated and launched considerations on how to align their pre-existing sector-specific definitions with the EC definition. Following the launch of the review of the Recommendation in 2014, both sectors decided to wait for the results of the review and eventual revision of the EC definition.

2.4. Reasons for delay in the uptake of the EC definition

The **uptake** of the EC definition has therefore been mixed. Once attempted, uptake approaches slightly varied. The main delays can be only in minor part attributed to the Recommendation itself. The definition has been taken up without delay where the nanomaterial-specific provisions were introduced for the first time and the timing coincided with their introduction, such as the revision of the Biocidal Products Regulation and the Commission proposal for a Regulation on medical devices, both in 2012. The latter was eventually adopted in 2017, with its delayed application starting on 26 May 2021. Amendments of the REACH technical Annexes introducing nanomaterial-specific provisions[27], including the definition of nanoform based on the Recommendation 2011/696/EU, took place in 2018, with its mandatory application from 1 January 2020.

2.5. Ability of the EC definition to meet or be adapted to specific regulation

In all the cases where the definition of Recommendation 2011/696/EU was taken up by legislation, experience on its **implementation** indicate that the definition was successfully applied on a variety of materials, allowing application of specific regulatory provisions associated with the nanomaterial identification. However, specific implementation challenges were identified either due to perceived ambiguity of certain elements of the definition or due to analytical limitations in the available measurement procedures.

Experience with the definition and its implementation has significantly improved through the years. Support became available from the results of the dedicated research project NanoDefine[18] (providing a number of technical reports, a methods manual, the NanoDefiner e-tool and case studies), from dedicated implementation work provided by

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[25] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001; OJ L 327, 11.12.2015, p. 1–22

[26] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products; OJ L 342, 22.12.2009, p. 59–209

[27] Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances; OJ L 308, 4.12.2018, p. 1–20

JRC[15], from sectoral guidance (e.g., by ECHA and EFSA), and from the repository of analytical measurement methods[16,17].

Where the Recommendation has been used, it is instructive to see the form the definition has taken. In some cases, a reference is made to the Recommendation itself (e.g. REACH: "*On the basis of the Commission Recommendation…*", or footnote reference in the Ecolabel decision). In all cases, the definition is used by adapting the text in the Recommendation and placing it directly in the Regulation.

The complementary options to use specific surface area by volume (VSSA) and the flexibility of the value of the default 50 % threshold, i.e. to lower the threshold as part of the implementation of a sectoral regulation, are not taken up in any of the cases involving EU legislation[28]. Identified reasons for this include simplicity (avoidance of potentially conflicting outcomes by allowing VSSA as a complementary decision-making tool and the need for an additional regulatory process to determine the value of a flexible threshold fraction) as well as the lack of scientific evidence at those times to consider a lower threshold. These aspects, together with arguments brought forward by the stakeholders, have been assessed during the review and are elaborated in Section 3 of Review-2, with the summary presented in the respective subchapters below.

Choosing to exclude specific elements of the EC definition represents an important reason to include the text of the definition in the regulation rather than refer to the Recommendation. The option to at least allow the possibility to refer to the Recommendation played a part in the incorporation consideration of potential changes to the EC definition.

2.6. Identifying the 'right' materials: reflection on the tools, scope and main elements of the EC definition

2.6.1. Comparison with other definitions

Section 2 of the Review-1 compiles an overview of national and international nanomaterial definitions whether based on the EC definition or not, whereas Section 2 of the Review-2 identifies the level of divergence with the EC definition and presents the rationale and context in which the EC definition is to be used. The following list of assessed definitions is an updated excerpt from the analysis.

Table 1: *List of selected definitions assessed in the Review-2 report (as updated).*

Institution/Country	Main reference to the definition	Comment on scope
ISO and CEN	Multiple relevant documents[29]	
Scientific Committee on Emerging and Newly Identified Health Risks	2010 "Scientific Basis for the Definition of the Term Nanomaterial"	No definition per se, different solutions presented

[28] Notably, the flexibility clause is included in the French decree establishing national register of nanomaterials. Beyond contribution of FR authorities in stakeholder consultations, assessment of their implementation experience has not been performed as part of this review.

[29] Status November 2021: ISO/TS 80004-1:2015 with core terms is currently under revision. A proposal has been made to withdraw ISO/TS 80004-4 and transfer the definitions of nanostructured materials to the next revision of ISO/TS 80004-1.

(SCENIHR)		
American Chemistry Council (ACC)	2013 "Comparative assessment of nanomaterial definitions and considerations for implementation" as presented at the 52nd annual meeting of the Society of Toxicology	Panel concluded on need for consistency in several core elements
International Cooperation on Cosmetics Regulation (ICCR)	2010 Report of the ICCR Joint Ad Hoc Working Group on Nanotechnology in Cosmetic Products: Criteria and Methods of Detection	Set for purposes of the International Cooperation on Cosmetics Regulation
International Council of Chemical Associations (ICCA)	2010 "ICCA Core Elements of a Regulatory Definition of Manufactured Nanomaterials"	
German Chemical Industry Association (VCI)	2010 “VCI position on the definition of the term nanomaterial for use in regulations laying down provisions on substances"	
ETUC	2014 Concept of a regulatory definition for a substance in the nanoform	
Cosmetic Products Regulation No 1223/2009		
Novel Food Regulation (EU) 2015/2283, (also Food Information to Consumer Regulation No 1169/2011 and Food Additives Regulation (EC) No 1333/2008)		Definition of ‘engineered nanomaterials’ linking intentional production with functionality Extensive similarity and use of terms of the definition in Commission Recommendation 2011/696/EU. No use of 50 % threshold.
Medicinal product legislation (Directive 2001/83/EC)		No specific provisions for nanomaterial, 2006 EMEA reflection paper identifies ‘nanometre scale’ and ‘nanotechnology’.
Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food		References are made to substances in ‘nanoform’ without explicit definition of the term.
Swiss Secretariat for Economic Affairs (SECO)	2012 Swiss guidelines on compilation of safety data sheet for synthetic nanomaterial	
The United States of America	2011 Guidance "Considering Whether an FDA-Regulated Product Involves the Application of nanotechnology” by FDA 2010 “Manual of Policies and Procedures (MAPP 5015.9)” by FDA	

	Center for Drug Evaluation and Research (CDER) 2011 EPA significant new use rule under TSCA for two rutile-based chemicals substances	
Taiwan	2012 within the context of Chemical Substance Nomination & Notification, definition is published by The Council of Labour Affairs	
Korea	2011 "Guidance on safety Management of Nano-based products"	
China	GB/T 19619-2004: 纳米材料术语 (Terminology for nanomaterials)"	
Australia	Definition of the Australian Industrial Chemicals Introduction Scheme (AICIS, ex-NICNAS)[30] as part of the regulatory programme on " chemicals at the nanoscale"	
Canada	2011 Health Canada "Policy Statement on Health Canada's Working Definition for Nanomaterials"	

After the publication of the Review-2, the U.S. FDA published the final version of "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology. Guidance for Industry" and the U.S. EPA issued the final rule "Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements":

U.S. FDA	2014 "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology. Guidance for Industry" (final version)	The points to consider are: Whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm); Whether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are

[30] Review update: This public inventory is no longer available. It has been replaced since 2020 with Australian Industrial Chemicals Introduction Scheme AICIS.

		attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm).
U.S. EPA	2017 "Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements" (Final rule)	"This rule applies to chemical substances, as defined in section 3 of TSCA, that are solids at 25 °C and standard atmospheric pressure; that are manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1–100 nanometers (nm) in at least one dimension; and that are manufactured or processed to exhibit one or more unique and novel properties. This rule does not apply to chemical substances manufactured or processed in forms that contain less than 1% by weight of any particles, including aggregates and agglomerates, in the size range of 1–100 nm."

To compare intended **purposes and scopes**, the following aspects were considered: the legal status, the scope, the origin of the material addressed in a definition and whether a material is particulate or nanostructured.

- Most of the nanomaterial definitions presented above are advisory, non-normative and non-regulatory and give guidance or recommendations only. Exceptions are the EU sector-specific legislation and national registries, mandatory reporting schemes in EU Member States, and the reporting rule by the U.S. EPA, where the associated definitions are legally binding. The EC definition, while by itself a Recommendation only, is an instrument aiming explicitly at harmonisation of existing and future legislation with the aim to defining a nanomaterial in a regulatory context.
- With regard to scope, the EC definition follows the broadness of definitions proposed by some international organisations or national authorities, not restricting its applicability to certain (chemical) compositions or to certain application fields. In contrast, the definitions and nanomaterial specifications from EU sector-specific legislation (whether or not aligned with the EC definition) have a scope limited to the area of the legislation in question, emerging from the well-defined area of application of the regulations themselves.

- The origin of the material is not addressed in some of the definitions, while most definitions would limit their scope to "intentionally manufactured", "engineered" or "processed" materials. The EC definition not only includes intentionally manufactured materials, it also explicitly includes incidentally generated and naturally occurring particles, thus omitting the origin of the materials from consideration. As noted above, it is the scope of the regulation that may potentially determine a narrower scope.
- The scope of the EC definition, compared to some other existing definitions, is restricted when it comes to nanostructured materials, as the only structures in nanoscale considered relevant are those generated by particles, on their own or aggregated or agglomerated in larger particles/structures/ensembles.

Comparing the **technical aspects**:

- The defining property that all nanomaterial definitions have in common is the size of microstructural features. The nanoscale size range is identical (1 nm to 100 nm) for almost all definitions. Whereas several definitions refer to both external and internal structural features, the EC definition is limited to the external dimensions of the constituent microstructural features i.e. particles. The 2010 SCENHIR opinion additionally considers materials with a median size between 100 nm and 500 nm as a nanomaterial, if a statistical extrapolation of the average size and associated standard deviation indicates that possibly 0.15 % or more of the (number of) particles are smaller than 100 nm. Similarly, the SECO guideline uses the 1 nm to 100 nm interval, and in addition considers a material with an average particle size below 500 nm to be a nanomaterial if the particle size distribution is not known. The SECO guideline, as well as the EC definition (Recommendation 2011/696/EU and definitions based upon it in EU regulations) explicitly include fullerenes, graphene flakes and single wall carbon nanotubes even if their relevant external dimension is below 1 nm.
- The EC definition is distinguished by its 50 % (or down to 1 % under specific conditions) threshold value for the fraction of particles in a particle size distribution falling within the defined nanoscale size range. Some definitions do not use the particle size (distribution) as the main identifying parameter (ISO, ICCR, and Asian national definitions). For those definitions referring to both internal and external nanoscale features, it is even less straightforward to set up such quantitative criterion. Only for definitions that refer to a specific property induced by the nanostructure of the material could one set a threshold based on this specific property. The definitions that contain a threshold fraction of particles fall in two categories: the fraction is based on particle mass or on particle number. Particle mass-based size distributions are used in definitions of the EPA and chemical industries associations (ACC, ICCA, VCI), which set a mass-based threshold of 1 % (EPA) or 10 % (ACC, ICCA, VCI). The definition proposed by ICCA specifies an additional cut-off of 50 % (mass-based) if aggregates/agglomerates consist of nano-objects. For the particle number-based thresholds, the threshold value of 50 %, as in the EC definition, is used in legislation within the EU's jurisdiction. The Australian working definition for industrial nanomaterials specifies a 10 % particle number-based threshold and the SECO guideline stipulates a 1 % number-based limit. It is not clear whether and how these lower threshold values are being applied in practice. The SCENIHR opinion suggests the lowest threshold value, by proposing that a material is a nanomaterial when more than 0.15 % of the particles have a diameter below 100 nm. However, this value cannot directly be compared with the 50 % value of the

EC definition as it follows from a statistical reasoning that takes into account the width of the particle size distribution. More specifically, the SCENIHR definition includes materials for which the measured average particle size is above 100 nm but only if the standard deviation of this average value indicates the likelihood that at least 0.15 % of the particles are smaller than 100 nm in diameter, making the upper size limit (100 nm) less rigid. The ETUC concept proposes an 80 % threshold for the number of particles with a diameter of 100 nm or below. In the case of a particle size fraction below 100 nm between 10 % and 80 %, ETUC speaks of a multi-constituent substance composed of the nanoform and the bulk material.

- Agglomerates and aggregates are not explicitly addressed in ISO, ICCR, and most Asian national definitions.
- In addition to the EC definition, specific surface area is a complimentary criterion only in the VCI and SCENIHR definitions.
- Novel properties or properties or phenomena attributable to a material's [nano] dimensions, or nanoscale properties are used in a number of definition (ACC, national definitions of USA, Taiwan, Taiwan, China, Australia and Canada), linked also to the concept of "engineered" or "manufactured or processed" nanomaterials. The EC definition is size-based only and therefore not limited to materials produced intentionally.
- Solubility (or biopersistence) is another parameter employed in the cosmetics sector (ICCR, EU Cosmetic Product Regulation) and by ACC, whereas the EC definition is restricted to size only.
- The definition by EPA is the only one explicitly referring to particles that are solids at 25 °C and standard atmospheric pressure.

2.6.2. Stakeholder experience (2013-2015)

As a first step of the review, a survey was conducted by JRC already in August-September 2013, collecting feedback from relevant actors with presumed practical experience. The stakeholders were identified from industry and trade associations, private companies, EU agencies, international organisations, government authorities, academic/research organisations, non-governmental organisations (NGOs), and other organisations. Of the 255 invitations sent out to stakeholders, a total of 63 replies were received of which about two third came from private companies, industry and trade associations. A complete overview of the survey questions and corresponding results are provided in the Review-1, both as global statistics (Section 7), full transcript (Annex to Section 7) but also as an input to the other sections of the report. The survey queried about the overall experience on implementation and support provided to date (e.g., the Q&A published on the COM website), the clarity of the wording, terms and thresholds applied in the individual elements of the definition and its scope. Participants were also asked to provide an estimate of resources required to implement the definition, results of particle size distributions already measured, and future needs.

The experience can be summarised as follows:

- Having a horizontal definition, to be used for regulatory purposes across legislation wherever nanomaterial-specific provisions are considered necessary, is advantageous. This definition, however, must be complemented by the use of the definition in sectoral legislation in a legally binding manner.

- The definition lacks clarity as regards certain terms applied and the wording used (e.g., contain, unbound).
- The definition is challenging to implement (e.g., limited/complex methods to obtain number-based particle size distribution, identify constituent particles in certain cases).
- A majority of the respondents would like to see changes to the definition. Many also proposed to retract from its main approaches and instead apply definitions adopted by international standardisation organisations (e.g., ISO, CEN).

Specific issues with regard to the main elements, clarity of terms and the measurement challenges have been assessed in the Review-2. Conclusions of the assessment are presented in the subsequent chapters (for a more detailed and complete rationale the reader is referred to the JRC report.)

2.6.3. Origins of material – is broadness of scope justified?

Comments were received on the unnecessary broadness in terms of origins, the conceptual approach and the application show that the broadness may in fact be necessary to ensure that the EC definition can be applied in different regulatory settings. It is the scope of those settings that will restrict the materials subject to the requirement to identify as nanomaterials. In this manner, the Recommendation works as intended.

2.6.4. Particulate vs nanostructured nanomaterials

The current definition is explicitly limited to particulate matter and its provisions are specifically designed and tailored to address this type of material. This approach was inspired by earlier reports from SCENIHR and JRC, which state that human and environmental exposure is more likely for particulate materials than for "embedded" nanomaterials, and hence the former are considered more relevant in the regulatory context.

Nanostructures that are not themselves aggregates or agglomerates of particles, regardless of their nanoscale features are therefore excluded from the definition as soon as their external dimensions exceed 100 nm.

Section 15 of the Review-1 provides an extensive investigation of different nanostructured materials, their manufacturing and characterisation methods. Section 7 of the Review-2 uses this information to assess also the regulatory relevance and in return the appropriateness of the choice to consider them or not in the definition, which is elaborated in terms of options in Section 2.2 of the Review-3 report.

Several classes of nanostructured materials were identified to be potentially of regulatory relevance (i.e. their members may be subject to regulatory assessments), namely:

- Materials with surface structures at the nanoscale;
- Nanocomposites (in particular materials with a defined microstructure of matrix and dispersed phase, as opposed to hetero-aggregates);
- Nanoporous materials and solid nanofoams, if they can easily release nanoparticles or disintegrate into nanoparticles;
- Fluid nanodispersions and nanoemulsions.

Among them, the classes would differ in ways and criteria to identify their nanoscale features and the measurement methods required. Even that might still not be enough and

additional qualifiers would likely be required; for example, the vast majority of solid materials have at least some parts of their surface structure at the nanoscale.

Solutions required to incorporate nanostructured materials, other than those consisting of agglomerates and aggregates of particles, would render the definition significantly more complex and difficult to implement, as criteria linked to particle size distributions would not be applicable and would either have to be replaced or significantly complemented. No conceptual proposition could be followed by the methodological support necessary for the intended regulatory purpose and such extensions were therefore not pursued further.

2.6.5. The particle number-based particle size distribution as the defining feature

The **size range of 1 nm to 100 nm**, as used in the definition, is well defined with clear and fixed boundaries, primarily introduced with the regulatory purpose of the definition in mind. The Review reports describe reference cases of materials whose intrinsic properties change pronouncedly (e.g., due to quantum effects) when their external dimensions are reduced within the range of 1 nm to 100 nm. This holds true as well for their behaviour in biological systems ('extrinsic properties' e.g., interference with biological pathways), although these changes occur less abruptly. Other materials exhibit less sudden changes in their properties or behaviour and at times to a lesser degree due to increased specific surface area. Which properties change significantly, and which not, is material dependent. Although the size range 1 nm to 100 nm, with fixed boundaries, may not capture all relevant "nanoscale" properties, the vast majority of such phenomena are observed in this size range. It is noted that external dimensions of certain engineered structures (e.g., nanocarriers) often exceed the 100 nm limit and that some definitions extend 'nanoscale range considerations' to 500 nm or even up to 1 μm (see 2.6.1), however maintaining the most generally accepted interval is considered as most appropriate. Consideration of definition 'outliers' that however might potentially warrant specific scrutiny, or even application of same tools designed for nanomaterials, has been identified already in the introduction (chapter 1.1) and is further revisited in chapter 4 on Implementation.

Since the **particle's external dimension** (or size) is a main element in the definition, it is relevant which of the multiple size features of a particle exactly would be measured, also in view of how particles' shapes may influence the outcomes. Section 13 and Section 4.3.5 of the JRC reports Review-1 and Review-2, respectively, discuss typical shapes of nano-objects and their relation to particle size measurements.

While the impact of the choice of the size convention employed on the definition is clear for spherical particles, in the case of particles with irregular shapes, the analysis shows that a simple single prescribed size parameter or a measurand is often not attainable. For that reason, different size parameters have been developed specifically for probing the external dimensions and surface features of particles. Parameters that target the minimum external dimension of a particle, and which are thus particularly relevant for the implementation of the EC definition, include the minimum Feret diameter and the diameter of the largest circle that can be drawn inside the contour of a 2D image of the particle. Notably, these specific parameters are only applicable to measurements performed on the basis of image analysis.

Guidance with best practice of how to provide full transparency when reporting the methods and measurement procedures employed, and their results, are considered to be the most appropriate response to facilitate implementation while ensuring comparability of assessments.

Use of **particle number-based particle size distribution (PSD)** is one of the key defining features of the EC definition. Many respondents of the JRC survey (see Section 7 of Review-1) and of the 2021 targeted stakeholder consultation (see subchapter 2.10) agree with the identification of nanomaterials based on the median value determined from particle size distribution (PSD) data, but they argue also for the mass-based PSD mostly due to its more routine nature. However, the number-based PSD is the only metric that can provide a reliable representation of all particles present in a sample. PSDs applying other more common metrics (e.g., mass-, volume-, intensity-based metrics) are known to be more sensitive to large particles than to small particles and, as a result, the median values of those PSDs can be significantly biased, leading to incorrect nanomaterial identifications.

As indicated previously, the main purpose of the definition is to classify materials and not to identify materials that may be of potential safety concern. The available evidence suggests that for nanomaterials, the most relevant dose metric varies for different materials and for different toxicological endpoints and is associated with the mode of action.

It is however important from the safety point of view that nanoscale particles present in a material/product are identified prior to the assessment, ensuring that the most suitable methods are employed. This metric does not prejudge the eventual metric employed in the toxicological assessment, but can prevent – through identification as nanomaterial and specific provisions in the regulation - that inappropriate methods are used in the material characterisation (and further testing) due to oversight.

Unless deliberate attempts are made to disperse and stabilise nanoparticles, for example using surface functionalisation, they tend to ‘stick’ together or on the surface of bigger particles, forming larger particles. Certain manufacturing methods allow nanoparticles to form strong bonds thereby creating aggregates, but nano-specific properties can be preserved when particles are aggregated, although this is not always the case. For example, the photocatalytic properties and the UV-absorption characteristics of TiO_2 persist when the nanoparticles are aggregated. On that basis, ‘counting’ **constituent particles**, rather than their aggregates or even agglomerates formed during manufacturing or processing would be a more appropriate way of characterising the nanomaterial.

The size distribution of the constituent particles also represents a more intrinsic and stable property of the material that may not be influenced as easily with changes in the environment (such as temperature, pH, composition), providing for a more relevant identifier. In the following chapters, some practical difficulties associated with a nanomaterial definition that is based on particle number-based PSDs of constituent particles are discussed, together with possible strategies to mitigate those problems.

The choice for the **50 % threshold** in the number-based particle size distribution establishes the identification of a nanomaterial based on a majority constituent. Whether the ‘right’ materials are captured can be assessed by looking at a set of materials, as has

been done in Section 3.2 of the Review-2 report, based on the data on some representative materials and information obtained through the stakeholder survey. Other materials have also been measured and reported in the activities following the same JRC report and have been considered in the review.

Several borderline cases have been identified in these reports, but as with any provision that embodies a quantitative threshold, borderline cases are to be expected. Their frequency or potential clustering of particular types of materials/products at or near the threshold value did not lead to the conclusion that the selection based on the default threshold of 50 % is unsound.

The principal borderline dilemma arises when the application of different measurement methods, different measurands, or even differences in sampling procedures lead to results with opposing conclusions. Therefore, as emphasised in chapter 2.8.1 of this SWD and in the Review-1 and Review-2 reports, it is crucial that operators remain transparent on the measurement methods and the data evaluation applied.

While in practice borderline cases seem to have been identified primarily with the upper size limit of 100 nm, they would nevertheless exist also with the lower limit of 1 nm, where the execution of a measurement is even more demanding. With regard to the value of the threshold, responses of the stakeholders continue to vary and include diametrically opposing views. As reported in Section 7 of Review-1, most respondents from trade and industry associations are concerned that many materials, produced since a long time and generally considered safe for use, would now fall under the definition of nanomaterial. Another concern is that the use of the default threshold (and in particular any value in a potential lowered threshold between 1% and 50%, see also below) would classify too many materials as nanomaterials, e.g., many industrial particulate materials are known to contain a small but significant fraction of particles in the nanoscale.

Alternatively, some stakeholders consider that the default 50 % threshold value is set too high, as even a small fraction of nanoscale particles may pose a potential risk and should correspondingly be covered by the definition to ensure such risk is adequately addressed.

As indicated already in the introduction (see 1.1), the definition is not intended to be set in relation to hazard/risk, but as a delimiter for a class of materials that could be expected to differ in properties from their 'bulk' chemically identical counterparts and thus may require specific scrutiny provided through nanomaterial-specific provisions. There is not enough knowledge, and too large physicochemical variety among nanomaterials, to carve out all-inclusive criteria and still be both implementable and not lead to 'false positive' classifications (i.e. include a significant number of materials for which scrutiny might not have been warranted). The default threshold particle fraction value of 50 % threshold seems to be a pragmatic and scientifically sound criterion for which the review did not identify systemic and scientifically underpinned reasons to deviate from. As argued above, decreasing this threshold in any significant manner would result in identifying significantly more materials as nanomaterials, as well as exacerbating the number of the respective borderline cases.

The definition in Commission Recommendation 2011/696/EU includes the **flexibility** to lower the threshold: "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 %...". Section 3.3. of the

Review-2 report assesses exposure, consistency and implementation considerations for this flexibility clause. The flexible approach impacts negatively on the transparency of the legislation addressing nanomaterials; materials may be regarded as nanomaterials or not, depending on the legislation. It also counteracts the intention of the definition that a material, which would be regarded as nanomaterial in one sector, will be given the same classification if used in another one.

In practice, it becomes increasingly difficult to provide effective implementation guidance and support, when this support needs to cater for a wide interval of thresholds. Last but not least, regulatory processes would have to be established to determine the variable threshold.

The possibility of having a flexible threshold, i.e., lowering the number size distribution threshold in specific cases and where warranted by concerns for the environment, health, safety or competitiveness from 50 % to a value of between 1 % and 50% will not solve the issues associated with the fact that the threshold has a fixed value. This means that the definition as a whole cannot cover any individual material not falling within the threshold but for which nano-specific considerations might be considered appropriate, regardless of the value of such a threshold. If a regulatory provision applying the definition is not capable to address this potential issue, allowing flexibility in the threshold would neither resolve it, but rather would bring a number of issues, as identified.

The Commission therefore considers it appropriate to remove the flexibility clause from the revised definition.

2.6.6. Materials explicitly included in the EC definition

Given the vast diversity of materials generally perceived as nanomaterials, the aim of the definition to capture nanomaterials with a single, common and verifiable approach is bound to lead to some 'known nanomaterials' being excluded from the approach. A pragmatic solution taken in the definition was to expand the core definition with a list of explicitly mentioned materials, namely fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions smaller than 1 nm. Based also on the compilation of data and information from the survey presented in Section 7 of the Review-1 report, Section 6 of the Review-2 report discusses a number of other materials that could be added to such list, and the approach itself.

Expansion of the list could be considered for materials with particles with external dimensions smaller than 1 nm and materials with particle sizes above 100 nm, as well as other materials presently excluded (e.g., nanostructured materials).

Members of the first subclass are potentially all particulate graphene materials with different morphologies and chemical form (nanoribbons, nanocones, nanodots, multilayer graphene, and graphene oxide), nanotubes (of chemical elements other than carbon) and nanoclays. For these types of materials, it has been considered that their common features can be effectively integrated in the definition by complementing the identified standard 'nanoscale particle' with rod-like and plate-like particles with at least one external dimension smaller than 1 nm, when comparing their total fraction with the 50 % threshold. The change has been provided for consideration in the targeted stakeholder

consultation reported in chapter 2.10 and is incorporated in the revised definition (see chapter 3).

Expanding above the upper limit of 100 nm or listing specific nanostructured materials is more complex. There are no known listings of materials from which one could populate the list with perhaps even the most uncontroversial additions, such as "particulate engineered nanostructures with external size above 100 nm with deliberate features at nanoscale". There is not even an agreed material identification scheme akin to chemical substance naming.

Based on the replacement of the existing listing with a generic inclusion (the specific case of fullerene single molecules is discussed in the chapter 2.7 below) and the absence of a further list of nanomaterial candidates, the present derogation can be removed from the definition.

2.6.7. Materials not perceived as nanomaterials but included in the definition

One of the most frequent issues reported is the unjustified identification of certain materials or sets of materials as nanomaterials 'only' due to the choice of the main elements of the definition. Section 3.2.3 of the Review-2 report discusses materials not perceived as nanomaterials, at least by some stakeholders. The reported arguments mostly focus on evidence of long-term safe use (i.e. lack of concern) again linking the definition to hazard and risk or inclusion of many/most insoluble materials due to their 'nano-tails' with a number-based fraction of nanoscale particles exceeding 50 %, even if their volume/mass fraction may be very low (argued as incidental and irrelevant).

These points have been addressed already in the previous chapter (1.1). The remainder of the cases can be associated with interpretative issues (e.g., liquid containing few incidental particles) and the corresponding need for clarification, addressed in the chapter 2.7 below.

2.6.8. Complementary elements and methods to facilitate implementation

The limitation of the definition to the external dimensions of particles is deliberate. Considering additional elements could significantly complicate the practical implementation of the definition. Complementary elements that would facilitate implementation have however been reviewed and are presented here or alternatively in the chapter 2.7, in case these complementary elements have actually been part of the established Q&A and implementation practice.

In depth compilation of related data and the assessment are available in several chapters of the Review-1 and Review-2 reports.

2.6.8.1. Application of information on volume specific surface area (VSSA) of the material

The EC definition presently includes a 'secondary definition' with which the identification of a nanomaterial through its VSSA value (i.e. when larger than 60 m^2/cm^3) is possible "*where technically feasible and requested in specific legislation*". 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 nanostructures, rather than from the surface of constituent particles inside aggregates or agglomerates.

Moreover, particle shape and size polydispersity can strongly influence the relation between the particle size and VSSA-based thresholds.

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 on identification of nanomaterials through measurements[16].

VSSA measurements can be considered as a tool for the exclusion of a material as a nanomaterial, avoiding additional (costly) measurements. Based on a large set of different commercial materials, the NanoDefine project demonstrated with great certainty, that materials with a VSSA equal or less than 6 m^2/cm^3 do not have the number-based particle size distribution of a nanomaterial and can be excluded from the definition without further consideration.

Both changes have been provided for consideration in the targeted stakeholder consultation reported in chapter 2.10 and are incorporated in the revised definition (see chapter 3).

2.6.8.2. Introduction of an additional criterion based on mass fraction

The option of introducing an additional criterion based on particle mass has been considered in the review, not to challenge the number-based PSD approach but to complement it for the purpose of excluding 'unlikely' nanomaterials based on the low mass fraction of nanoscale particles and is as such also presented in option 2 of Section 3.2 of the Review-3 report.

The measure has been subsequently excluded from further considerations as the required threshold that would be sufficiently validated (in analogy to the VSSA criterion) is unknown, but estimated to be extremely low due to the variety of possible distributions.

Using higher thresholds would effectively undermine the core definition and policy considerations associated with it, as it would be providing a possible driver for exclusion of a significant number of materials based solely on the presence of a limited number of large particles.

2.6.8.3. Permission to only measure particles below 100 micrometres

This measure is considered here, unlike other issues related to measurements, as it would require reference in the definition itself. Excluding counting the particles with at least two orthogonal external dimensions above 100 micrometres, which are not themselves 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 (see also 2.7.2) and a larger solid product, such as a large material sheet that should not be covered by the definition.

In the targeted stakeholder consultation, the measure did not receive unequivocal support (see 2.10). Based on the comments received, it was concluded that the measure should be employed, however, a specific guidance will be required to allow for a responsible use of this provision.

2.7. Need for clarification of the terms and concepts in the definition

Since the very introduction of the Recommendation and the publication of related Q&A on the DG ENV website (Q&A was considered satisfactory only by one third of

respondents in the survey reported in Section 7 of the Review-1 report), requests for clarification and changes to the definition have been made. While some issues with core elements of the definition have already been presented above, Section 4 of the Review-2 report compiled issues requiring further clarification, in guidance or another interpretative document, or by changes to the definition itself. The report splits them into four blocks: clarification on purpose, scope, terms used, and implementation.

Issues on the purpose and scope are addressed in chapter 2.6; so is the clarification on how to implement the definition, addressed also partly in chapter 2.8 with regard to analytical challenges, whereas, guidance considerations are covered in chapter 2.9. What remains are the differences in understanding of the core terms, individually listed below. They may influence both the understanding of scope, as well as the way how the definition is to be implemented.

2.7.1. When does a material 'contain' particles?

This issue has been reported by several respondents to the survey in 2013, despite the clarification provided in the Q&A document (Questions 3, 10, 11 and 18), stating "*if a nanomaterial is used amongst other ingredients in a formulation the entire product will not become a nanomaterial*".

Some confusion may have arrived from the difference in the translations of the original version of the Recommendation (in English), where for example the French, Spanish, German, Italian, and Swedish versions use words which are equivalent to "*contain*", whereas the Dutch and Danish versions use words equivalent to "*consist of*".

Calling a material a nanomaterial is making a statement about the material as a whole. Therefore, when judging whether a material is a nanomaterial, it is not sufficient that the material "*contains*" a fraction or phase that has significant nanoscale aspects. Instead, the material should be evaluated based on what it mainly "*consists of*".

The change to the wording in the new definition has been proposed accordingly.

2.7.2. What is a particle?

An important issue to consider in the context of nanostructured materials is the definition of "*particle*" and its interpretation in different contexts. Section 4.3.1 of the Review-2 report provides an overview of definitions of the term "*particle*", which vary even between standards of the same organisation (e.g., ISO).

Currently, the EC definition employs the definition from the withdrawn ISO standard ISO 14644-6:2007: "*Particle - minute piece of matter with defined physical boundaries*". The same definition was also used in the withdrawn CEN ISO/TS 27687:2008 standard, one of the earliest ISO Technical Specifications addressing terminology in nanotechnologies. This ISO definition further specified that a physical boundary could also be described as an interface and that a particle can move as a unit.

None of the ISO definitions provides a size limit above which a discrete piece of matter would not be called a particle anymore, "*minute*" and "*small*" being unprecise qualifiers.

The definition applied also does not take any position as regards a single molecule (not) being a particle. There is no reference to single molecules in the Recommendation 2011/696/EU, but the corresponding Q&A clarified that single molecules, even when

exceeding 1 nm, should not be considered as particles. This put the definition in slight internal mismatch regarding the fullerenes. Under strict reading, fullerenes larger than 1 nm in diameter would not need to be identified as nanomaterial, because they are molecules, whereas the smallest (those under 1 nm) would be nanomaterials on the basis of the derogation in Point 3.

To identify a nanomaterial with the definition is to measure the external dimensions of its constituent particles. The Commission interpretation of the particles addressed by the definition (Q&A, also the Staff Working Document[31] accompanying the EC's Second Regulatory Review on Nanomaterials[32].) have consistently followed the defined objective, restricting implementation to nano-objects/particles with a defined, rigid shape, thus in essence solid nano-objects. The highly dynamic nature of the external dimensions of non-solid objects that could also be considered particles, such as micelles or nanoscale droplets in emulsions, would prevent the use of external dimensions as the defining property.

Can (clusters of) molecules such as proteins, complex carbohydrates (i.e. starch, fibres) and other macromolecules with external diameters above 1 nm be considered as nanomaterials? Can the concept of *'solid'* be reasonably applied in such context? Section 4.3.1 of the Review-2 report proposes to consider entities as particles if their physicochemical properties would not change drastically when one such entity is divided in two new entities. Consequently, if their external dimensions are in the nanoscale, they would be considered as nanomaterial. For example, a polystyrene nanoparticle would just break into two pieces of polystyrene that could therefore be considered a nanomaterial. In contrast, breaking a protein would lead to two materials (protein sub-units and eventually amino acids) with different functions. Hence, it would not be called a particle or considered as a nanomaterial. On the other hand, protein clusters which can be disintegrated into individual, equivalent protein constituents, would consequently fall under the scope of the definition

The Commission considered different options to address the points above through a more comprehensive definition of particle (see Section 2.7 in the third JRC report), but finally decided to maintain the current particle definition and opted for only two changes:

- to explicitly exclude single molecule as a particle in the supporting definition of *'particle'*, and
- to restrict application of particle size distribution in the main text of the definition to solid particles (as opposed to liquid particles encountered in emulsions or even gaseous particles, e.g. bubbles).

The changes should provide a clear marker with regard to the scope of the definition. However, it is acknowledged that further interpretative guidance is required to advise application and possible borderline situations (see 2.9).

2.7.3. Unbound state and physical boundaries

The two terms, used in the definition when referring to individual particle, have received further calls for clarification, also due to the fact that the particles may not be the only

[31] SWD(2012)288

[32] COM/2012/0572 final

constituents of the material. Section 4.3.2 of the Review-2 report provides an interpretation linked to the thermodynamic description of a particle in its environment.

The role of the term *'unbound'* in the definition is only to convey the distinction between the individual particles and the particles that may have been aggregated or agglomerated into larger particles/structures. The review concluded that the confounding reference to unbound state can simply be eliminated through better drafting, addressing in the same change also the inclusion of the concept of 'constituent particles' directly in the definition (see 2.7.4 below).

While different solutions were considered in an attempt to better define the term 'physical boundaries' used in the particle definition (see Section 2.7 of the Review-3 report), it has been considered that clarification, supported also by advice regarding implementation, is best described in guidance (see 2.9).

2.7.4. Agglomerates and aggregates, constituent particles

As the Section 4.3.3 of the Review-2 report stipulates in more detail, the definitions for the two terms applied in the definition, while following part of the ISO definitions, are very succinct and to some extent ambiguous, e.g. including terms such as *'weak'*, *'strong'* and *'fused'* that would by themselves merit own definitions. Any attempt to distinguish between the two cases in a material would require further clarification, specification of thresholds, etc. It is likely that such specification would become to some degree material-dependent and that it would increase the number of borderline cases. Both terms are also often used incorrectly or not in accordance with the ISO definition or with the interpretation of the Recommendation 2011/696/EU.

In the definition, the difference between the two has no impact on the outcome. They both serve in the same way, as vessels for '**constituent particles**'. Further clarification of the two terms is therefore not necessary.

Survey respondents (especially industrial associations or individual companies) argue that considering aggregates as well as agglomerates as nanomaterials includes too many materials. Further proposals are made to distinguish the two, in particular, in order to define aggregates (or specific subclass of aggregates) for which constituent particles would no longer need to be identified and counted in the PSD. The rationale provided includes the (relevance of) aggregate constituents in the toxicological profile, and measurement challenges. The former argument is discussed in chapter 2.6.5, while the latter has been subject to extensive assessment (see chapter 2.8 below with references to the Review-1 and Review-2 reports), leading also to propose a modification to the text to restrict the application of PSD determination to '*identifiable constituent particles*', acknowledging practical limitations.

Section 4.3.3 of the Review-2 report identifies a possible question of interpretation when it comes to the difference between an aggregate and a microparticle that is built as a deliberate assembly of different nanoparticles. The term aggregate is usually reserved for the assemblies of particles of the same nature originating from a single production process, and not for the bottom-up assembly of multiple particles of different nature and with different functions, or, e.g., the production of multi-layered core-shell particles. If overall external dimensions of such a construct fulfill the definition criteria, this would result in a 'multicomponent' nanomaterial. A larger construct deliberately assembled

from multiple particles of different function and nature by bottom-up technique, it would most likely be more an article than a "material". However, when such objects release individual nano-components, those can form a nanomaterial.

The report also describes the confusion with the use of the term '**primary particles**'. In ISO terminology, it is defined as "*original source particle* of agglomerates or aggregates or mixtures of the two". Despite having undergone a growth process, fusion, covalent binding or coalescence with other particles, primary particles can sometimes still be inferred from the shape and structure of a larger particle. However, these inferred primary particles have often lost their individual existence and their properties (e.g., size) are disassociated with the 'original source particle'.

Instead of 'primary particles', the EC definition uses the term '**constituent particles'** but does not explicitly define it. Q&A and other supporting documents effectively describe it as an integral component of a larger particle (read: aggregate or agglomerate), a description taken forward also by ISO in further development of the terminology (see ISO/TS 80004-2:2015, Nanotechnologies — Vocabulary — Part 2: Nano-objects). For this reason, primary particles are often not constituent particles. This observation also limits to some extent the potential to use knowledge on the manufacturing process as an alternate way to apply the definition (see 2.8.2).

As proposed also by some respondents in the stakeholder surveys, an approach to address these issues could be to step back from the concept of constituent particles and rather use the result of a defined dispersion procedure as the arbiter which particles should be included in the PSD, i.e. the concept of "smallest dispersible units". While it may relieve some experimental challenges (see 2.8.1) it would introduce new demands to define and validate dispersion protocols for such purpose, with likely need for consideration of different conditions for specific materials.

The review concluded that the 'constituent particle' approach should be maintained. However, since 2011 the work on dispersion protocols, also for purposes beyond the definition (e.g., characterisation as part of toxicological testing), importantly supports consistent implementation of the definition, is already an integral part of the supporting documentation and should be included in the guidance (2.9).

The lack of a definition of '*constituent particle*' can most simply be addressed by redrafting part of the main definition, including the phrase within: *" ...consisting of solid particles that are either present on their own or as identifiable constituent particles in aggregates or agglomerates and ...*".

2.8. **Analytical implementation and challenges**

2.8.1. Principal methods, their application and known issues

Technical work identifying the applicable measurement methods and procedures, and their limitations, represents the most substantial part of the Review-1 and Review-2 reports. It is also under continuous review, with every single technical report prepared by the JRC[15,16,17] that updates previous knowledge with new data, methods and insight. The OECD Test Guideline No. 110 on particle size distribution measurements, of which an amended version is likely to be published in 2022, also includes explicit considerations and key steps of sample preparation and measurement which can be of use in the context of the EC definition.

Readers interested in the current status of analytical methods are invited to reflect particularly on the two JRC reports[16,17].

A high-level conclusion of the review is that, for many nanomaterials, methods to implement the definition exist and are accessible, at least to the extent expected to cover regulatory needs. There is universal method available can measure and identify all existing nanomaterials, and one will most likely never exist, considering the breadth of materials to be covered. However, there are a number of relevant standardised methods, and guidance supporting selection of the appropriate method(s), also in a tiered approach to minimise resources required. While a guidance (2.9) should list those methods, it has not been considered necessary to include a positive list of methods in the Recommendation. The same applies for performance indicators such as detection limit, working range, and measurement uncertainty. With the availability of horizontal guidance, the likelihood for divergence between regulatory sectors also with regard to expectations regarding performance will be limited.

Highly advanced and specialised analytical instruments (e.g., electron microscope), which may be required at least for certain types of materials, are not available in every laboratory tasked to identify a nanomaterial, but a number of accredited contract laboratories provide the service. Within the mandate of the NanoDefine project, the NanoDefiner e-tool was developed.[33] This tool includes a decision support framework that can help in selecting the most suitable method for a certain type of material under specific conditions, and in reporting the outcomes.

One should note that at least for the purpose of fulfilling regulatory requirements, taking the measurement to apply the EC definition of nanomaterial should not be seen as 'routine' for economic operators – its application is mostly required during regulatory dossier preparation and not necessarily for frequent subsequent quality control, let alone as a monitoring parameter in a manufacturing process loop. In the latter cases, proxies (see 2.8.2) can likely be identified that adequately cover the needs. Methods may need to be more routinely applied by the enforcement authorities.

The following changes to the definition were at least in part triggered by issues related to analytical methods and their implementation:

- association of horizontal guidance (see 2.9);
- inclusion of the word 'identifiable' when it comes to constituent particles;
- threshold particle fraction value of 50 % and removal of the flexibility in this threshold flexibility: allowing for a single threshold is importantly strengthening the ability to optimise analytical approaches, simplifying protocols, minimising uncertainties and maximising reproducibility;
- focus with regard to supporting facilities such as fit-for-purpose certified reference materials and representative test materials for calibration and quality assurance purposes.

2.8.2. Alternative analytical routes to implementation

The most explicit alternative analytical route, included in the EC definition, is the use of volume specific surface area (VSSA, presented extensively in Section 5.4.1 of the

[33] Brüngel, et al., NanoDefiner e-Tool: An implemented decision support framework for nanomaterial identification, Materials, 12,2019, 3247

Review-2 report, which has been addressed already in the chapter 2.6.8.1. There are however additional measurement options, covered by initial reflection in Section 11 of the Review 1 report and by assessment in Section 5.4 of the Review-2 report. Both aspects are summarised below.

A common conclusion of the review for any of these methods and measurement options is that while it should not be necessary to explicitly exclude them as acceptable alternatives, their range of applicability is likely to be very narrow and limited to few selected use cases only. None of the methods warrant a reference in the definition itself, but they should be identified in the Guidance at least for the purpose of avoiding their inadequate application.

2.8.2.1. Conversion of other size distributions to particle number-based size distributions

The EC definition relies on methods and measurement procedures that can count how many constituent particles are within and outside the 1 nm to 100 nm particle size range. Many of the commonly used methods are 'ensemble methods' which means that they are unable to count individual (constituent) particles. As a result, the principal PSDs obtained by ensemble methods are based on other metrics, i.e., functions that define the relative amount of the detected particles based on their mass or on the intensity of a measurement signal. Ensemble methods can include both non-fractionation (e.g., dynamic light scattering, DLS, or laser diffraction, LD) and fractionation methods (e.g., centrifugal liquid sedimentation, CLS, or field-flow-fractionation combined with dynamic light scattering, FFF/DLS). To use the results of these methods for assessment against the EC definition requires a mathematical conversion of the data from their original metric into an equivalent particle number-based PSD. It is also a condition for nearly all ensemble methods that full dispersion into constituent particles is achieved as remaining aggregates/agglomerates are detected as single particles.

Reliable conversion between PSDs based on different size metrics requires in practice that all particles have the same (regular) shape and approximately the same size, except for fractionation methods which can, at least in principle, deal with polydisperse samples. In addition, a correct conversion requires that certain intrinsic material properties (e.g., complex refractive index) are accurately know. These properties are usually only known for the bulk material and not for its nanomaterial counterpart.

These conditions may be fulfilled for some materials that are manufactured with a very specific purpose, but for them, the question whether they are nanomaterial or not, is most likely trivial. The majority of materials will not have the level of monodispersity (for non-fractionation methods) and regular particle shape required for reliable data conversion, and will often contain remaining aggregates and/or agglomerates, limiting the usefulness of converted data.

In specific cases, unconverted data may, however, be used for positive nanomaterial screening (strategy applied also within the NanoDefiner e-tool), and converted data might have an application in batch quality control.

2.8.2.2. Simplified binary binning methods

Binary binning methods correspond with methods based on separation (filtration or other) of nanoscale particles within the sample, enabling ‘simple’ counting in the two

bins[34] without further need for size determination. No such method that could be applied for a variety of materials, well-defined external particle size and the 100 nm threshold (issue with dispersion of constituent particle indicated in 2.8.2.1 apply) is known at present.

2.8.2.3. Considerations of manufacturing information

Section 5.4.4. of the Review-2 report lists different manufacturing methods and explores how their process parameters dictate external particle size of the manufactured materials. While modelling of some processes is possible, it can be used for process control even if determining the achievement of the desired result still relies on careful characterisation. The evaluation illustrates that many production processes are in fact optimised to produce powder materials that will almost certainly fall within, or outside, the recommended EC definition, and that a significant number of products would not need to be re-examined to determine their nanomaterial classification. The particle number–based PSD would in many cases still be required to fulfil characterisation requirements e.g. under REACH.

Additionally, some but not all bottom-up processes are suitable for analysis of constituent (or primary) particles before aggregation/agglomeration takes place post-production, thereby offering an opportunity for more reliable and possibly less costly classification against the EC definition.

2.8.2.4. Read-across from information on other materials

The concept is well-known in the chemical community, but is mostly reserved for the hazard identification based on structural similarities. The Review-2 report (Section 5.4.5) hypothesises on analogue concepts of ‘read-up’ and ‘read-down’, allowing to model, on the basis of additional proxy information available for two materials, whether the median value of the size distribution of the target material is higher or lower relative to the source material with known media size. The approach could potentially be applied with product families, relating information on individual members to a carefully characterised lead product.

Interesting as a concept, lacking also the driver of avoiding animal use and required time to perform higher tier animal studies, it is likely that full TEM analysis would be a faster and more economic approach than an extensive read-up justification study, unless large numbers of materials would be covered by the study.

2.9. Case for a horizontal guidance

The chapters above have indicated at several instances the need for dedicated guidance. Guidance can provide additional information that helps understand and implement the EC definition, thereby keeping the actual definition lean and placing detailed explanations and interpretations elsewhere. It also allows for a quicker adaptation to evolving circumstances such as technical and material development, as guidance documents do not require the same decision process as formal pieces of legislation.

[34] Analog method using air cyclon is employed in measurement of particulate matter of different micrometer sizes in air.

Individual legislation incorporating the definition is usually complemented by guidance. Such sector-specific guidance should include the application of the nanomaterial definition in the regulation, as it may provide proper framing in relation to the object of application (e.g., active substance under BPR), the nanomaterial-specific provisions and reporting.

On the other hand, it would be an inefficient use of resources and a potential source of divergence and inconsistency across sectoral applications, to duplicate common information across sectoral guidance when a single horizontal guidance could be employed and kept regularly updated to address new information, technical developments, as well as any emerging questions on implementation.

While it may not address (all) sector-specific issues, horizontal guidance requires general acceptability across all sectors and actors implementing the definition. Its development and update must be transparent and adoption to some degree formal (e.g., Commission Notice), ensuring wide stakeholder participation from across all sectors.

Horizontal guidance on the following issues could be envisaged:

- Clarification, also via illustrative cases and a more in-depth reference to internationally standardised terminology, of the terms and concepts employed. This should provide actionable advice for decisions on scope, e.g. is a material a collection of single molecules, particles or nanostructure(s).
- Good measurement practice, listing applicable measurement methods and procedures, their typical performance characteristics, measurement uncertainty and limitations, to guide appropriate selection and application, as well as corresponding sample preparation. It should provide advice on issues like selection of appropriate determination of external dimensions of particles and information on the detection and measurement of identifiable constituent particles. It should include consideration on the use of VSSA, tiered approaches (decision trees) and alternative methods (e.g., data conversion).
- Give guidance on minimal (adequate) reporting elements regarding the application of the definition.

JRC has already published several reports[15,16,17] supporting implementation of the definition in Recommendation 2011/696/EU. These will constitute a basis for the horizontal guidance. Within the Commission, JRC is uniquely placed to develop the guidance and keep it under periodic review.

2.10. Targeted stakeholder consultation – comprehensive summary of responses and feedback

From the 6th of May until the 30th of June 2021, the Commission carried out an online targeted stakeholder consultation. The consultation aimed at collecting data on how stakeholders perceive the Commission's proposals to revise the nanomaterial definition included in the Commission Recommendation 2011/696/EU. A total of 137 responses were received, of which 74 were from industry and trade associations, 20 from citizens, 17 from governments/competent authorities, 10 from public (or partly public) research organisations, 8 from NGOs and 8 from private service organisations.

Evidence from the stakeholder consultation confirms, in general, that the proposals made by the Commission are relevant and will reduce legal uncertainty by eliminating ambiguity about specific terms used in the EC definition (2011/696/EU). At the same

time, many stakeholders strongly called upon the Commission to provide comprehensive guidance on the (new) terminology used in the new Recommendation and on measurement aspects that support the implementation.

Opposition, however, was received from NGOs who are concerned about the absence of a clear link with hazard and risk management. The Commission acknowledges and appreciates the precautionary position taken by the NGOs, and some other stakeholders, but reminds and reassures that specific provisions against potential risks and hazards from nanomaterials and conventional materials will be adopted by sectoral legislation.

The results of the targeted stakeholder consultation with a detailed statistical analysis of the structured responses (including analysis between and within the different types of stakeholders), a summary compilation of the unstructured (open question answers) and the summary response by the Commission services can be found in Annex 1.

3. NEW COMMISSION RECOMMENDATION C(2022) 3689

3.1. The new Recommendation and the description of changes to the definition compared to 2011/696/EU

The new Recommendation follows the Commission's legal drafting, with recitals providing short context (objective of a horizontal definition, replacement of the Recommendation 2011/696/EU and rationale for the individual points in the main legal text, also in comparison to the definition being replaced).

The definition part of the main text stands as follows:

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

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

   (b) the particle has an elongated shape, such as a rod, fibre or tube**,** where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;

   (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.

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

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

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

   (a) 'particle' means a minute piece of matter with defined physical boundaries; single molecules are not considered 'particles';

(b) ‘aggregate’ means a particle comprising of strongly bound or fused particles;

(c) ‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.

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

(a) by the Commission, when preparing legislation, policy programmes or research programmes and when implementing such legislation or programmes also with other Union institutions and agencies;

(b) by Member States, when preparing legislation, policy programmes or research programmes and when implementing such legislation or programmes;

(c) by economic operators, when preparing and conducting their own policies and research.

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

Point 1 carries the definition of nanomaterial and is supported by the definition of core terms under Point 2. The changes in the “new” definition in comparison to the “old” definition in the Recommendation 2011/696/EU go as follows (additions/modifications are underlined; deletions not visible in the text above are presented at the end of the list):

- *‘contain’* has been replaced with *‘consist’.*
- Only *‘solid’* particles should be considered.
- ‘*in an unbound state*’ has been replaced by ‘*on their own*’.
- ‘*as an aggregate…*’ has been replaced ‘*as identifiable constituent particles in aggregates…*’.
- Point 1 b) added including thin (< 1 nm) elongated particles to the tally of nanoscale particles, if they are not included already.
- Point 1 c) added including thin (< 1 nm) plate-like particles to the tally of nanoscale particles, if they are not included already.
- Condition is added that particles larger than 100 μm need not be counted.
- Condition is added to exclude materials with very low specific surface area by volume (< 6 $\underline{m^2/cm^3}$); use of volume specific surface area (VSSA) in Point 5 of in the Recommendation 2011/696/EU has been deleted.
- Clarification is added that single molecules are not nanomaterials.
- Flexibility provision in Point 2 second paragraph of the Recommendation 2011/696/EU to “*In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % replace by a threshold between 1 and 50 %*” has been deleted.
- Derogation in Point 3 of the Recommendation 2011/696/EU including fullerenes, graphene flakes and carbon nanotubes, has been deleted.

Rationale for the consideration of the above changes has been presented in the review chapter above, in particular chapters 2.6.6 (Materials explicitly included), 2.6.8.1

(VSSA), 2.6.8.3 (Measuring larger particles), 2.7 (Needs for clarification) and as well the 2.10 (Feedback to targeted stakeholder consultation) and will not be repeated here.

3.2. Horizontal guidance and the review clause

As explained in chapter 2.9, the Commission will develop horizontal guidance to support the implementation of the new definition. It will organise consultation with users prior to publication of a Commission Notice containing the Guidance. Afterwards, it will monitor its use and set periodic review to account for the technical progress in the future.

The definition itself should at some point in time be reviewed, and if deemed necessary, revised again. A moratorium on the revision of at least five years is recommended to provide required stability and allow uptake in the legislation.

3.3. Analysis of impact of the changes to the definition of nanomaterial

To a large extent, the changes represent clarifications and codification of already established best practice. The impact of these clarifications as well as the supporting Guidance is expected to bring both minor increases and decreases in the number of nanomaterials identified. It cannot be claimed that these nanomaterials are caught 'in addition' or 'lost', as the scope of the definition due to these changes has not really changed.

The change in scope triggered by the replacement of a material-specific derogation with a more generic addition of similar type of particles will however result in an increase of materials identified. This has been anticipated (see several identified classes of materials in chapter 2.6.6) and was also investigated via a separate Part 3 of the targeted stakeholder consultation (see chapter 2.10 and related Annex 1) where respondents identified 8 additional materials.

4. IMPLEMENTATION AND USE

4.1. Uptake of the revised Recommendation – generic considerations

The application of a horizontal definition in different sectors is achieved by the 'uptake' of Recommendation C(2022) 3689 in the sectoral legislation with nanomaterial-specific provisions.

The formal process is set by legal provisions in each individual piece of legislation, the discussion of which is beyond the scope of this staff working document. It is also expected that the timing of the inclusion (or in some cases revision) of the definition will be determined by the sectoral consideration.

The changes to the definition, compared to the Recommendation 2011/696/EU, facilitate direct referencing of the Recommendation by the legislation, which can be done, e.g., as follows: "An [ingredient/substance/product] is considered a nanomaterial/nanoform under this legislation when it fulfils the definition of a nanomaterial in the Recommendation C(2022) 3689".

Direct reference is a recommended approach, but it does not exclude the possibility to copy the text of the definition, in which case Points 2-3 should be taken in full, without changes. Acknowledgment of the provenance of the text ("On the basis of…" or similar)

and the reference to Point 4 (guidance) is recommended to be included to avoid any misunderstanding.

As can be seen in the Point 4 of the revised Recommendation: "*…set out in the latest recommendation or other act providing a definition of nanomaterial for horizontal policy and legislative use adopted by the Commission or Union legislator is used…*", the Commission is not excluding that Recommendation may be in some time in the future updated again or even effectively replaced by an act carrying the definition for EU horizontal policy and legislative use. In such case, the direct reference as mentioned above would even allow 'dynamic link' in case of future revisions of the definition.

In cases where the specific provisions are expected to be triggered for nanomaterials only where additional conditions are fulfilled (e.g. insoluble nanomaterials only), the wording should state that clearly to preserve the horizontal identification as nanomaterial. The same applies to potential triggering of same or similar specific provisions also for other classes of materials or even individual materials; similar provision should not be confounded by same identification as nanomaterial.

The Guidance should be explicitly referred to in any sectoral implementation support (guidance etc.).

Annex 1 Targeted Stakeholder Consultation

5. PROCESS AND CONTENT

The Commission invited interested and affected groups, such as industry, citizens, governments/competent authorities, NGOs, private service providers and (partly) public research organisation, to provide written contributions on the proposed possible amendments to the nanomaterial definition of Commission Recommendation 2011/696/EU.

A web-based, targeted stakeholder consultation was set up using the EUSurvey tool.[35] The consultation was launched on May 6 and closed on June 30, 2021.

The consultation, which provided the participants with a summary of the interim review findings and links to relevant documents and reports, aimed to:

- verify or complement the findings of the review;
- gather precise and structured technical feedback on the identified technical elements of the definition that could be addressed by changes to the definition;
- gather input on the impact of the changes under consideration.

Following the introduction, instructions for the respondents, and the default section with general questions about the respondent's profile, the questionnaire included 19 questions spread over three structured response sections or 'parts':

- Part 1: general observations;
- Part 2: the individual elements considered for revision;
- Part 3: on the identification of materials affected by a possible extension of the derogation currently focused on carbon-based materials and the resulting impact;

The bulk of the survey focussed on Part 2 and Part 3. Questions were either closed-ended or open-ended. The latter allowed stakeholders to provide further depth and understanding through free text answers.

The Commission received 137 contributions[36] submitted through the EUSurvey platform (four sent by e-mail due to IT issues). The replies of the individual respondents, are listed in a spreadsheet whose link can be found on the following website https://ec.europa.eu/environment/chemicals/nanotech/review_en.htm.

The following sections provide overall statistics and findings on the consultation responses.

6. METHODOLOGY

To allow a thorough analysis of the contributions received, the elaborated two-tiered methodology described below was applied.

All contributions received through the EUSurvey platform were exported and collated in an Excel file. Two identical submissions (by the same respondents) were deleted and two contributions received by email were manually retrofitted into the Excel spreadsheet.

[35] https://ec.europa.eu/eusurvey/home/welcome

[36] For determining the number of stakeholders, each respondent was counted only once.

Tier 1:

For each closed-ended question in the consultation, the contributions were first parsed into the contribution elements that were relevant for answering the given question. In the next step, the contributions were broken down into three different main categories:

- type of organisation or stakeholder category;
- topic area of most interest;
- size of organisation *(only for industry).*

Based on the respondents' declared general information (Part 1), stakeholders were sorted and categorised in the following stakeholder groups:

- citizen or general public;
- government/competent authority (e.g., EU/national/regional authority, agency);
- industry (e.g., company, trade or business association);
- NGO (e.g., environment, public health, animal welfare, other/multiple);
- private service provider (e.g., desk consultancy, contract research organisation);
- public (or partly public) research organisation (e.g. academic, mixed research consortium).

Given the fact that the Recommendation provides an overarching definition for the term nanomaterial for use in a regulatory context, the 137 respondents were additionally categorised according to their picked topic area of most interest. Areas of most interest consisting of only one respondent (e.g., biocides and plant protection products, energy, sports materials) were merged with the group "Other (incl. multiple/general)".

The responses received for the closed-ended questions that were based on discrete ordinal Likert-type items[37] were converted into an equally spaced 5-point Likert scale, i.e. 5 = strongly agree, 4 = mostly agree, 3 = don't know/no opinion, 2 = mostly disagree, 1 = fully disagree, 0 = no answer. In order to give broad estimates of agree or disagree, the top two boxes (i.e. sum of 'strongly agree' and 'mostly agree') and the net top boxes (i.e. difference between top box and bottom box, with result in the range of -100 % to 100 %) were calculated. In addition, basic descriptive statistics such as the arithmetic mean, standard deviation and median were calculated from the frequency data. The average level of sentiment was assessed based on the arithmetic average (calculated on the number of respondents that provided an answer to the question). The coefficient of variation (CV), which was obtained by dividing the standard deviation by the arithmetic mean, represents a measure of consistency or dispersion of the respondents' results. The validity of transforming ordinal level data into an interval scale, and the use of parametric tests for quantifying such transformed data, is considered suitable when measuring less concrete concepts.[38]

Finally, the consultation results were displayed in tables, pie charts, and regular and diverging stacked bar charts allowing visualisation of the consultation results. For tables and graphs that show frequency distributions it should be noted that the percentages were rounded to the nearest whole number and they therefore may not always add to 100 %.

[37] R. Likert, A technique for the measurement of attitudes. Arch. Psychology, 1932, 22:55.

[38] G. Norman, Likert scales, levels of measurement and the "laws" of statistics, Adv. Health Sci. Educ. Theory Pract., 2010, 15:625-32.

Tier 2:

Any trends or patterns identified, the rationale behind the answers to the closed-ended questions as well as additional information and insights, were further analysed qualitatively by reviewing the textual responses of the corresponding open-ended questions. [39]

All individual comments have been considered and, where relevant, reflected in the revised recommendation. A summary feedback is also provided under each individual heading.

7. OVERVIEW OF RESPONDENTS' PROFILES

"Please indicate whether you consent to publication of all information either including or excluding personal data."

Of the total 137 respondents, 57 % gave consent to publish all information in the submitted contribution, including personal data (name and email, country of residence, profession, self-declared area of competence and information about the represented organisation). The remaining 43 % gave consent to publish all information in the submitted contribution except explicitly requested personal data. All respondents declared that none of the submitted information was under copyright restrictions.

"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.)?"

The 137 respondents were categorised into six different stakeholder groups. Most respondents were from industry (54 %) as shown in ***Table 2***, but it is noticeable that almost 15 % of the contributions were submitted by individual citizens (i.e. in their own name). The third largest group included the respondents from governmental authorities (12 %). The remaining 19 % were almost equally spread over the NGO, private service provider and public research organisation stakeholder groups.

The industry group included a mixture of individual companies (47 %) and trade/business associations (53 %). Almost 32 % were large companies (> 250 employees), about 17 % were medium-sized (51-250 employees), almost 32 % were small companies (11-50 employees) and about 19 % were micro companies (1-10 employees).

Table 2: *Number and percentage of respondents (total n = 137) categorised in stakeholder groups.*

Stakeholder group	Number	Percentage (%)
Citizen	20	15
Government/competent authority	17	12
Industry	74	54

[39] G.W. Ryan, R.H. Bernhard, Techniques to identify themes in qualitative data, Field Methods, 15:85-109.

NGO	8	6
Private service provider	8	6
Public research organisation (or partly public)	10	7

"Self-declared area of competence"

As illustrated in ***Figure 1***, almost a quarter (23 %) of the respondents selected industrial chemicals as topic area of most interest, followed by products safety, workers and/or consumer protection (15 %), cosmetics (12 %) and nanotechnology (12 %). The former two groups were mainly formed by industry (77 % for industrial chemicals and 89 % for cosmetic products).

"Please indicate the Member State (or EU) and the name of the institution"

Respondents from 21 countries replied to the consultation (***Figure 2***). The large majority (84 %) of respondents were headquartered in EU-27 Member States. A minor fraction (3 %) of replies were received from EFTA countries (Switzerland and Norway). The remaining respondents (13 %) were headquartered in non-EU/-EFTA countries such as the United Kingdom, United States of America, Japan and Australia.

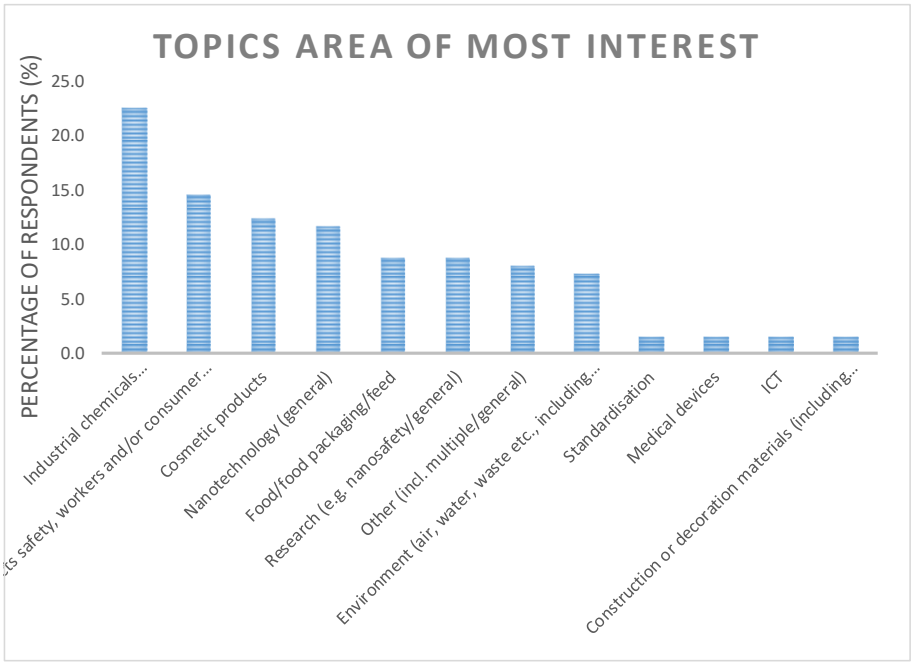

Figure 1: *Topics area of most interest picked by the respondents.*

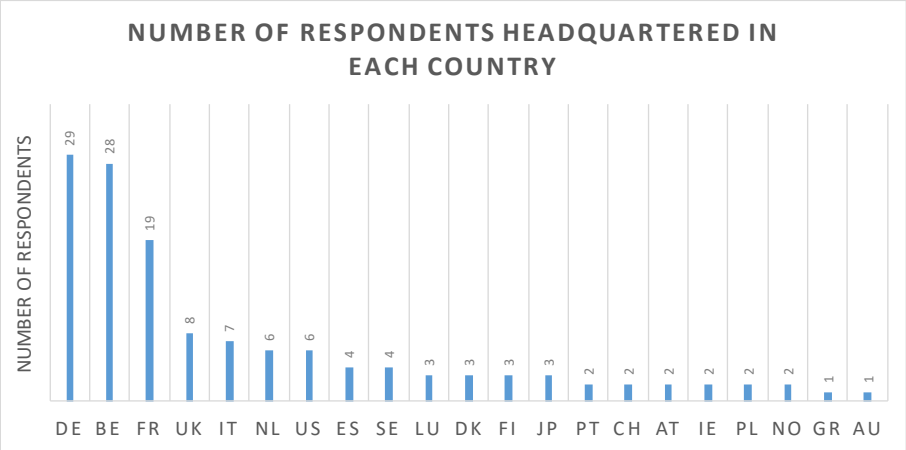

Figure 2: *Number of respondents headquartered in each country ranked in descending order.*

About 42 % of the replies received were from organisations registered in the Transparency Register[40]. A total of 54 unique Transparency Register numbers were identified from the information received from the respondent and by consulting the Transparency Register for those respondents who did not provide a register number.

Breaking down the respondents group by organisation size (**Figure *3*** left) shows a good mix of micro (1-10 employees), small (11-50 employees), medium-sized (51-250 employees), large (251-1000 employees) and very large (>1000 employees) organisations. It should be noted that this break down is based solely on the organisations' numbers of employees/members. It does not take into consideration their turnover or balance sheet totals, which is normally used to define small and medium-sized (SME) enterprises. Respondents who selected "Unknown" were either citizens or officers from government/competent authorities. When considering only the industry segment (***Figure 3*** right), then notable shares of 32 % and 24 % are seen for small and very large organisations, respectively. Slightly lower shares of almost 20 % are found for micro and medium-sized organisations.

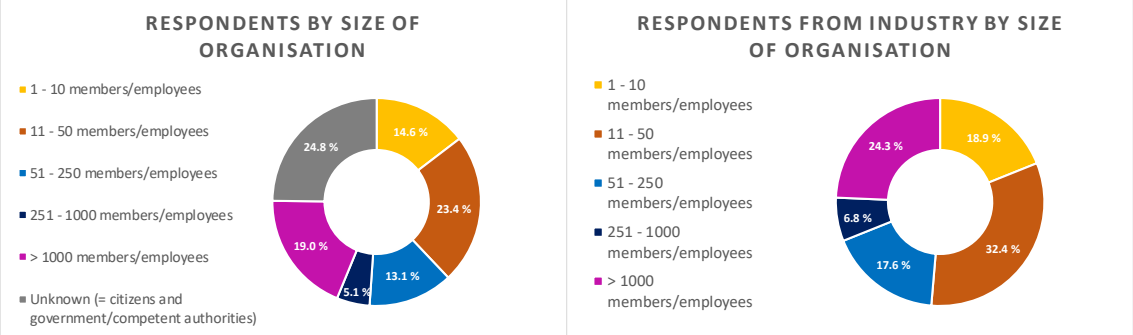

Figure 3: *Size of organisation by all respondents (left) and by industry segment (right).*

The questionnaire consisted of three distinct sections or parts (see 4.2). ***Figure 4*** shows how the respondents were distributed between the three main sections of the questionnaire. The large majority of respondents engaged in providing feedback to Part 1 (general observations) and Part 2 (individual elements considered for revision). About

[40] https://ec.europa.eu/transparencyregister/public/homePage.do

42 % replied to Part 3 (on the possible extension of the derogation currently focused on carbon-based materials) and 26 % responded in the final open question providing space for any additional observation. After having completed Part 1, 10 out of the 137 respondents proceeded directly to the final question. These respondents did thus not provide feedback on the bulk of the survey. Evaluating the composition of this minor group did not reveal any trend towards a specific type of organisation.

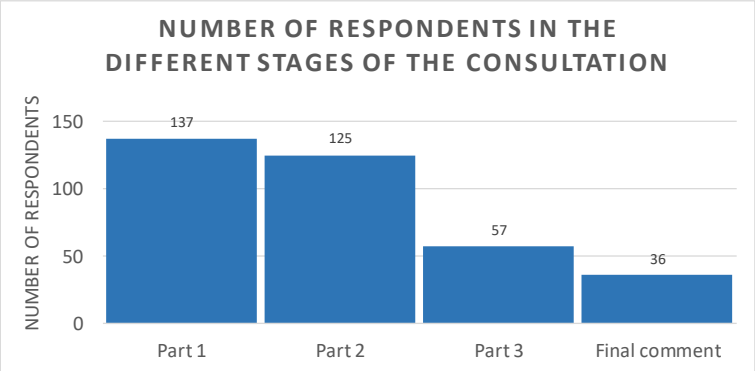

Figure 4: *Distribution of respondents over the different sections of the questionnaire.*

Part 3, primarily dedicated to industry that might be affected by the change of classification of materials in their portfolio, was responded by 57 respondents, of which 29 came from industry, 9 were citizens, 8 research organizations, 5 NGO and 5 private service providers. One response came from a competent authority.

8. ANALYSIS AND ANSWERS TO THE SURVEY QUESTIONS (PART 1)

8.1. Fitness for purpose of the Recommendation

Consultation question 1: "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."

The above-mentioned question invited the respondents to select up to three preferences from the following list of seven predetermined answers:

- **Answer 1:** Nanomaterials are materials/chemicals like any other and do not require special legislation or special provisions;
- **Answer 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;
- **Answer 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;
- **Answer 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;

- **Answer 5:** A common definition of nanomaterial used across legislation and sectors increases efficiency and consistency of implementation.
- **Answer 6:** None of the above;
- **Answer 7:** I have no view.

The 137 respondents provided a total of 283 preferences, with the distribution as depicted in Figure 5. An overwhelming number (78 %) of respondents selected Answer 5 thus highlighting that the Recommendation should preferably propose a single, uniform and overarching definition of the term nanomaterial. A slightly lower fraction of respondents (66 %) indicated that nanomaterials should not require legislation as a separate category of materials/chemicals, but specific nanomaterial provisions may be required within specific sectoral legislation (Answer 2). About a quarter of the respondents selected Answer 1 or Answer 3 and only 10 % opted for Answer 4.

Notably, 32 out of the 37 respondents for Answer 1, or almost 87 %, are linked to the industry stakeholder group. A similar trend for the industry group, but with slightly lower values, can be observed for Answer 2 (65 %) and Answer 5 (54 %). Replies for Answer 4 were distributed more homogeneously between the different stakeholder groups.

From the stacked bar chart (***Figure 5***), it can also be concluded that 110 respondents selected at least two preferences. The 36 respondents, or 26 %, selected a third preference, with 33 out of the 36 choosing Answer 5 as third option. Answer 5 was chosen mostly by the respondents as second and third preference, while Answer 2 was mostly selected (i.e. 66 respondents) as first preference.

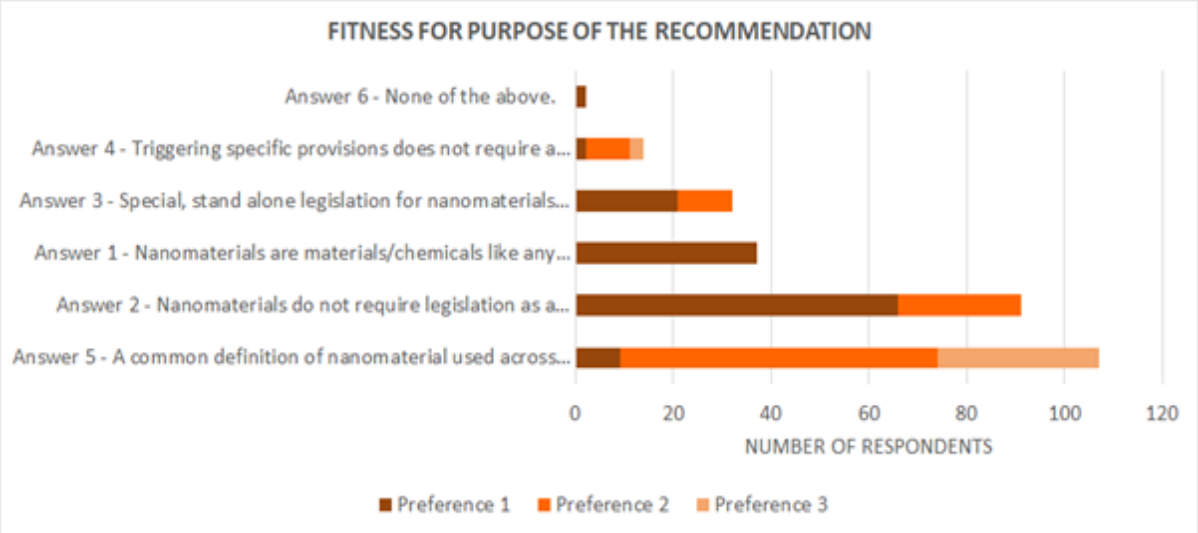

Figure 5: *Distribution of respondents over the preferred fitness for purpose of the Recommendation. Answer 7 (I have no view) has not been used.*

8.2. Consistency of nanomaterial definition in regulatory context

Consultation question 2: "Which of the answers below corresponds best with your position regarding the (harmonised) approach to nanomaterials in EU regulation? *(at least 1 choice(s))"*

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

- **Answer 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.
- **Answer 3:** The present approach is adequate.
- **Answer 4:** There is no inherent need for harmonisation – any definition needed for triggering specific provisions should be determined within the individual sector.
- **Answer 5:** None of the above.
- **Answer 6:** I have no view.

Across the above six predefined answers, 160 responses were received from the 137 respondents. The respondents showed a very strong preference for Answer 1 and Answer 2 (***Figure 6***). The preference rates for the other four possible answers are small and not significantly weighted towards a specific stakeholder group(s).

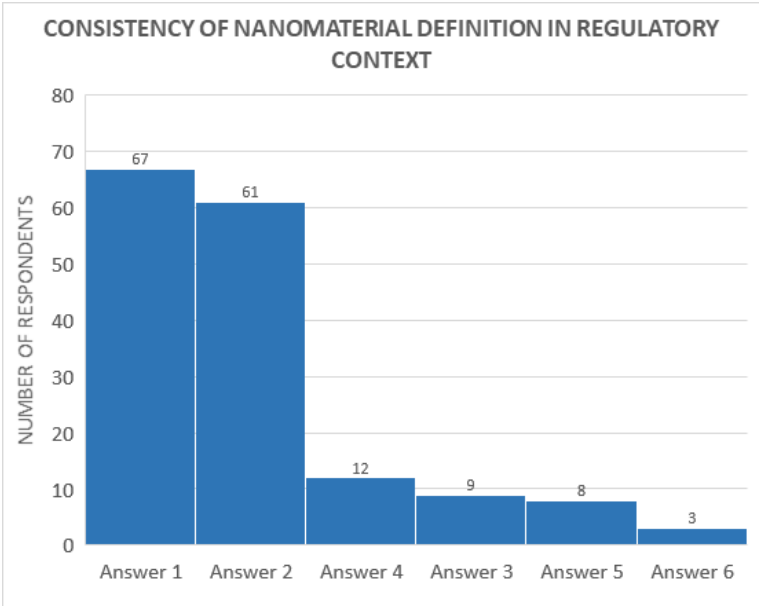

Figure 6: *Distribution of respondents over the preferred consistency of the nanomaterial definition in a regulatory context.*

8.3. Agreement with the review interim findings

Consultation question 3: "Do you agree with the interim review findings[12,13,14] regarding the present Recommendation 2011/696/EU, as presented in the bullets 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. 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.

Figure 7 depicts the frequency distribution of all 137 respondents' answers to Question 3. The top two box score of 77 % and the net top box score of 17 % indicate overall agreement of the respondents with the above interim review findings. An arithmetic mean of 3.7, median of 3.3 and a CV of 0.3 were calculated from the dataset. From the rounded arithmetic mean it can be concluded that the total sample of respondents 'mostly agree' with the interim review findings. Breaking down the main dataset into its different stakeholder groups (***Figure 8***) and topic areas of most interest (***Figure 9***) shows that the disagreement shown in ***Figure 7*** is not heavily weighted towards particular sub-groups.

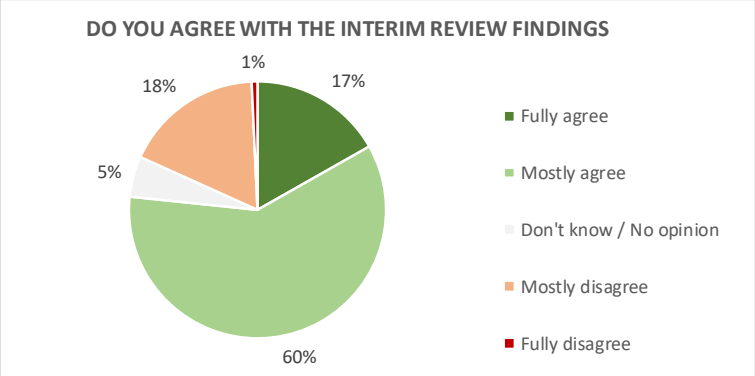

Figure 7: *Frequency distribution of all respondents regarding the agreement with the interim review findings.*

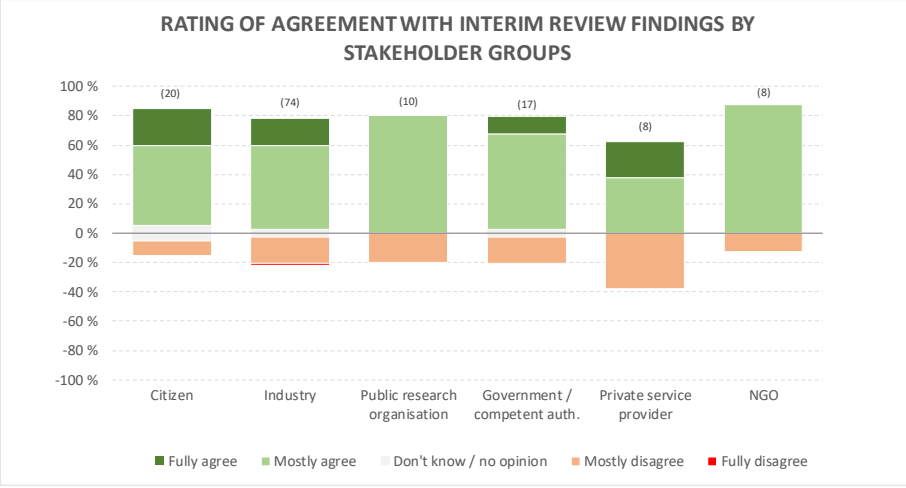

Figure 8: *Diverging stacked column chart of stakeholder groups' ratings on the agreement with the interim review findings. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

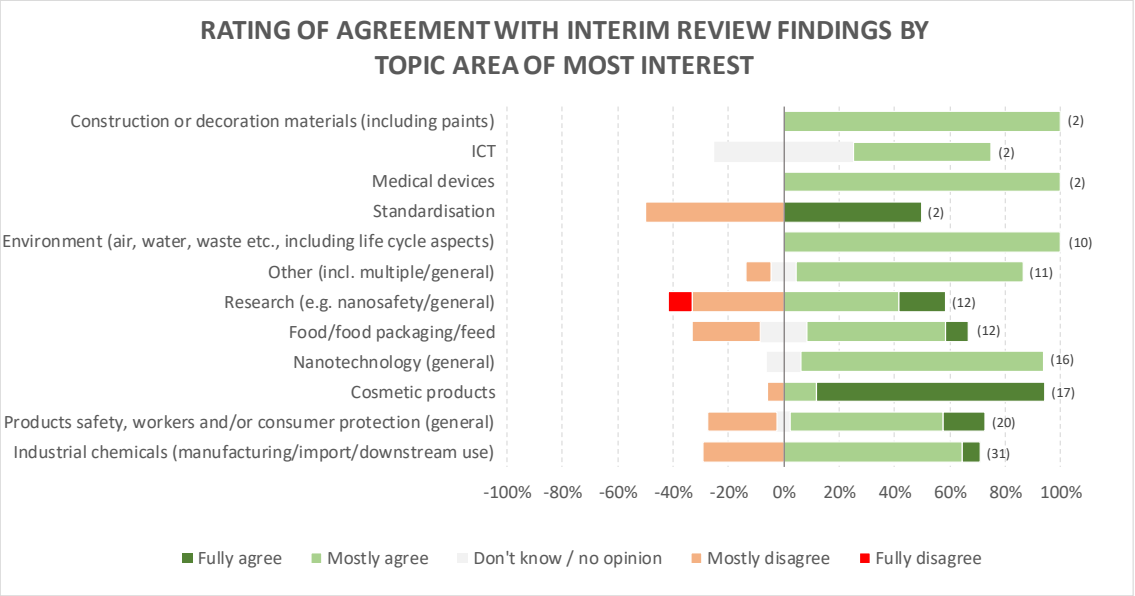

Figure 9: *Diverging stacked bar chart of ratings on the agreement with the interim review findings by topic area of most interest. The numbers shown within parentheses represent the number of respondents within each group.*

A number of respondents elaborated their disagreement with the individual interim findings. Many respondents replied that the current nanomaterial definition is not fit for purpose **(finding a)** because it is based only on the (median) particle size and does not take into account other physicochemical properties, nor the material's behaviour and potential risks to human health and the environment. Some respondents propose that exposure potential should be considered to waive unnecessary testing and reduce costs. Ohers consider the explicit limitation to solid particles not appropriate, because they claim certain classes of "soft" nanomaterials that are typically used as nanocarriers can interact with biological systems in a similar way to solid particles. Another critical shortcoming of the definition, according to several respondents, is its failure to discriminate between natural nanomaterials and novel or engineered nanomaterials.

Certain respondents emphasised a lack of clarity and understanding of, including but not limited to, the terms 'aggregate', 'particle', 'unbound', 'identifiable', and therefore called for clear and scientifically defined terms and guidance. Specifically, guidance documents should be made available to assist in the definition's implementation in the different sectors. Several respondents indicated that the actual purpose of the definition is not understood. A minority of respondents said that the thresholds upon which the definition is based must be scientifically motivated, instead of applying arbitrary cut-off points. Some respondents remarked that the upper limit of the nanoscale range is highly arbitrary, as it does not necessarily coincide with the unique physicochemical properties that are typically attributed to nanomaterials. They stated that for many materials, those unique nanomaterial-specific properties disappear when nanoparticles are agglomerated or aggregated, while some other materials (e.g., ultrafine metal powders) do not exhibit nanomaterial-specific properties at all. Hence, these respondents asked for introducing a link to nano-specific properties and urged to remove agglomerates and aggregates from the definition. Finally, few respondents considered the definition as a disproportionate burden that hinders trade, innovation and productivity growth. They stated that the application of the precautionary principle that requires manufacturers of nanomaterials to

demonstrate that their materials are safe creates an exceptionally high and disproportionate barrier in particular for those materials that have existed on the consumer market already for many years (e.g., clays). Few respondents also claimed that the current definition has negatively influenced the public's perception of nanomaterials.

Regarding the uptake of the definition in sectoral legislation **(finding b)**, respondents from cosmetic industries appreciated the availability of a single overarching definition that is broad in scope, provided that the respective sectoral legislation is sufficiently flexible and tailored to different types of nanomaterials. Contradictory, an important share of other stakeholders claimed that the scope of the definition is too broad and that its relation with sectoral legislation is not fully understood. In particular for food products, which are consumed daily, additional specific criteria may be required. Finally, few respondents stated that the limited uptake of the definition so far, as well as the non-harmonised sectoral legislation that is still in place, may be a consequence of the definition's lack of fitness for purpose.

A significant number of respondents agreed that 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 **(finding c)**. However, several respondents expressed concern about the generic inclusion of rod-like and plate-like particles with at least one external dimension smaller than 1 nm. They fear that the presence of monolayers of metal films, which are commonly applied in semiconductor applications, or layers of clay, can render the materials to be counterintuitively classified as nanomaterials. Finally, few respondents stressed that fullerenes are considered molecules rather than particles.

Despite the significant progress over the last ten years in the development of testing methods and technological advances owing to particulate materials, many respondents addressed the remaining practical and technological challenges, and costs, involved in the implementation of the definition **(finding d)**. Some respondents referred to the difficulty to measure reliably the size of nanoparticles that are smaller than 10 nm in diameter, or to exclude non-solid particles (e.g., micelles, liposomes) from particle size distributions. Others warned for the limitations of traditional methods to cope effectively with materials whose particle size distributions span different orders of magnitudes. Several respondents questioned why the definition is not aligned with terms and concepts recommended in documentary standards issued by international organisations (e.g., ISO, OECD) and few stated that the intended revision should also aim at solving the implementation problems. Redefining the scope of the definition, based on internationally accepted terms, should improve the coherence and clarity of the definition. Some respondents suggested that, from a method perspective, mass-based size distributions should be considered instead of particle number-based size distributions. They state that mass-based size distributions are not only easier to measure, but they are also less prone to distortion by the presence of very small fractions, at impurity levels, which may render a material to become a nanomaterial. In addition, the inclusion of aggregates that consist of fused particles was sometimes questioned. To be fit for purpose, some respondents expect that the new definition should not invoke new or underdeveloped metrology requirements, but should ideally be based on existing and simple testing methodologies that do not create undue burden on economic operators. They noted that the correct implementation of technically complicated definitions can be

extremely challenging for those actors who are not intending to manufacture or use nanomaterials, as they generally lack the required expertise to make valid assessments. The metrology has also been identified as issue is of importance for MS authorities responsible for inspection. Finally, one respondent also reminded the Commission that variation in linguistic translation should be avoided as this can cause different legal effects across Member States.

Summary response

With regard to the legal standing of the definition, it should be recognised that although the definition in the Commission Recommendation itself is not legally binding, the combined impact of one agreed definition with its consistent uptake by the sectoral regulation addresses effectively the initial objective of the European Parliament's resolution of 24 April 2009[41] urging the European Commission to adopt a harmonised and comprehensive science-based definition for use in relevant horizontal and sectoral legislation. At the same time, the approach is allowing to accommodate specific circumstances, terms and conditions the legislator in each sector used to introduce nanomaterial-specific provisions. The uptake in the sectoral Regulation links the definition of nanomaterial precisely with the material to be assessed (substance potentially in nanoform, ingredient, formulation), may connect to further conditions (e.g., insoluble nanomaterials) and eventually to specific further obligations in the sector (additional provisions regarding characterization, risk assessment, labelling etc.). It is worth noting that defining nanomaterial in a regulation would still require legal action within the sector to link such Regulation to the specific provisions, and that Recommendation is no less stable in providing a coherent basis than the Regulation would be, with both being subject to Commission scrutiny and adoption process.

Extensive consideration regarding size as the only defining property can be found in the chapter 2.6.5 in the main text of this Staff Working Document. It can be summarised around a few main arguments:

a) It has been scientifically proven that novel intrinsic properties of materials can emerge (but not exclusively) when the external dimensions of the constituent particles approach, or fall within, the nanoscale range (this is the size range of 1 nm to 100 nm). For this reason, particle size has become the physical property most commonly used to define nanomaterials at the international level. Particle size is a measurable quantity that can be readily (albeit challenging at times) compared against regulatory criteria. Adding further physico-chemical parameters as additional or complementary conditions that would allow differentiation based on 'novel property' would increase complexity, require extensive implementation support while not necessarily adding to the effectiveness of the tool.

b) Provenance or intent behind the material (natural, incidental, manufactured) may, in spite of potential challenges to correctly classify intent, support the specificity of regulatory objective. However, these objectives may differ, and properties of the material (which are the principal reason for specific provisions introduced in regulation) are not predicated by the provenance; a definition serving a wide spectrum of legislation, its scope and objectives, should thus not be restricted in such a way. These should partly address also 'clarity of purpose' questioned by some respondents: the definition should be able to be applied as a trigger, while

41 P6_TA(2009) 0328.

purpose behind triggering may vary. The definition should not be locked to a single purpose.

c) Using risk and/or hazard to help identify a nanomaterial is highly material dependent, would particularly compromise the generic and broad character of the definition and also largely defeat its purpose: the majority of specific provisions, requiring a definition to trigger them, are set to ensure an adequate assessment of hazard/risk in the first place. The generic link between risk and nanomaterial, even only a perceived one, is not supported by scientific evidence and is also highly detrimental to the innovation potential that nanomaterials bring.

Different nanomaterial definitions are available from various national and international standardisation organisations and committees and have all been assessed when developing the Recommendation. These definitions, which have often been developed and tailored by their members on a voluntary basis, promote a common understanding, benchmarking, and facilitate compatibility, transparency and consensus formation for specific standardised applications. They (or rather one of them) however cannot replace regulatory requirements and it would prove challenging to trigger specific provisions set in the regulation. Reasons are diverse and elaborated in chapter 2.6.1, linked to ambiguity that is not coherent with regulatory implementation (e.g. 'approximately in range' 1 nm-100 nm'), scope and implementability (e.g. link to intent or novel properties). Core terms and thresholds have however been as much as possible invoked from the internationally agreed definitions, principally by ISO (e.g. see definition of agglomerate, aggregate), following scientific advice (SCENIHR) and, when required to introduce a new particle fraction threshold value, also the generally accepted convention to base classification on the majority component of the material. The objective to have an unambiguous and implementable definition, as expected by the respondents, has been pursued in the revision. It has been considered necessary to support the definition with an accompanying horizontal Guidance, formally linked to the Recommendation, that would take up a limited number of clarifying elements as well as support to the implementation, listing methods and best practices (see chapter 2.9).

8.4. Considered modifications

Consultation question 4: "Overall, as compiled in the attached document, are the considered modifications of the Recommendation sufficiently comprehensive and clear?"

Figure 10 shows the frequency distribution of all 137 respondents' answers to Question 4. The top two box score of 61 % and the net top box score of 4 % indicate overall agreement of the respondents with the above interim review findings. An arithmetic mean of 3.3, median of 3.1 and a CV of 0.3 were calculated from the dataset. From the rounded arithmetic mean it can be concluded that the total sample of respondents 'mostly agree' with the comprehensiveness and clarity of the considered modifications. Breaking down the main dataset into its different stakeholder groups (***Figure 11***) shows that the proportion of disagreement (~33 %) shown in Figure 10 is shared by most stakeholder groups. However, NGOs did disagree more whereas the opposite was seen for the responding citizens. Focussing on the topic areas of most interest (***Figure 12***) reveals that stakeholders within the groups of environment (mainly NGOs), product safety and industrial chemicals disagreed more, compared to other groups. Within the groups of food- and cosmetic-based products, most stakeholders seem to agree with the considered modifications.

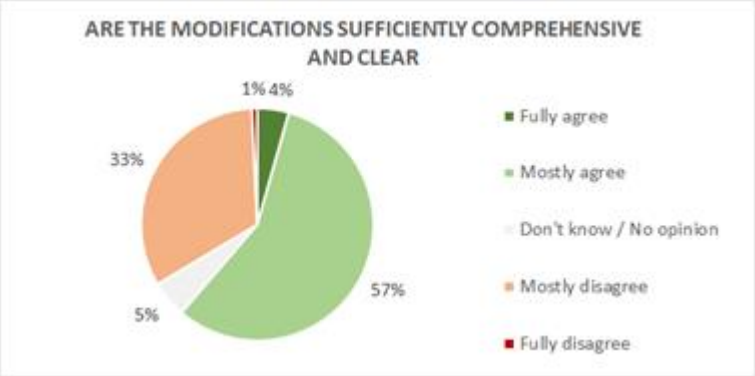

Figure 10: *Frequency distribution of all respondents regarding the comprehensiveness and clarity of the considered modifications.*

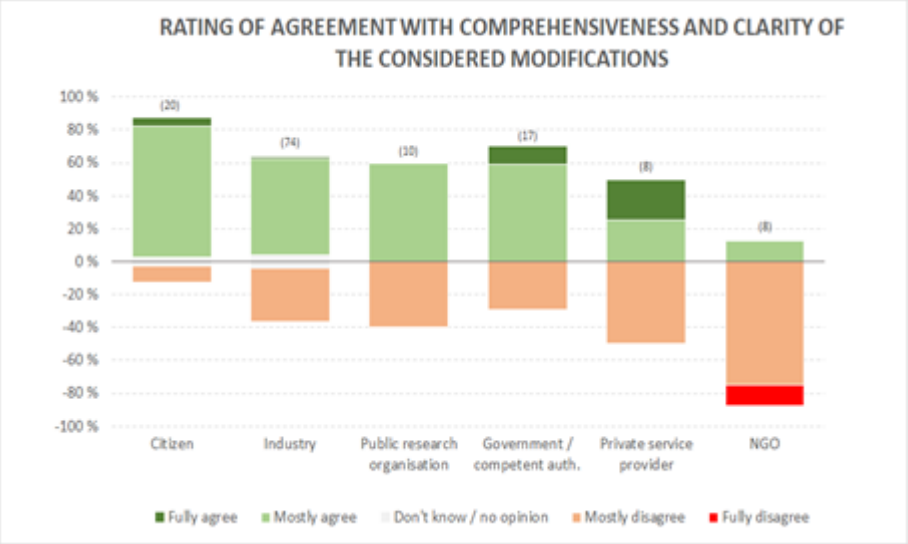

Figure 11: *Stakeholder groups' ratings on the agreement with the comprehensiveness and clarity of the considered modifications. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

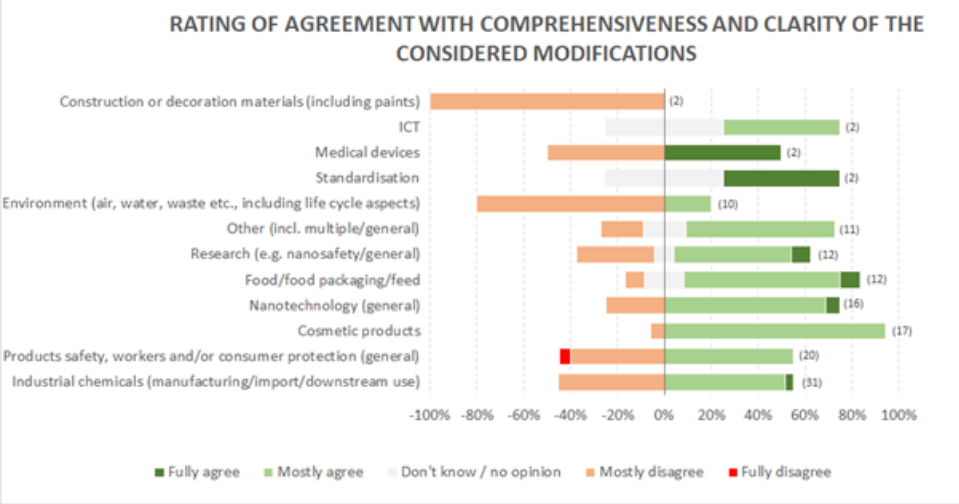

Figure 12: *Stakeholders' ratings on the agreement with the comprehensiveness and clarity of the considered modifications by topic area of most interest. The numbers shown within parentheses represent the number of respondents within each group.*

While the important purpose of the revision exercise has been to eliminate ill-defined and unambiguous terms from the current definition, an important number (22) of respondents echoed that the considered modifications introduce several new terms and elements that can lead to confusions if not well explained. The lack of a clear rationale and details regarding the regulatory context in which the revised definition will operate, are considered as a main shortcoming. Furthermore, several respondents criticised the Commission's review methodology and wondered why no progress towards a revision has been made since 2012. Also, according to few respondents, the Commission should have first reviewed the efficiency and relevance of the current definition. Some respondents encourage the Commission to apply a more flexible review process and hope that a third review will be conducted and completed before 2026 – a date indicated as the first possible time for potential review and revision.

Some of the responses project a sense of disappointment regarding the scope and extent of the current revision exercise. For instance, the absence of an underpinned motivation for the inclusion and/or exclusion of certain types of materials (e.g., micelles, nanostructured materials, particles held within a matrix), the arbitrary nature of the applied thresholds and the lack of a link to hazard and risk assessment, is not always appreciated. Regarding the latter, some respondents are concerned that materials which are not formally classified as nanomaterial, but which contain a small but significant fraction of particles with external dimensions at the nanoscale, may slip through the net posing risks to consumers, noting that for this very reason, the European Commission mandated the European Food Safety Authority (EFSA) to publish a guidance on technical requirements for identifying and quantifying fractions of small particles in food and feed products[42]. Finally, a number (11) of respondents called upon the Commission to reconsider aggregates and exclude them from the definition as the constituent particles of aggregates cannot be easily released under normal handling conditions and use.

Many (22) respondents repeated that for regulatory purposes all terms, used in both the definition and in the associated guidance documents, must be unambiguous and well defined. For instance, the revision intends to replace the ambiguous word 'unbound' by 'identifiable' but the latter requires precise details of the test scenarios and measurement conditions. Other recurring examples of concepts for which the respondents require further details were 'weakly and strongly bound' particles, 'constituent' particles, 'elongated shapes', 'solid', the difference between aggregates and different crystal phase, and the difference between 'single molecules' and particles. Regarding the former, one respondent highlighted that agglomerates usually occur as rather loose assemblies whereas aggregates are much denser. Regarding the differentiation between single molecules and particles, for which proteins and polymers are typical borderline materials, one respondent reminded that single molecules and particles typically differ in terms of solubility (i.e. cross-linked polymers do not dissolve) whereas another respondent referred to the differentiation between polymers and substances based on their relative molecular mass (cf. ECHA approach).

Several respondents flagged their concern about the definition's regulatory applicability of stable coatings or films with a thickness of less than 100 nm, in particular when these coatings are applied to particles that are larger than 100 nm in diameter.

[42] Reference https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2021.6769

Some respondents asked the Commission to justify why a specific surface area by volume (VSSA) of 5 m^2/cm^3 is considered as cut-off value while the NanoDefine project has provided a scientific basis for different shape-dependent VSSA cut-off values.

Finally, few respondents stated that a 'one size fits all' definition will fail to capture what is actually important, i.e. protection of consumers against potential risks. Therefore, regulators should consider and define additional metrics and include a corresponding triggering mechanism.

Summary response

Points put forward in the answers under this question vary. Information on the scope, objectives and timing of the review of the Recommendation 2011/696/EU are outlined in chapter 1.2 and elaborated in chapter 2. The chapter 1.1 goes 'beyond the definition', touching also on the different regulatory solutions to adequately assess risks from specific materials of potential concern that do not meet the nanomaterial classification criteria, while they may potentially share some of the features and therefore also solutions addressing nanomaterials. Cases include specific materials containing small fractions (< 50%) of nanoscale particles or containing majority of particles that may still be relatively small but in median larger than 100 nm. The motivation with regard to the specific options put forward, and definitions of the terms used, are summarised in chapter 2 that itself relies heavily on the comprehensive assessment in the Review reports 1-3. Case for additional guidance has been made already under the previous question (see chapter 2.9 in the main text) that is expected to provide illustrative cases regarding the use of the definition for specific materials identified as 'borderline' above. For example, thin coatings of larger non-nanoscale objects would not be, as is already the case now, considered nanomaterials.

More specific arguments on individual elements of the definition are made also below, where the same or similar feedback has been provided by some of the respondents to the questions in Part 2.

9. ANALYSIS AND ANSWERS TO THE SURVEY QUESTIONS (PART 2)

9.1. Change from 'contain' to 'consist of'

Element E1 of the questionnaire discusses the following proposed revision of point 2) of the current Recommendation: change from 'containing' to 'consisting of'.

Consultation question 5: "Does the change from 'containing' to 'consisting' clarify the scope of the definition?"

The pie chart shown in ***Figure 13*** represents the frequency distribution of replies from all 137 respondents on Question 5. The top two box score of 72 % and the net top box score of 46 % indicate that the respondents generally agree with the proposed revision. The arithmetic mean, CV and median were 4.1, 0.3 and 4.0, respectively.

Breaking down the main dataset into its different stakeholder groups (***Figure 14***) shows that all NGO stakeholders 'mostly disagree' with the proposed revision while, for example, all public research organisations responded positively. A further break down of the industry stakeholder group does not flag any heavily weighted preferences towards a particular size of company. The NGO disagreement shown in ***Figure 14*** is also visible in

Figure 15 (see 'environment'), which groups the data according to topic area of most interest.

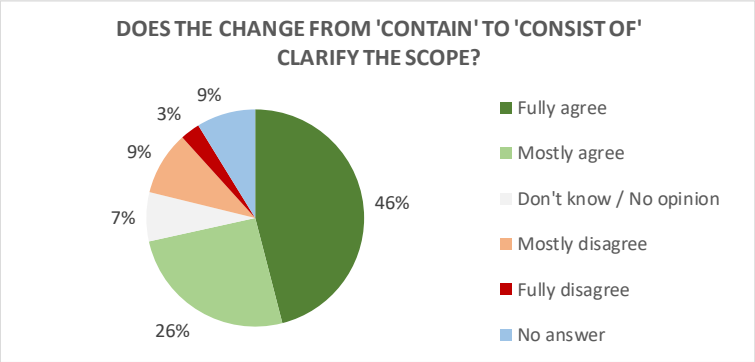

Figure 13: *Frequency distribution of all respondents regarding the agreement with the interim review findings*

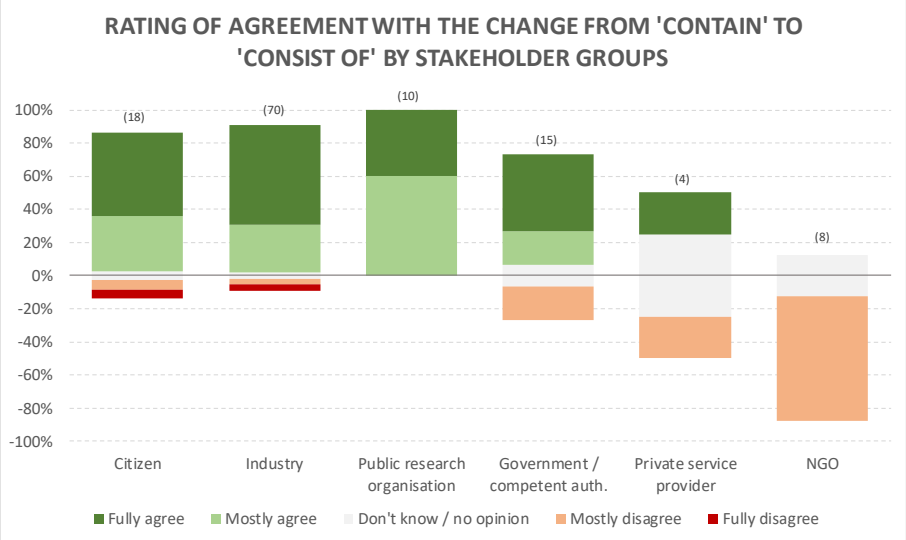

Figure 14: *Stakeholder groups' ratings on the agreement with the change from 'contain' to 'consist of'. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

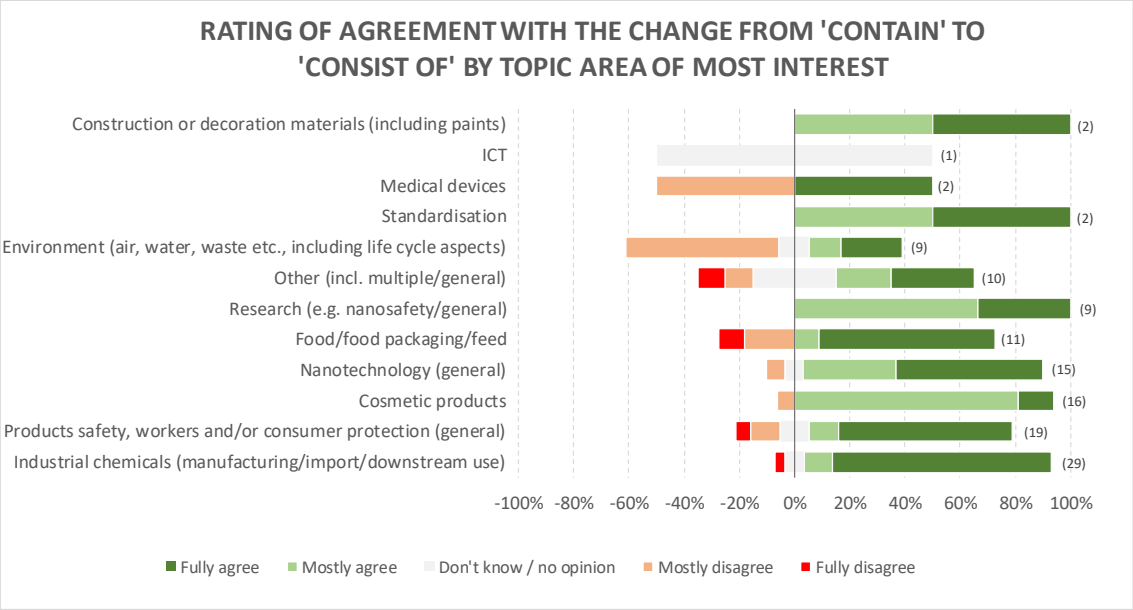

Figure 15: *Stakeholders' ratings on the agreement with the change from 'contain' to 'consist of' by topic area of most interest. The numbers shown within parentheses represent the number of respondents within each group.*

The comments generally expressed the need for clarification of the term "consist of", rather than arguing against the EC proposal. Some respondents argued that if "consist" is used it would be necessary to make a full declaration of the substances of a material, whereas if "contain" is used the rest of the ingredients/material components not necessarily need to be listed. In both cases, the quantity of the individual components should be declared. For colloids, which contain solid nanoparticles, it should be explained whether the entire colloidal dispersion (including liquid) or just the solid nanoparticles would be considered as nanomaterial. In general it was argued that the change from 'containing' to 'consisting of' further clarifies the scope of the definition, but an explanation should be provided how to deal with mixtures. In conclusion, there was not so much direct opposition against the proposed change, but respondents express the need for more clarification.

Summary response

Argumentation regarding this change is provided in chapter 2.7.1. The responses confirm the benefit of further information provided in the Guidance. While the regulatory requirements with regard to the documentation of the materials under assessment are set in each legislation separately, the Guidance is expected to provide best practice to document the application of the definition, including the testing conditions.

9.2. Changes to 'particles'

Element E2 of the questionnaire discusses five proposed changes that are related to 'particles'.

Consultation question 6: "Do you agree with the restriction to 'solid' particles only?"

From the pie chart shown in ***Figure 16***, and supported by the descriptive statistics (i.e. arithmetic mean and median are 4.1 and CV is 0.3), one can conclude that the stakeholders 'fully agree' with restricting the definition to 'solid' particles only. Despite

this overall agreement, a notable fraction (11 %) of respondents disagreed either mostly or fully.

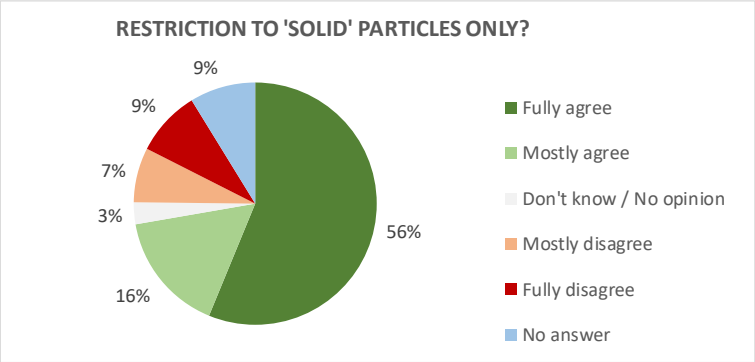

Figure 16: *Frequency distribution of all respondents regarding the agreement with the restriction to 'solid' particles only.*

Evaluating the responses of the different stakeholder groups shows that citizens and industry favour the proposed revision, but that government/competent authorities, private service providers and particularly NGOs, disagree (***Figure 17***). The break down in topic area of most interest (***Figure 18***) shows, when acknowledging also the relative representation of stakeholders across topic areas, that the disagreement is shared fairly across the different topic areas.

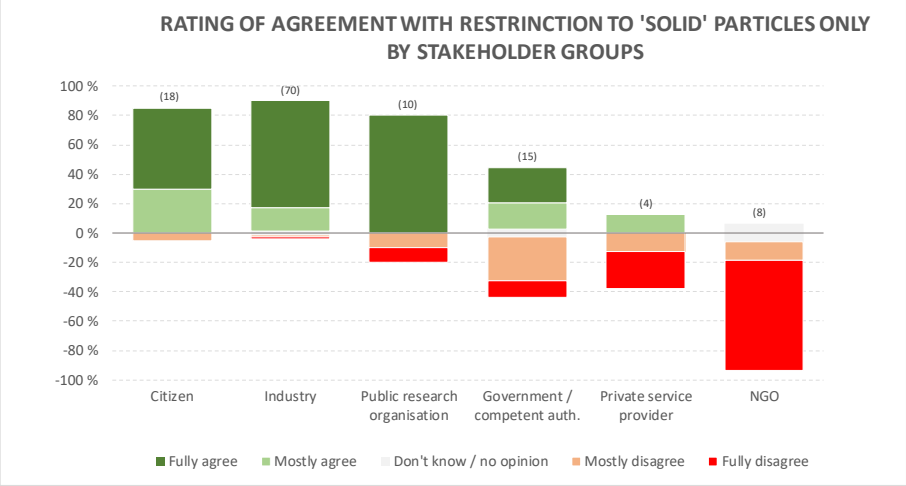

Figure 17: *Stakeholder groups' ratings on the agreement with the restriction to 'solid' particles only. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

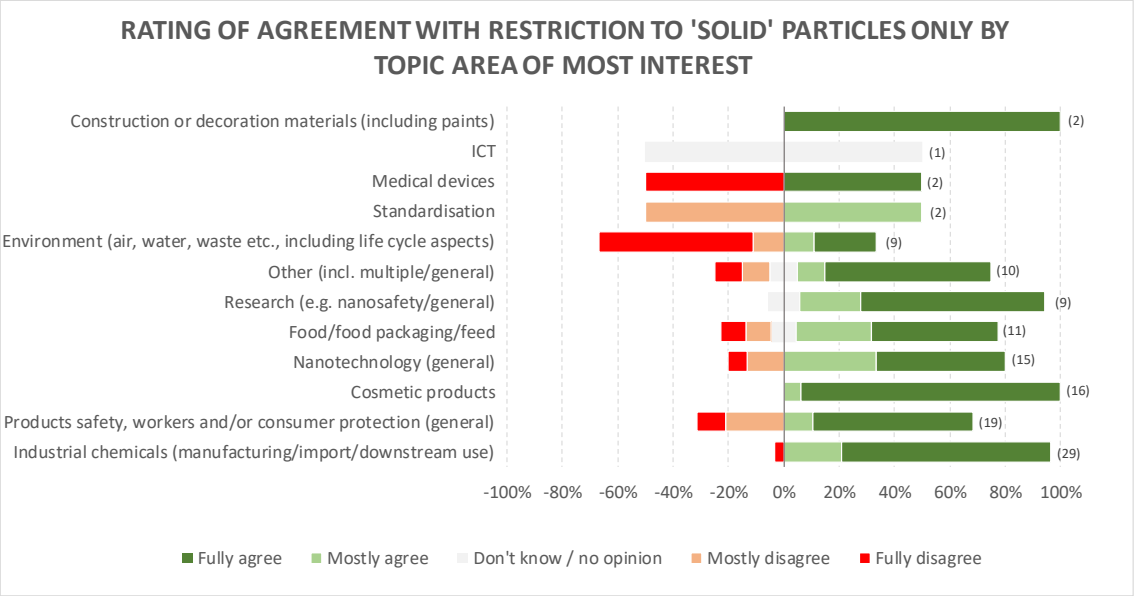

Figure 18: *Stakeholders' ratings on the agreement with the restriction to 'solid' particles only by topic area of most interest. The numbers shown within parentheses represent the number of respondents within each group.*

Answers by respondents from several sectors indicate that certain non-solid or soft materials such as micelles, liposomes and nanocarriers are often clearly considered nanomaterials in their community (food, cosmetics and medical sector) and they are used because of their nanosized, "particulate" properties. These materials are also often novel, advanced materials and the respondents indicated that their safety assessment should specifically take into account that their size is in the nanoscale range. Respondents correspondingly criticised the restriction to 'solid' particles, arguing that various types of non-solid or liquid-phase nanocarriers can be modified or engineered to maintain their structure and external dimensions. As a result, these particles are able to move as a unit and show properties assignable to the unit as a whole, similarly to solid particles. Moreover, some respondents stated that the rationale for excluding certain types of nanomaterials on criteria that are not exclusively based on the particle's external dimension is not scientifically justified and that such decision can possibly lead to the exclusion of several families of relevant nanomaterials such as polymers, nanoplastics and fullerenes.

Respondents from cosmetic and food industries generally agreed on a restriction to solid particles but requested to include an additional qualifier such as insolubility or biopersistence, in analogy with the cosmetic products Regulation (EC) No. 1223/2009 and the EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. Their underlying motivation is that the specific potential toxicity of nanoparticles is supposed to depend on their ability to interact in the body while remaining in their original solid state and thus can show different effects compared to their soluble counterparts. In addition, it was pointed out that it may not always be technically feasible to measure the particle size of soluble substances/ingredients, falling under the nanomaterial definition because of their initial powder status, since most techniques (including electron microscopy) require the preparation of sample suspensions. By their account, the nanomaterial definition should ideally also provide a criterion for solubility/insolubility

to reinforce the distinction between solid and non-solid particles, referencing the OECD Test Guidelines No. 105 and No. 120.

Many of the stakeholders called upon the Commission to clarify further what must be understood by the term "solid". Some respondents reminded that the actual state of matter – solid, liquid, gas – is defined by the environmental temperature and pressure. Others suggested that solidity should not be defined as contrast to liquid or gaseous, but should be based on viscoelastic properties or melting points. As nanoparticles may show fluid behaviour, they claim, the distinction between solid and non-solid can be challenging.

Summary response

Rationale for the inclusion is provided in chapter 2.7.2. The ISO definition of "particle" is too wide for the definition as it includes also liquid particles (droplets) and even gaseous particles (bubbles). Maintaining "solid" would give the definition a better-defined scope, but indeed the term itself, due to the need to applying in the nanoscale domain, requires further interpretative illustration, also via concrete cases and indication of relevant particle properties that support the decision of inclusion/exclusion in this regard. This is planned to be provided in the Guidance. Many relevant considerations, such as expected use of normal temperature and pressure conditions, are being applied already in the implementation of existing definition.

The Commission is aware of the increased use of nanocarriers such as liposomes and micelles, for instance for targeted medicine release in new cancer therapies. Although nanocarriers with external dimensions in the nanoscale may display properties and behaviours similar to solid nanoparticles, their structure and external dimensions can also be more dynamic due to the high frequency of molecules leaving and entering the liquid structure. As these dynamics are strongly driven by external stimuli, the external dimensions of such soft particles can vary depending on the environment, leading to an ambiguous identification of nanomaterials.

The revised Recommendation will provide a comprehensive and overarching definition of the term nanomaterial for regulatory applications in the EU. Specific provisions for nanomaterials are addressed in the relevant sectoral legislation and might, where considered appropriate, include further qualifiers to modify the scope of materials under specific scrutiny (see also chapter 4.1 on implementation). As example, the Regulation (EC) No. 1223/2009 on cosmetic products is presently restricting the specific nanomaterials focus to materials that are "insoluble" and "biopersistent"

Consultation question 7: "Do you agree with the reference to the 'unbound state'?"

The majority of the respondents (almost 80 %) are of the opinion that the revised definition should be applicable to particles that are present either on their own or as identifiable constituent particles (***Figure 19***). The corresponding average level of sentiment is 'fully agree' (arithmetic mean of 4.2). Because of the large degree of agreement (CV of 0.2) amongst the 137 respondents, no further data analyses were performed on this particular question.

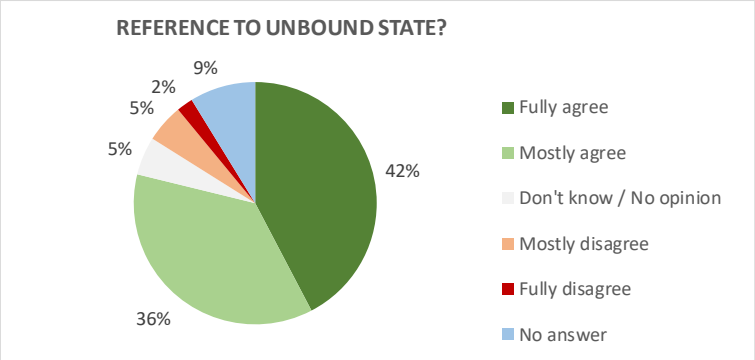

Figure 19: *Frequency distribution of all respondents regarding the agreement with the reference to unbound state.*

Scrutinising feedback in the free text responses, no arguments against the proposed change could be found. Arguments put forward were instead mostly related to the proposed introduction of the new term "identifiable constituent" particle (see question 8).

Consultation question 8: "Do you agree with the reference to the 'identifiable constituent' particles?"

In contrast to the answers received for the previous question 7 on the 'unbound state', a large share of the respondents does not agree with the Commission's proposal to include a reference to 'identifiable constituent' particles (***Figure 20***). Despite the strongly varying opinions, the calculated arithmetic mean of 3.3 shows that the average level of sentiment of the respondents is still 'mostly agree'. The median value is 3.1.

Evaluating the data by stakeholder groups (***Figure 21***) reveals that concerns regarding the proposal, when expressed, are shared by most stakeholder groups, in particular by industry (~50 %) and NGOs (80 %), and in a lesser extent by citizens (25 %) and governmental/competent authorities (24 %).

By mapping the sectoral domain of the respondents (***Figure 22***), one can conclude that the stakeholders linked to cosmetic products, industrial chemicals, product safety and environmental protection are clearly more concerned than stakeholders from the other sectors. In contrast, research groups and stakeholders related to the food chain heavily agree with the proposed revision.

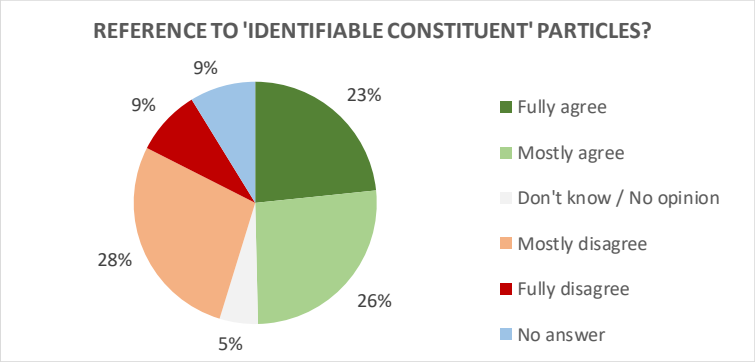

Figure 20: *Frequency distribution of all respondents regarding the agreement with the reference to 'identifiable constituent' particles.*

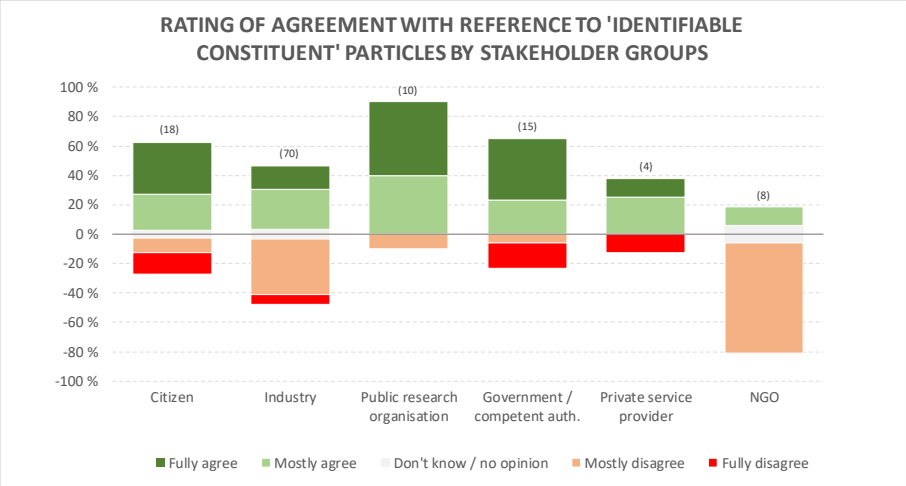

Figure 21: *Stakeholder groups' ratings on the agreement with the reference to 'identifiable constituent' particles. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

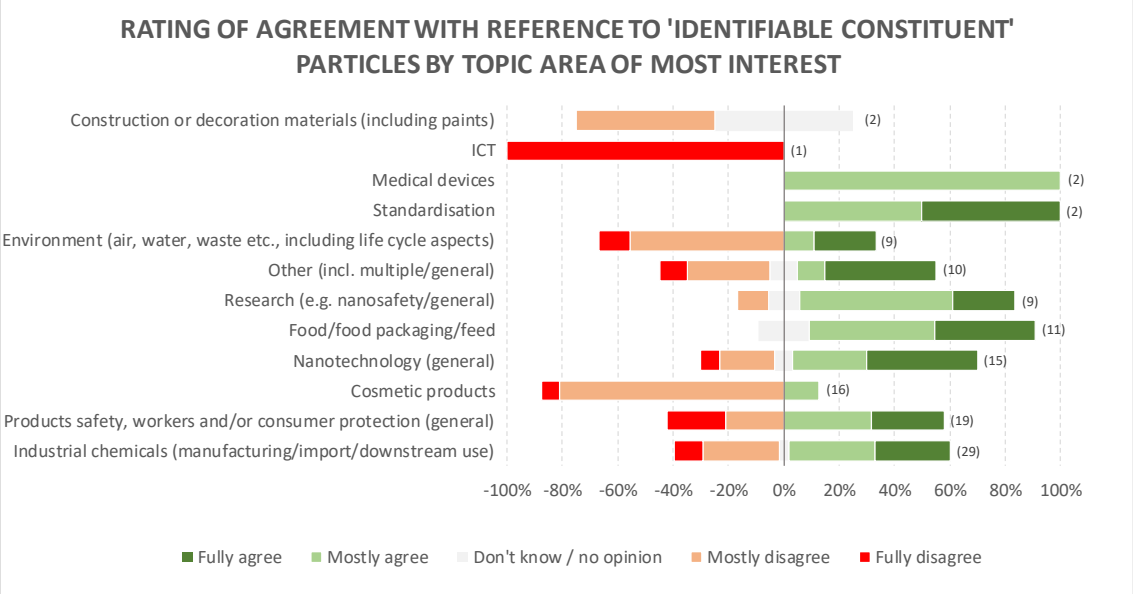

Figure 22: *Stakeholders' ratings on the agreement with the reference to 'identifiable constituent' particles by topic area of most interest. The numbers shown within parentheses represent the number of respondents within each group.*

Further elaboration of the sentiment has been provided by the respondents and is organised under the following headings:

- *New terms are not clear:* The majority of the stakeholders that replied negatively to the Commission's proposal to replace "particles in an unbound state or as an aggregate or as an agglomerate" by "particles that are either present on their own or as identifiable constituent particles in aggregates or agglomerates", highlighted that the newly introduced qualifiers **"identifiable" and "constituent" are vague and ambiguous** and can lead to increased regulatory uncertainties when not clearly defined.
- *Identifiable or not identifiable? That depends on the identification method:* Several respondents emphasised that the **identification of constituent particles highly depends on the applied measurement procedure/method** and that dedicated

guidance should therefore be made available to overcome the related analytical challenges. According to one respondent, the guidance should also explain whether non-identifiable constituent particles, i.e. constituent particles whose properties/quantities intended to be measured are outside the **working range** of the applied method, will be considered as unidentifiable. Finally, few respondents are unsure how the Commission will enforce that applicants select the most appropriate method for specific materials.

- *The cost and complexity of electron microscopy:* A major concern raised by several respondents is that the identification of constituent particles strongly relies on morphological evidence that is **only accessible by the application of expensive and complex techniques such as electron microscopy**. Such advanced instrument is not readily available in all laboratories.
- *The need for clear physical boundaries between constituent particles:* Some point out that the analysis of micrographs does **not always provide an unambiguous distinction between nanostructured/fused particle and "true" nanoparticles**. As alternative, respondents suggested that constituent particles should have **clear physical boundaries**.
- *Aggregated particles, or particles that cannot be separated, should be counted as 1 particle:* As alternative, respondents suggested that **structures that are bound by covalent or ionic bonds should not be considered aggregates**, and that constituent particles should have **clear physical boundaries** and should be able to **exist and move on their own**. The latter suggestion in practice is similar to other suggestions to consider aggregates as single particles because the identification of their constituents can be extremely difficult or impossible, and because constituents of aggregates are not relevant for safety as it is not possible to break them up. In line with this suggestion, "identifiable constituent" should be based on the separability by some standardised procedure.

Summary response

Again, the rationale behind the approach is presented in chapter 2.7.4, but can be pulled in few lines in accordance with the split above:

- *New terms are not clear:* The proposal uses the terms 'identifiable' and 'constituent' in a connected way, as part of the concept "identifiable constituent particles in aggregates". By inserting this concept, the Commission acknowledges the fact that sometimes aggregation is the result of extensive diffusion and fusion processes during which atoms or molecules of the initial, so-called 'primary' particles, are to a large extent re-arranged and exchanged between different primary particles or between new sub-parts of the final resulting aggregate particle. This phenomenon is not unusual and occurs for instance in high-temperature particle manufacturing methods. It can lead to the formation of aggregates with external surface features that may refer to the size or shape of the original, primary particles, but which, in their interior, do no longer consist of different particles. If, on the other hand, the aggregates do consist of smaller but identifiable parts, these particles are called 'constituent particles', a term adopted by ISO in 2015 (ISO/TS 80004-2).
- *Identifiable or not identifiable? That depends on the identification method:* Indeed, different particle size analysis methods have different detection and quantification limits. The identification of constituent particles highly depends on the applied measurement procedure/method. Dedicated guidance already has been made available, e.g. in recent JRC reports[15,16,17]. The guidance supporting the revised

definition will effectively include an updated version of these reports. There is also ongoing effort in OECD to validate and standardise relevant methods for size and size distribution analysis of (nano)particles and fibres (OECD TG 110). As to the choice of a method, the Commission underlines that constituent particles smaller than the lower limit of the working range of a selected method cannot be considered as unidentifiable. Possible enforcement issues related to the choice of an appropriate analytical method will depend on the legal context in which the measurements are made.

- *The cost and complexity of electron microscopy:* The Commission acknowledges that currently, and possibly for many years to come, the measurement of the size of constituent particles inside certain aggregated particulate materials is possible only with electron microscopy. Over the last decade, the method has been intensively used to implement the existing nanomaterial definition, and efforts were made to develop tools that render this particular use more workable (NanoDefine[16], also ISO work ISO 19749:2021, Nanotechnologies — Measurements of particle size and shape distributions by scanning electron microscopy, ISO 21363:2020, Nanotechnologies — Measurements of particle size and shape distributions by transmission electron microscopy). The extent of the electron microscopy work needed is highly material-dependent. A good knowledge of the processing method used to produce the particulate materials will be key to assessing the most efficient analytical approach. The Commission also recognises that it cannot exclude that, in some cases, electron microscopy may not be able to provide the required answer. Depending on the particular regulatory context, the absence of a suitable analytical method for a particular material may be justified for such exceptional cases.
- *The need for clear physical boundaries between constituent particles:* By introducing the term 'identifiable constituent particle' the Commission already, and explicitly, recognises the need for a physical boundary between particles, for them to be counted as different particles in the particle size distribution. The identification of these boundaries, e.g. in micrographs, may be ambiguous. Guidance will provide clear indication how an analyst can demonstrate that he has applied a method of choice with sufficient care to conclude on the absence of physical boundaries between particles.
- *Aggregated particles, or particles that cannot be separated, should be counted as 1 particle:* many responses that, in one way or another, suggest that aggregates should be counted as single particles. Indeed, this would render the implementation of the nanomaterial definition much easier. On the other hand, it would also significantly reduce the scope of the current nanomaterial definition, in ways that are difficult to justify, mainly because of the fact that small nanoparticles, even when aggregated, may display different properties from larger particles with the same composition. The suggestion to introduce a new approach, based on the separability of the constituent particles of aggregates by some standardised procedure, has interesting features. However, in the absence of validated, recognised standard particle separation methods, the Commission is not in a position to take up this suggestion. The Commission will follow this line of thought, also because it may lead to sample preparation steps that facilitate the use of certain particle size analysis methods that do not coop well with strongly aggregated materials.

Consultation question 9: "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?"

Similar to Question 8 below, respondents gave also varying responses to the Commission's question whether specific larger particles should be excluded from the number-based size distribution (Figure 25). About 45 % responded positively and 27 % replied negatively. A significant share (18 %) of the respondents had a neutral opinion. The arithmetic mean and median are 3.3 and 3.0, respectively. The average level of sentiment is 'mostly agree'.

Shown in ***Figure 24*** is the break down by stakeholder groups. The level of sentiment is almost equally shared amongst all stakeholder groups.

The break down by topic area of most interest (***Figure 25***) shows that the stakeholders who disagree are linked to either product safety or industrial chemicals. These stakeholders correspond to almost 17 % of all respondents. Reasons for disagreement are shown in ***Figure 26***.

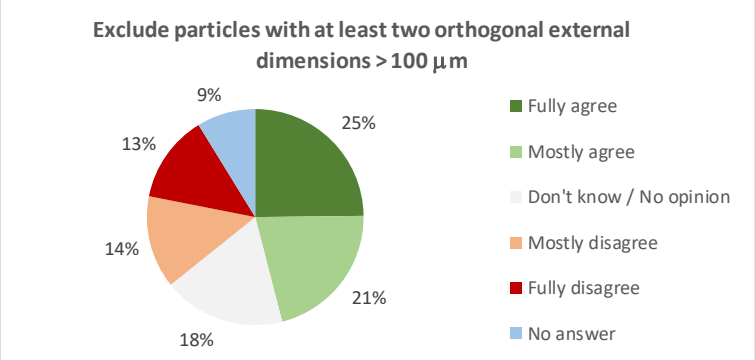

Figure 23: *Frequency distribution of all respondents regarding the exclusion of particles with at least two orthogonal external dimensions larger than 100 micrometres from the number-based size distribution.*

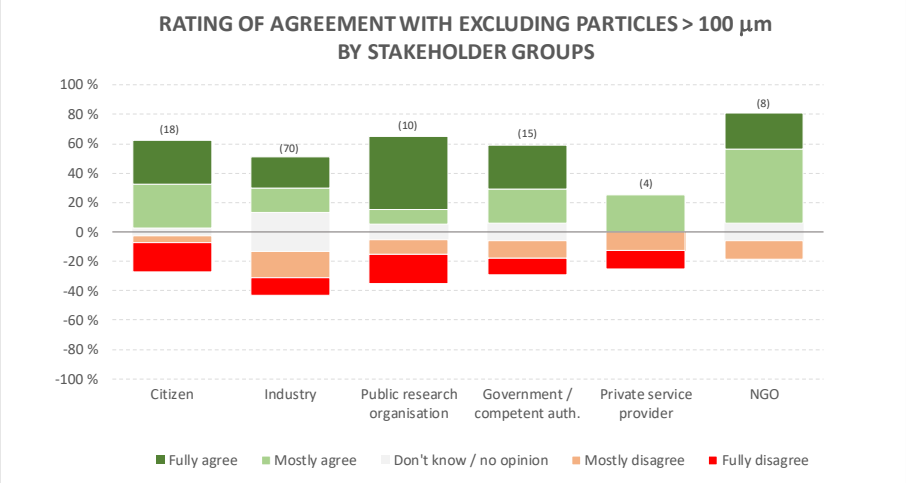

Figure 24: *Stakeholder groups' ratings on the agreement for excluding particles with at least two orthogonal external dimensions larger than 100 micrometres from the number-based size distribution. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

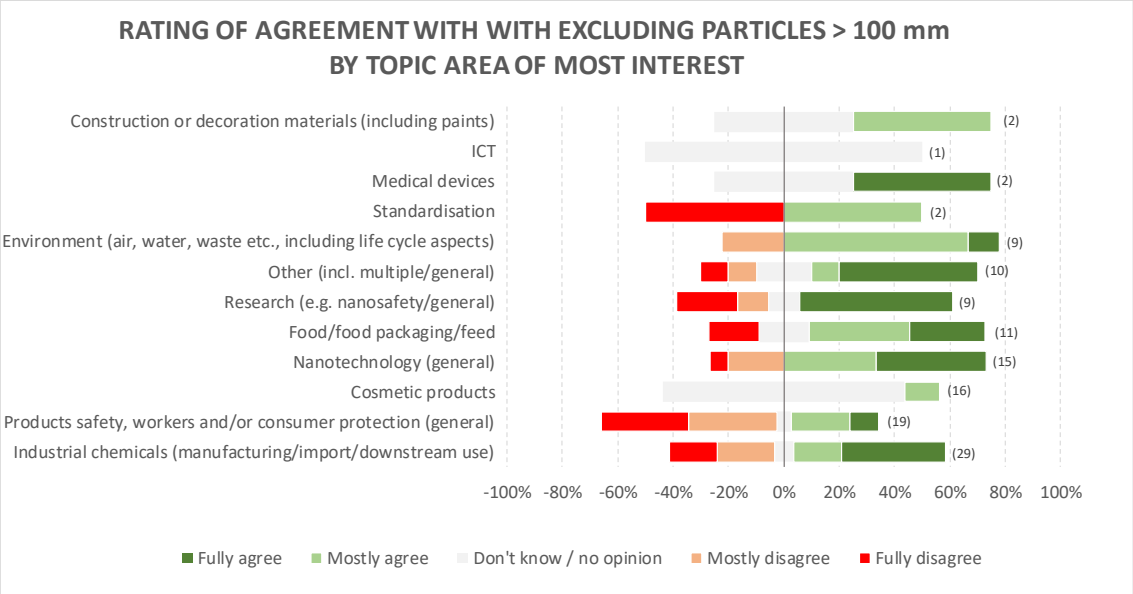

Figure 25: *Stakeholders' ratings on the agreement for excluding particles with at least two orthogonal external dimensions larger than 100 micrometres from the number-based size distribution. The numbers shown within parentheses represent the number of respondents within each group.*

Stakeholders who did not agree with the proposed change on excluding large particles were invited to provide additional clarifications by selecting one or more of the following reasons:

- **Answer 1:** The implicit exclusion of very large but thin (1-100 nm) platelets is not appropriate.
- **Answer 2:** An upper limit is useful but the proposed value or constraint regarding at least two orthogonal dimensions is not appropriate.
- **Answer 3:** The upper limit should apply only to specific types of particles.
- **Answer 4:** The definition should explicitly allow flexibility in whether particles larger than the upper limit are included or excluded in the tally.
- **Answer 5:** Other.

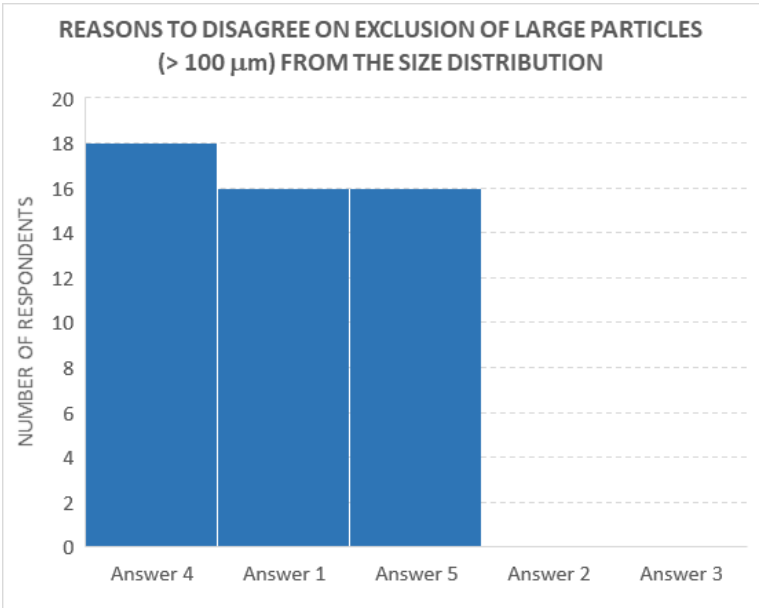

Figure 26: *Distribution of respondents over five pre-determined answers for possible disagreement with the exclusion of large particles from the number-based size distribution. Answer 2 and Answer 3 were not selected by any of the respondents.*

Several distinct arguments have been made. Several respondents argued that introducing such an upper limit for counting could potentially affect the representativeness of the measured particle size distribution and, as a result, lead to biased classification and, thus, many false positive identifications. For instance, materials consisting for 99 % of particles with diameter larger than 500 µm, but whose size distribution tails extend to the nanoscale range (cf. "nanotail"), could be (falsely) classified as nanomaterial. Materials should not be considered nanomaterials just because the particle size distribution has a nanotail (while the majority of particles are larger than 100 µm in diameter).

In avoiding that products containing wear particles could be classified as nanomaterials, some respondents request to introduce additional criteria such as a 0.01 % mass limit for particles < 100 nm. Several respondents questioned the arbitrarily proposed and counter intuitive size limit of 100 µm and/or suggested to consider a lower limit (e.g., 10 µm) that is scientifically justified, closer to the nanoscale range and/or toxicologically more relevant. Few respondents remarked that a size-based exclusion criterion may also lead to problems, as large platelets can break down easily during material handling and transport. Due to the emerging thin film technology, some industrial stakeholders proposed to consider a derogation for thin films, layers and 2D materials rather than applying an exclusion criterion. Such derogation, they claim, would avoid further measurement challenges that typically arise when particle size distributions span different orders of magnitude or contain two or more distinct particle populations across the nano- and (sub-)micrometre scale range. The proposed exclusion criterion can help to avoid in practice any potential ambiguity in differentiating between a particle and a large material sheet. However, one respondent stated that the potential toxicity of metal sheets mainly depends on the release rate of the surface rather than on the shape.

If exclusion criteria for large particles are to be adopted, then respondents generally require having the necessary practical measurement considerations available as guidance.

Summary response

Rationale for this exclusion is provided in chapter 2.6.8.3. Its objective is to facilitate implementation and not to introduce ambiguity to it. This exclusion is planned to be, alongside other implementation aspects, covered in the Guidance that should help identify in advance when applying this exclusion would not be appropriate. On should note also that realistic materials consisting mainly of large particles with a diameter >100 µm plus a fraction at the nanoscale (< 100 nm) would not be falsely identified due to the new VSSA criterion, according to which materials with a VSSA < 6 m^2/cm^3 are not considered nanomaterials. An additional mass-based criterion, as suggested by respondents, has been considered, but dismissed as it would effectively introduce an additional criterion to the definition, making it more complex and, unlike VSSA, likely internally inconsistent, regardless of the threshold eventually applied. With regard to a potential derogation for thin films and 2D materials, while representing only a subset of addressed situations, they are either already excluded (not particles) or would have to be unambiguously defined, very likely introducing some size-based criteria. One should also note again that the definition of nanomaterial is unrelated to a possible hazard of particulate materials. Assessment of hazard and risk is done according to sector specific legislation, with sector specific guidance covering all materials under its scope. For example, in the food sector, the guidance on risk assessment of nanomaterials also links to guidance on how to assess the risk of materials that contain small fractions of nanoparticles but are not considered a nanomaterial[39].

Consultation question 10: "Do you agree not to consider single molecules as 'particles' in the definition?"

As can be seen from ***Figure 27***, the top two box rating of 72 % and net top box of 57 % point at an overall agreement of the respondents. Based on the arithmetic mean and median (both 4.2), the average level of sentiment can be considered 'fully agree'.

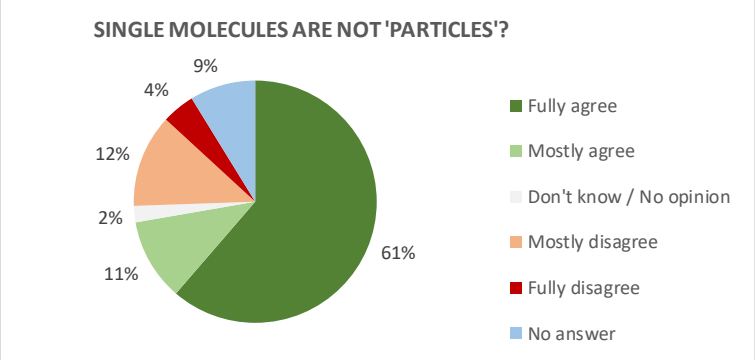

Figure 27: *Frequency distribution of all respondents regarding not to consider single molecules as 'particles'.*

Disagreeing responses were received mostly from NGOs (63 %), government/competent authorities (42 %) and public research organisations (30 %) (***Figure 28***). From ***Figure 29***, it can be concluded that stakeholders in the field of environmental protection seem to be more significantly concerned than others.

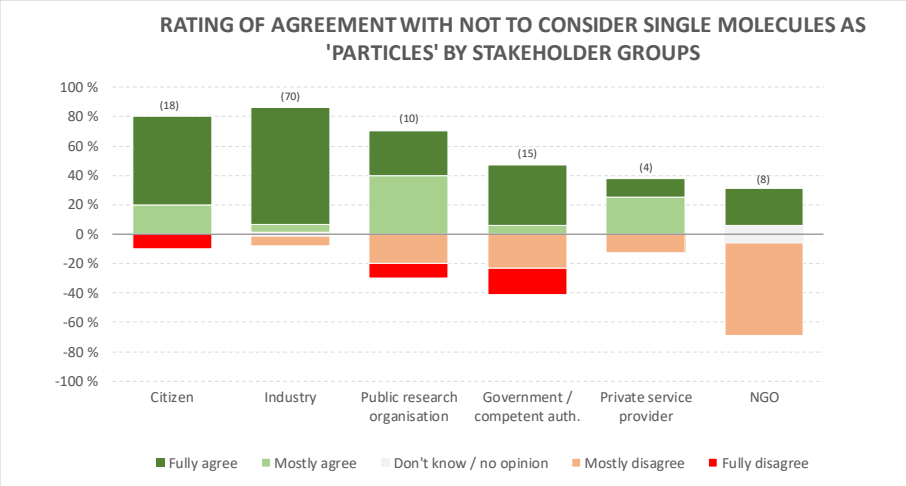

Figure 28: *Stakeholder groups' ratings on the agreement for excluding particles with at least two orthogonal external dimensions larger than 100 micrometres from the number-based size distribution. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

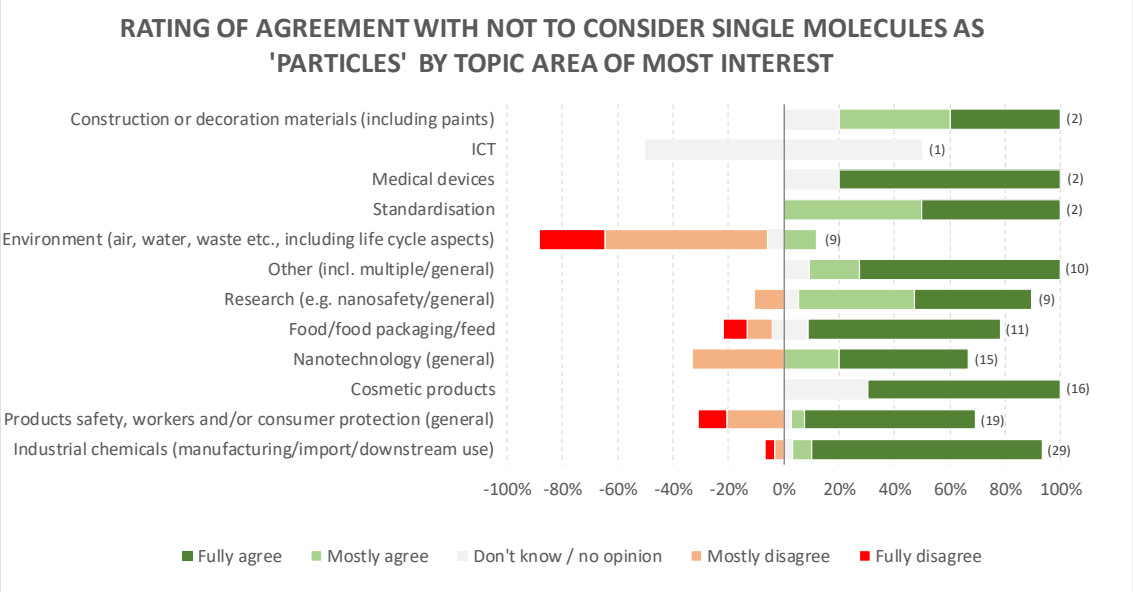

Figure 29: *Stakeholders' ratings on the agreement not to consider single molecules as 'particles' by topic area of most interest. The numbers shown within parentheses represent the number of respondents within each group.*

Some respondents stressed ambiguity of the term 'single molecule' and made proposals to allow case by case consideration, which could be elaborated in the Guidance. Proposals include comparison of consistency of relative molecular mass (cf. molecular weight) between particles (example based on polymer differentiation) or thermodynamic behaviour/solvation. Nanoplastic has also been put as an example of potential 'single molecule' and as an argument for not expanding conditions (solid, identifiable, single molecule...) beyond size. Other respondents align with a view that large molecules (e.g. also pigments, some advanced materials) may anyway share the 'particle effect' issues and resulting testing specificities. The respondents stated that this 'particle effect' might also apply to the proposed-to-be-excluded fullerenes. One stakeholder observed that 'not a molecule' might also be an ambiguous proposal when it comes to ionised gas clusters.

Another industrial association proposed to also explicitly exclude crystallites as particles, in line with the current approach in the identification of constituent particles in aggregates.

Summary response

Rationale behind the exclusion of single molecules is provided in chapter 2.7.2.

The term 'single molecule' is well-defined. It is acknowledged that some macromolecules may behave like particles, but not all; including molecules would introduce a disproportionate effort by all in demonstration of few and their particle nature. One should also note that the concerns for large molecules and for small particles are different: for molecules, the larger they are, the bigger the concern because they deviate from small molecules; for particles, the smaller they are the bigger the concern because they deviate from the bulk solid material. It is expected that the guidance will provide further illustrative cases where this differentiation may be challenging. For example, for plastics one should not really spend effort trying to prove singularity of molecules but rather assume, as soon as there is any divergence in masses of 'particles' going beyond the molecular weight distribution of the assessed polymer, that these are indeed particles. Ionised gas clusters are not considered a realistic material subject to regulatory assessment as nanomaterial. While the proposal on excluding crystallites is consistent with planned interpretation and implementation, including the term crystallite in the definition itself would not achieve the objective as it does not have an unambiguous definition itself.

As always, it should also be noted that specific material requiring additional scrutiny, perhaps even of the same type as mandated for nanomaterials in the legislation, can be handled in sector legislation. Fullerenes are an example of materials that could be considered in such a way.

Consultation question 11: "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 nanomaterial:

- **Answer 1:** No need for any additional inclusion of materials through criteria or specific derogation;
- **Answer 2:** Maintain current derogation;
- **Answer 3:** Update the current derogation list;
- **Answer 4:** Partially agree with the replacement of derogation but conditions need to be modified;
- **Answer 5:** Agree with the replacement of derogation with the inclusion of fibre- and plate-like materials as proposed;
- **Answer 6:** None of the proposed or no opinion."

From the 125 respondents, 52 (= 42 %) replied either that none of the proposed solutions are satisfactory or that they had no preference (***Figure 30***). 43 respondents (= 34 %) agree with the Commission proposal to replace the derogation with the inclusion of fibre- and plate-like materials.

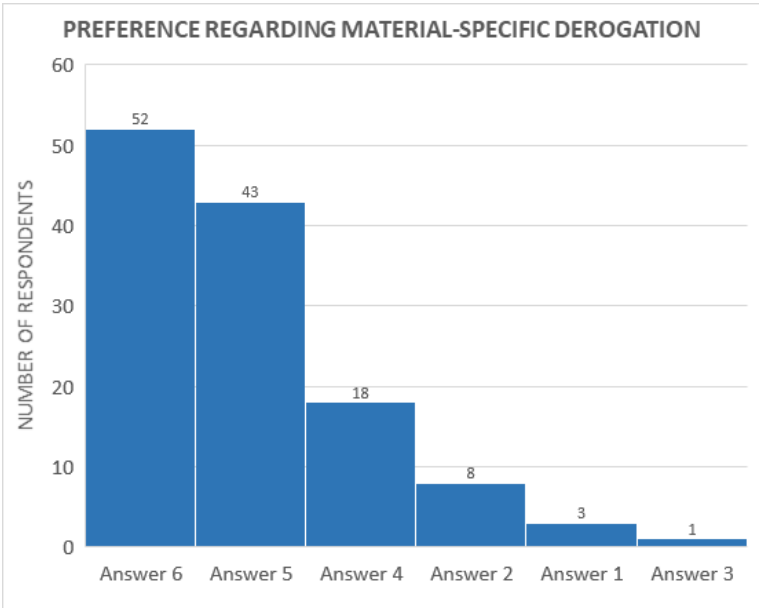

Figure 30: *Distribution of respondents over the preferred solutions in relation to material-specific derogations.*

Breaking down the data into stakeholder groups (***Figure 31***) shows that 41 out of 52 respondents from the industry group (or 59 %) chose Answer 6 while 13 % and 19 % selected Answer 5 and Answer 4, respectively. All other stakeholder groups heavily preferred Answer 5.

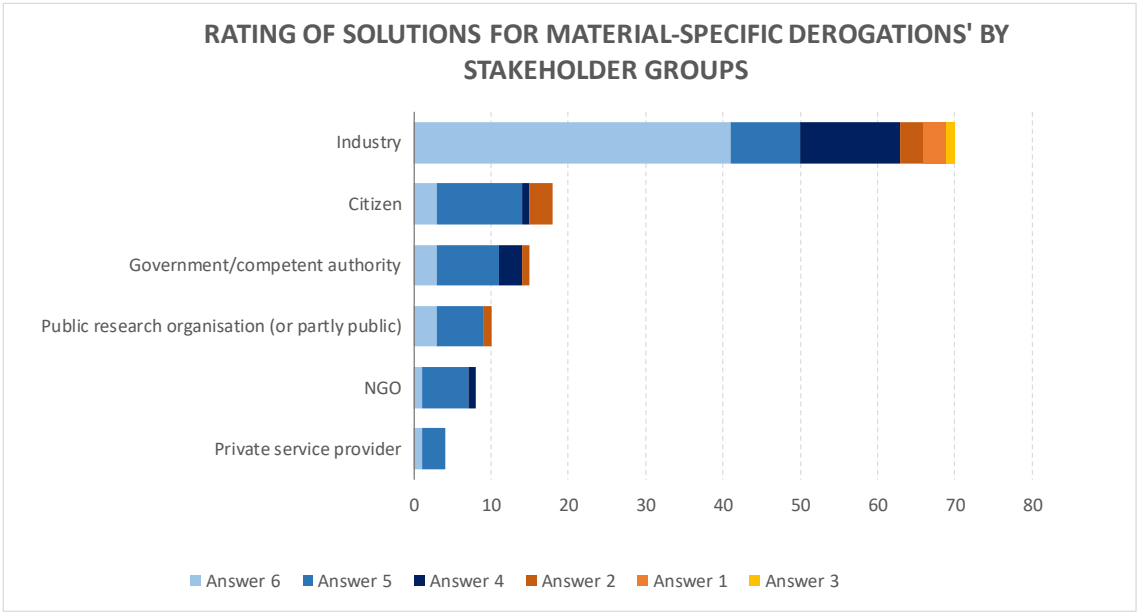

Figure 31: *Stakeholder groups' ratings on the possible solutions in relation to material-specific derogations.*

Some respondents, agreeing with the objective to generalise current derogation, are of the opinion that the change would not ensure that the carbon allotropes continue to be included, in particular the fullerenes, excluded by the single molecule exclusion. Therefore, some respondents recommended further additions and maintaining a list of 'always' nanomaterials, however without any concrete proposal.

Summary response

Arguments related to inclusion of specific materials as nanomaterials are addressed in chapter 2.6.6.

Consultation question 12: Do you agree that with these five changes particles are clearly and adequately defined for the purpose of the definition?

Although almost 50 % of the respondents agree that with the five changes particles are clearly defined, 35 % have an opposing view (***Figure 32***). A significant fraction (> 40 %) of the respondents from industry, public research organisations, and government/competent authorities believe that the term 'particle' should be better defined (***Figure 33***). Evaluating the data according to topic are of most interest does not flag specific trends (***Figure 34***). Worth mentioning is that 77 % of the stakeholders dealing with cosmetic products disagree.

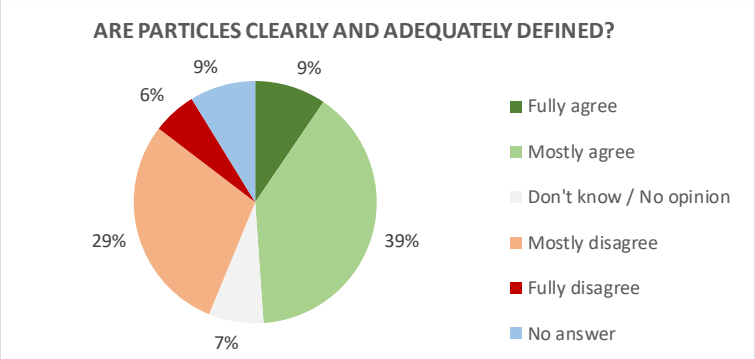

Figure 32: *Frequency distribution of all respondents regarding a clear and adequate definition for the term 'particle'.*

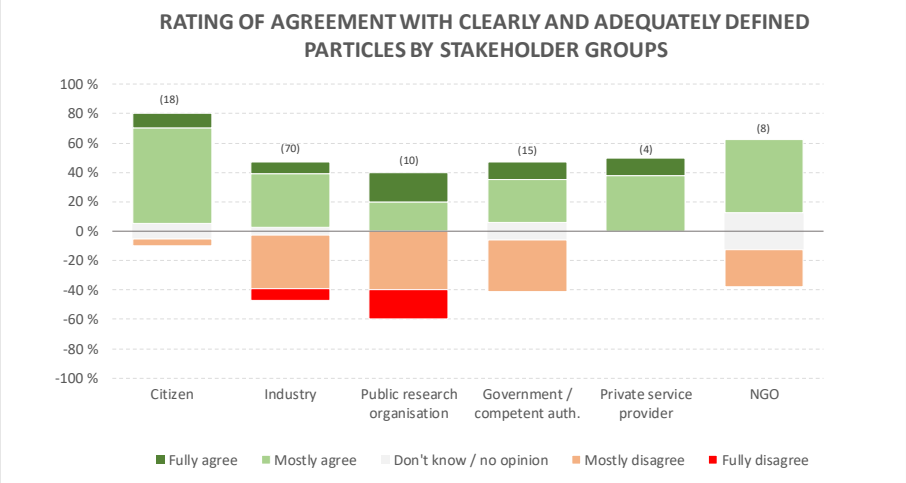

Figure 33: *Stakeholder groups' ratings on the agreement that with the five changes particles are clearly and adequately defined particles. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

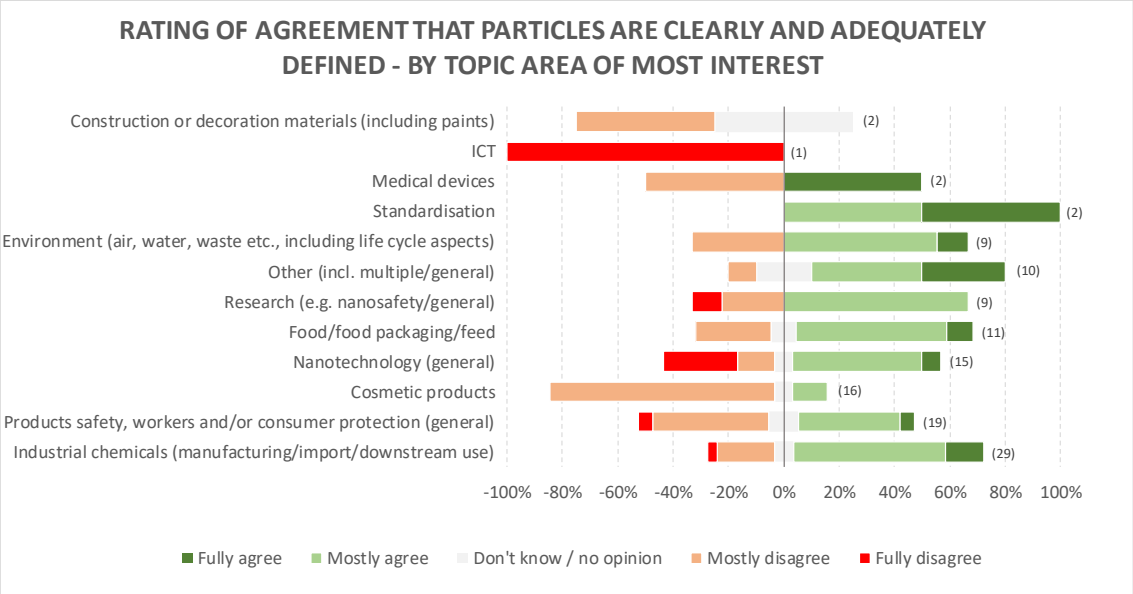

Figure 34: *Stakeholders' ratings on the agreement that with the five changes particles are clearly and adequately defined (by topic area of most interest). The numbers shown within parentheses represent the number of respondents within each group.*

In addition to a more generic observation that the changes do not sufficiently resolve the challenges, no additional observations were provided by the respondents under this question that were not already indicated above under individual elements. For example, crystallites were proposed for explicit exclusion alongside single molecule. Another respondent proposed an additional criteria: a) that the substance forms aggregates and agglomerates in the nanoscale (to be measured with standard dispersion process), and b) that the substance does not exist as a solvated moiety (i.e., does not thermodynamically behave more like a molecule than a particle, to be observed e.g. via thermal fluctuations or changes in apparent surface area upon slow solvent removal and BET).

Summary response

No additional response required. Proposal on crystallites has not been taken forward as the term would be associated with its definition challenges. The additional criteria proposed are considered interesting proposition to support implementation and will be looked into further, but not as additional criteria in the definition.

9.3. Flexibility of the threshold

Element E3 of the questionnaire discusses the flexibility of the threshold.

Consultation question 13: Do you agree with removing the flexibility of the (50 %) threshold?

The results shown in ***Figure 35*** show that the majority (71 %) agrees with removing the flexibility of the threshold. According to the calculated arithmetic mean of 4.2, the corresponding level of sentiment is "fully agree". The stakeholders' agreement is also reflected by the median value (3.7), the top two box (71 %) and the net top box (47 %).

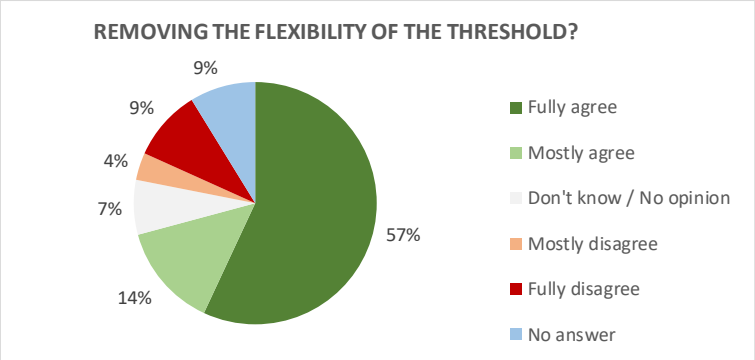

Figure 35: *Frequency distribution of all respondents regarding the agreement on removing the flexibility of the threshold*

Evaluating the data by stakeholder groups shows that industry and public research organisations heavily agree while NGOs heavily disagree (***Figure 36***). Citizens and private service providers generally agree. The preference for the government/competent authority stakeholders is not clear.

Plotting the data by topic area of most interest (***Figure 37***) shows that the disagreement mainly stems from stakeholders found in the fields of environment and product/worker/consumer safety.

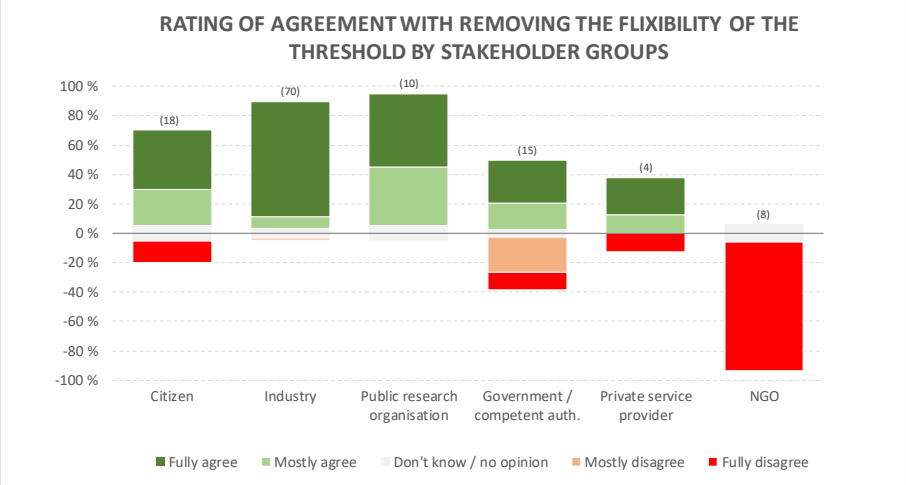

Figure 36: *Stakeholder groups' ratings on the agreement to remove the flexibility of the threshold. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

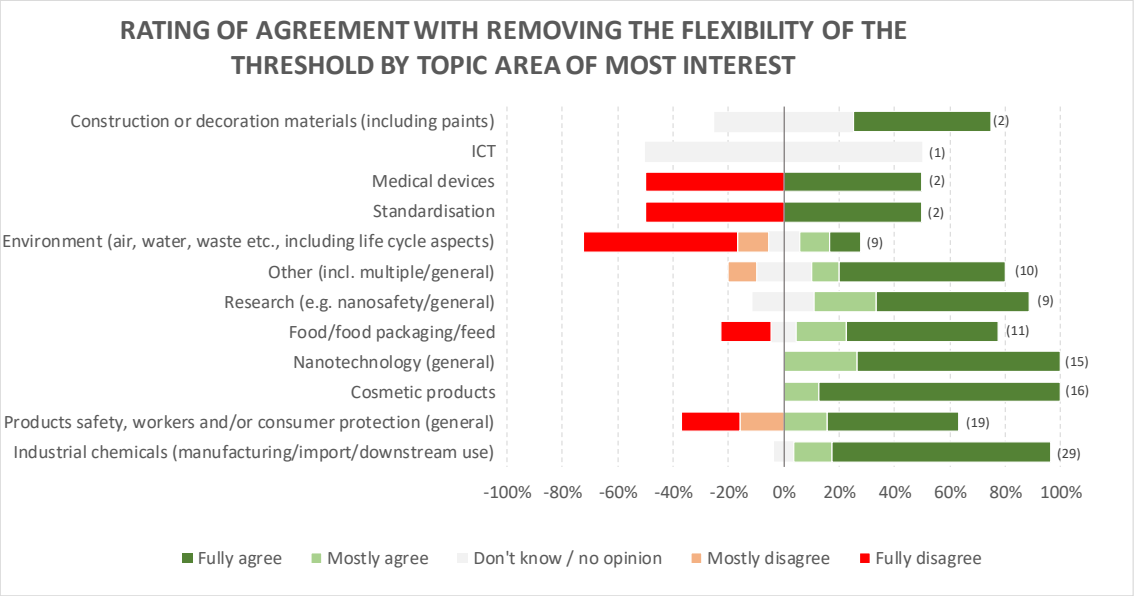

Figure 37: *Stakeholders' ratings on the agreement with removing the flexibility of the threshold (by topic area of most interest). The numbers shown within parentheses represent the number of respondents within each group.*

The respondents that were opposed to the removal of the flexibility clause mainly reported that the current 50 % threshold is too high for effective risk management purposes and that the flexibility should therefore remain. Few respondents also noted that, as the definition is disconnected from risk management, there is a need to develop sector-specific guidance for materials that contain nanoparticles, but which are not formally identified as nanomaterials according to the definition. The need for such guidance has for instance been recognised by the Commission in its mandate to EFSA to establish guidance for conventional materials that contain a fraction of small particles[39].

A few respondents countered the explanatory note of the consultation, which they interpreted that the Commission proposes to remove the flexibility of the threshold value because it has not been applied so far. As main argument, the respondents refer that the time since the adoption of the revised Annexes of the REACH Regulation (dd. 1 January 2020), which require companies to provide additional information on nanomaterials, has been too short.

Some respondents asked for a scientific motivation for the chosen threshold and for appropriate flexibility for the regulators to act when a particular particle size and/or particle shape has proven to be particularly hazardous (cf. WHO fibre requirements).

Summary response

The argument behind the removal of the flexibility clause is presented in chapter 2.6.5.

No arguments have been put forward that would make the Commission to reconsider its position on the flexibility. Classifying materials according to a fixed threshold value will lead to a more harmonised nanomaterial identification across legislation resulting in smaller legal uncertainties and less inconsistencies between different sectors. With a single threshold, support to implementation can also be much more targeted and effective. The flexibility of the 50 % threshold value in the current definition was introduced as a safeguard to allay concerns about uncertainty and lack of knowledge on

nanomaterials at the time. As indicated above, the definition is intended for material classification purposes, without prejudice about possible safety of certain materials.

The heightened scrutiny of nanomaterials should, through provisions in the legislation, lead to adequate risk assessment that would then inform risk management measures, where required. Assessment by the Commission had not provided indications of a need for a lower generic threshold (see also below), expanding the scope of materials requiring heightened scrutiny as nanomaterials. To address only specific materials, EU sectoral legislation already includes mechanisms to ensure the specific scrutiny and, where concern is confirmed, adequate risk management response, including limitation of their content in products. These tools can also deal with the materials with a lower percentage of particles in the nanoscale.

Consultation question 14: "Do you agree with maintaining the default threshold value of 50 %?"

Almost two-third (61 %) of the respondents agree with maintaining the default threshold value of 50%. The arithmetic mean and the median value are 3.7 and 3.3, respectively, indicating that the average level of sentiment is 'mostly agree', despite that 20 % of the respondents disagree (***Figure 38***). ***Figure 39*** shows that mainly the NGOs disagree, and most of them fully disagree.

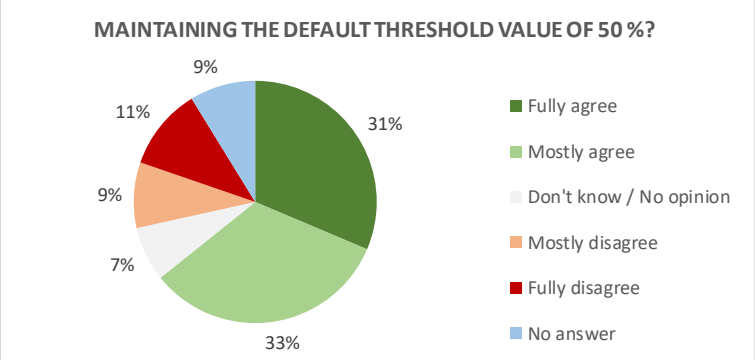

Figure 38: *Frequency distribution of all respondents regarding the agreement on removing the flexibility of the threshold.*

According to the data plotted in ***Figure 40***, the fraction of disagreeing responses is mainly weighted towards stakeholders found in the fields of environment and product/worker/consumer safety.

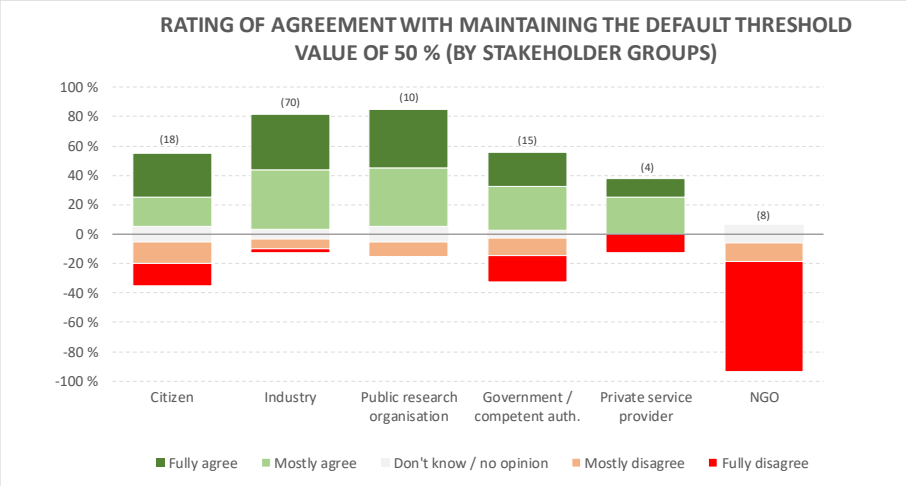

Figure 39: *Stakeholder groups' ratings on the agreement to maintain the default threshold value of 50 %. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

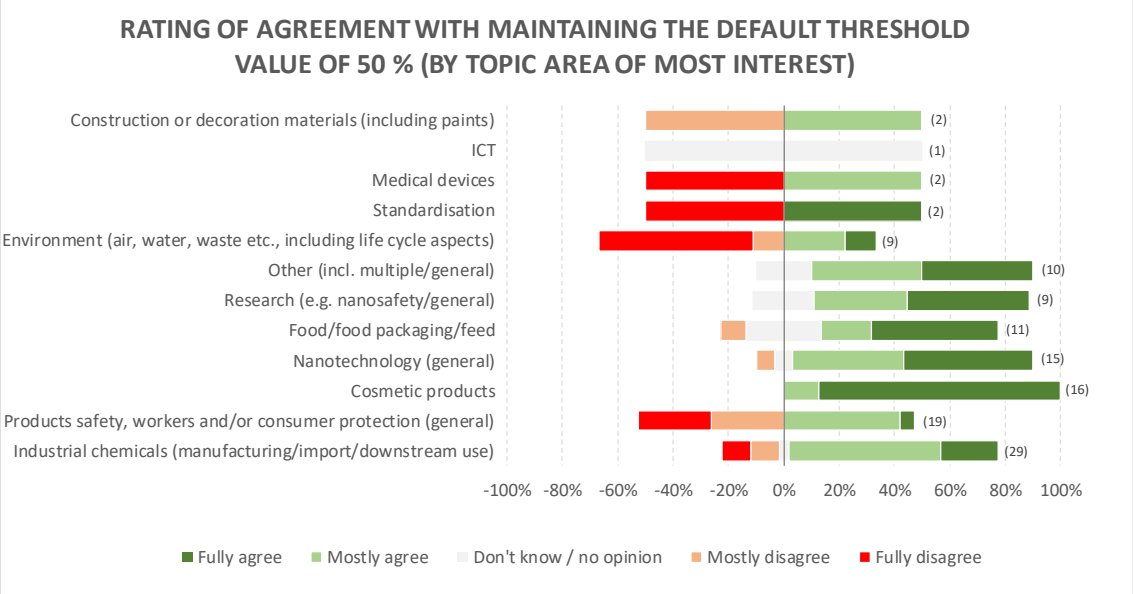

Figure 40: *Stakeholders' ratings on the agreement with maintaining the default threshold value of 50 % (by topic area of most interest). The numbers shown within parentheses represent the number of respondents within each group.*

One of the main arguments against the proposal to maintain the 50 % threshold value was that the current **value is too high for effective risk management** and should therefore be replaced by a scientifically underpinned and measurable lower threshold value. On the other hand, few respondents argued that the 50 % threshold value has been chosen arbitrarily by the Commission and that maintaining this value could complicate compliance assessments, and therefore constitutes a **possible barrier to trade and innovation**.

On the other hand, coming from a measurement perspective, several respondents advocated that the **threshold value should be expressed on a particle mass (or weight) basis** for three-fold reasons. Firstly, the majority of analytical techniques that are currently available, measure mass-based size results and only arrive indirectly at number-

based information through data conversion. Such data conversion is typically prone to high uncertainties. Secondly, quantifying nanoparticles in highly polydisperse samples whose size distributions span multiple orders of magnitude, is extremely challenging for even the most advanced techniques. Thirdly, the mass-based metric is less sensitive to nanoparticles that can be unintentionally but sometimes abundantly present in the lower size tail of the particle size distributions of materials that are not intended to be manufactured in the nanoscale range (e.g., pigments, fillers). According to some respondents, a possible remedy for the latter case would be the introduction of a 1 % mass-based threshold that either adds on to the existing 50% number-based threshold or, when particle number distributions cannot be determined, replaces it.

Summary response

The number-based particle size distribution of particles on their own or as constituents in aggregates or agglomerates represents a core element of the definition and is as such elaborated in chapter 2.7.4. Rationale for the choice of the threshold value and its review are covered in chapter 2.6.5.

In summary, the constituent particle number-based metric has been chosen as it represents an intrinsic property of the individual material and to relate more directly to the societal concerns that have led to the development of the nanomaterial definition i.e. individual nano-objects, avoiding being overshadowed by large particles. The threshold of 50% is a convention that links naming/classification of a material as a nanomaterial to the majority fraction of the relevant aspect of composition – the particles. The Commission acknowledges that most NGOs strongly disagree with a 50 % threshold; they perceive the value is too high. The Commission nevertheless intends to fix the 50 % threshold for the following reasons:

- There is no compelling scientific evidence that would steer towards a particular threshold. The chosen 50 % is a convention but is not arbitrary. The Commission chooses to uphold the logical convention that objects, or in this case substances, are named/classified after their main 'component of relevance within the context', in this case particles. If most particles in a substance have external dimensions larger than 100 nm, it would not be right to call the substance, including its major non-nano-component, a nanomaterial. Choosing the particle number-based size distribution as the basis for the definition already is stretching this general naming convention to the maximum extent possible, because in terms of mass or weight fraction, the 50 % of particles smaller than 100 nm will always be less (and often much less) than 50 % in terms of weight fraction. The Commission also wishes to stress again that, if particular concerns exist over the presence or effects of a smaller amount (< 50 %) of nanoparticles in a substance, in a mixture or even in a product or article in general, then dedicated measures can be envisaged, not requiring the substance, mixture or product to be called 'nanomaterial'. One example is the approach followed by the EFSA Scientific Committee in its Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles[39]. This EFSA document provides guidance on conventional substances that contain a smaller number of particles than a set threshold (10 % in this case), and on substances that contain particles that are larger than 100 nm (in this case up to 250 nm or even 500 nm).
- The Commission insists on using the particle number fraction instead of the suggested particle mass fraction as it is more directly related to the societal concerns

that have led to the development of the nanomaterial definition, namely the potential effect that individual, small particles can have, if they have properties that are unusual or unknown, or at least different from the properties of the bulk form of the same substance (if such substance exists). Nevertheless, the Commission acknowledges that the effect of exposure to nanoparticles is not always related to their number (in certain cases it relates more to the particles' surface area or mass), but among the different metrics, the particle number is the most precautionary and conservative. The Commission understands the arguments and challenges regarding measurability of particle number fractions in certain cases. This is the reason why it is proposing that, in certain specific cases where measuring a full particle number-based size distribution is impractical, other metrics and approaches are used (see chapter 2.6.8.1 on VSSA and chapter 2.6.8.3 on upper size limit).

9.4. VSSA

Consultation question 15: "Do you agree with deleting the use of VSSA as a surrogate for particle size distribution measurement for classifying materials as nanomaterials?"

Compared to most previous consultation questions, only 51 % of the respondents agreed with the given Commission proposal (***Figure 41***). About 27 % of the respondents disagreed. Despite the rather large variation of responses (CV of 0.5), the average level of sentiment is 'mostly agree' (arithmetic mean of 3.8); the median value was 3.1.

Figure 42 shows that the fraction of respondents who replied 'mostly disagree' corresponds to NGOs. On the other hand, the fraction (15 %) of the respondents who 'fully disagreed' can be linked entirely to citizens and industry.

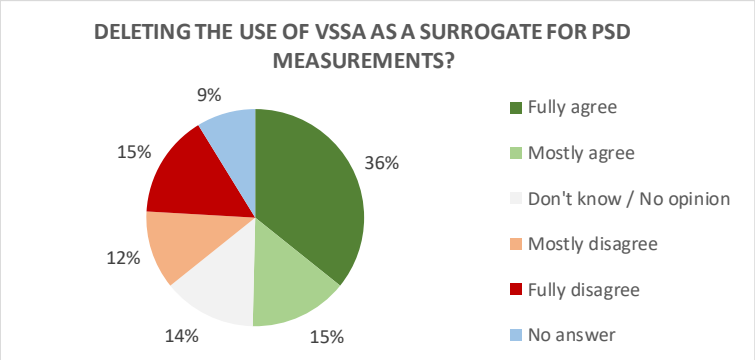

Figure 41: *Frequency distribution of all respondents regarding the deleting the use of VSSA as a surrogate for particle size distribution measurements.*

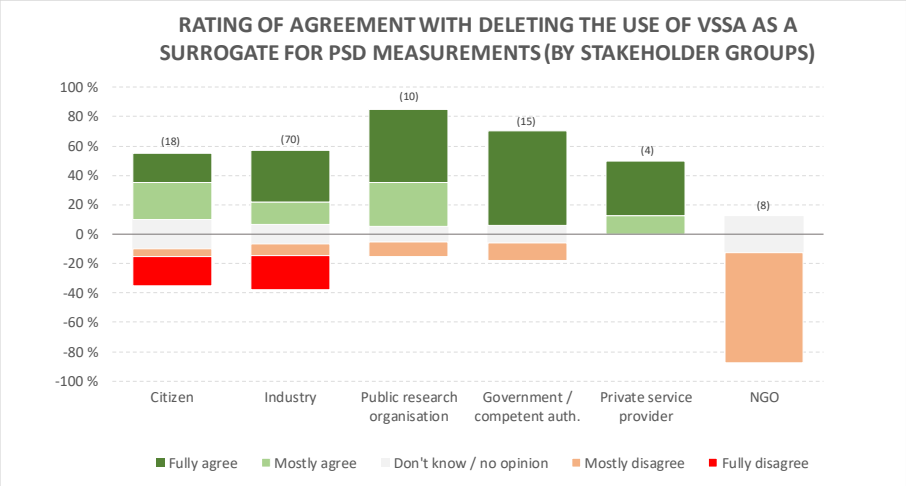

Figure 42: *Stakeholder groups' ratings on the agreement to delete the use of VSSA as a surrogate for particle size distribution measurements. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

Looking at the topic areas of most interest (***Figure 43***), it can be concluded that most respondents of the cosmetic products sub-group 'fully disagree'.

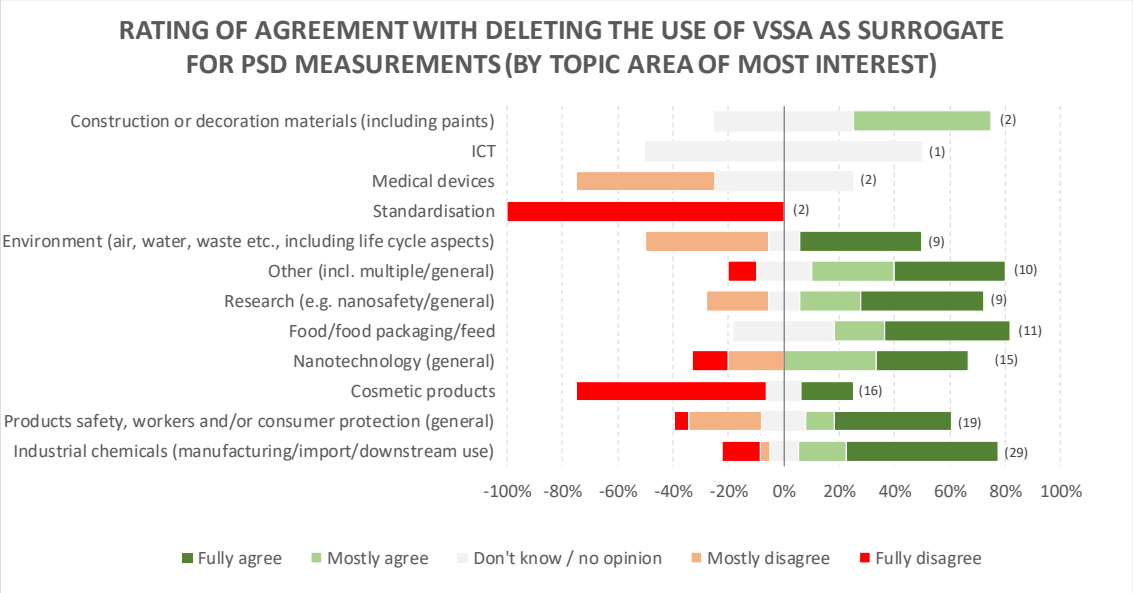

Figure 43: *Stakeholders' ratings on the agreement with deleting the use of VSSA as a surrogate for particle size distribution measurements (by topic area of most interest). The numbers shown within parentheses represent the number of respondents within each group.*

Some respondents who disagreed on the Commission's proposal to delete VSSA as surrogate criterion or proxy to facilitate the identification of nanomaterials argued that, in particular for homogeneous pristine powders, the VSSA method can be a quick and cost-effective alternative to PSD measurements. On the other hand, some respondents who followed the Commission's proposal highlighted that VSSA is indeed not an appropriate qualifier when materials consist of particle mixtures, matrix materials or nanostructured materials. However, they suggested that VSSA can play a role in the identification of non-nanomaterials.

Summary response

The approach to VSSA is elaborated in chapter 2.6.8.1. Maintaining VSSA as surrogate criterion in the definition would create ambiguity since particular classes of materials (e.g. nanostructured and microporous materials) can lead to 'false positive' results. The 'use case' for avoiding particle size distribution measurement altogether for identified nanomaterial is likely not very strong, as such information would likely be expected anyways as part of the regulatory requirement. However, as a screening tool, VSSA may continue to serve well and will as such have a place in the Guidance.

Consultation question 16: "Do you agree with adding a possibility to use a VSSA threshold value of 5 m^2/cm^3 as a threshold to exclude materials from the definition of a nanomaterial?"

Presented in ***Figure 44*** is the distribution of respondents regarding the agreement of adding an additional VSSA threshold of 5 m^2/cm^3. About 55 % of the respondents agreed to add an extra VSSA threshold as exclusion criterion and 21 % disagreed. A rather large fraction (16 %) of the respondents had a neutral position.

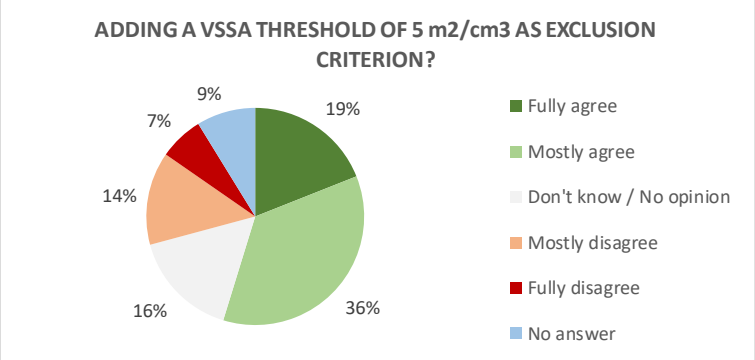

Figure 44: *Frequency distribution of all respondents regarding the agreement on adding an additional VSSA threshold value of 5 m^2/cm^3 to exclude materials from the definition.*

The distribution by stakeholder groups (***Figure 45***) shows that only a minor fraction of citizens and industry disagree with an additional exclusion criterion, and that the public research organisations and government/competent authorities submitted mixed responses. On the other hand, most NGOs disagreed. The degree of disagreement is relatively equally distributed amongst the different topic areas of most interest (***Figure 46***). Stakeholders in the sub-group 'environment' (weighed by strong NGO representation) disagreed more than others.

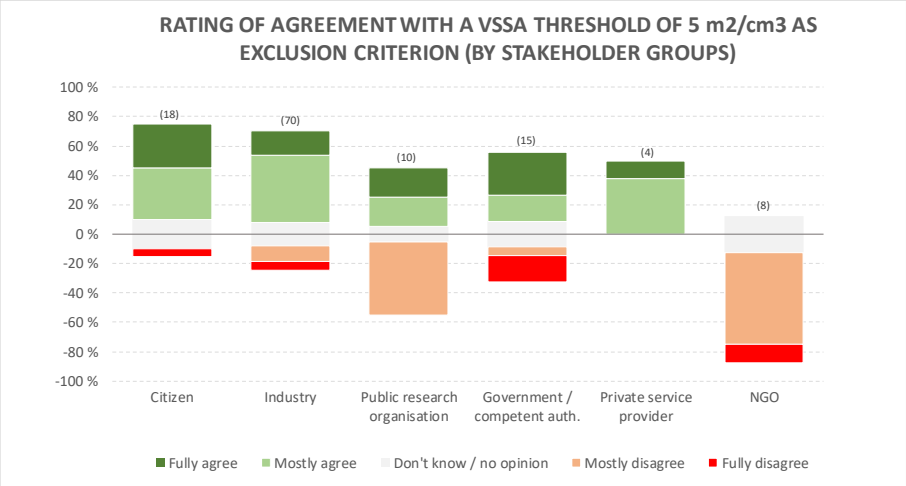

Figure 45: *Stakeholder groups' ratings on the agreement to add a VSSA threshold value of 5 m^2/cm^3 as exclusion criterion. The numbers shown within parentheses represent the number of respondents within each stakeholder group.*

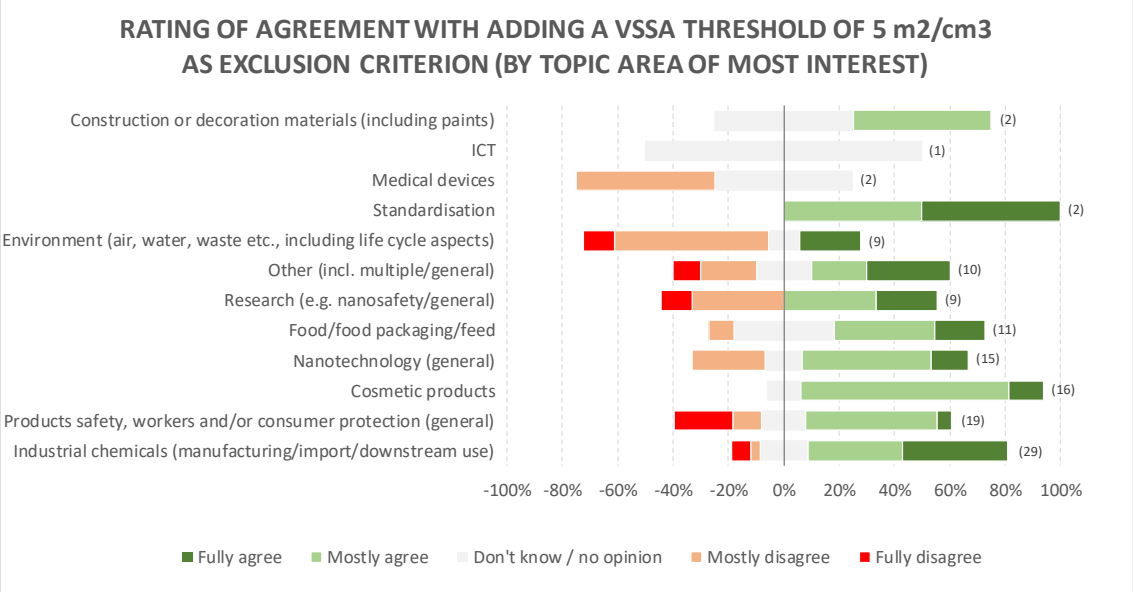

Figure 46: *Stakeholders' ratings on the agreement with adding a VSSA threshold value of 5 m^2/cm^3 as exclusion criterion (by topic area of most interest). The numbers shown within parentheses represent the number of respondents within each group.*

A number of arguments against the proposal are related to the nature of the proposal, as any 'secondary definition' is in general not desirable: if there is one, must be clear it is secondary; if not allowed for inclusion should not work for exclusion; application unclear. Further response points to measurement challenges vis-a-vis reliability. Sensitivity to presence of secondary material that can reduce VSSA, the specific surface area (SSA) of graphene and a general inability of VSSA to work well for some nanomaterials (in which case mass-specific surface area (MSSA) should be considered) have been further issues raised by different respondents.

The most common question by the respondents that may have well accepted the approach has been why the Commission proposed a threshold of 5 m^2/cm^3 and not 6 m^2/cm^3, as described and experimentally verified in NanoDefine. In the same manner, some

respondents stepped further and proposed that shape-dependent thresholds should be introduced.

Summary response

As the rationale behind the VSSA threshold is presented in chapter 2.6.8.1, it is not further elaborated here. It is clear that application of VSSA presents its own class of issues. Guidance will be provided to facilitate use and address potential challenges in measurement and interpretation. Introduction of shape-dependent threshold as verified by NanoDefine was considered as too complex for the introduction in the definition, in particular as it would necessarily require assessment of the appropriateness of the threshold chosen. Based on the feedback however, the value of 6 m^2/cm^3 (and not the rounded value of 5 m^2/cm^3 initially considered) has now been chosen for the revised definition.

9.5. Concluding visualisation on the structured feedback received for Parts 1 and 2

A summary of the Likert-type questions from Part 1 and Part 2 of the questionnaire is presented graphically in the following multi-layered pie chart (***Figure 47***). It can be seen that for most questions, the modal classes correspond either to the sentiment levels 'fully agree' or 'mostly agree'. Only for one question Q7, the modal class corresponded to 'mostly disagree'. The arithmetic means and medians are relatively consistent and range from 3.2 to 4.2 and from 3.0 to 4.0, respectively.

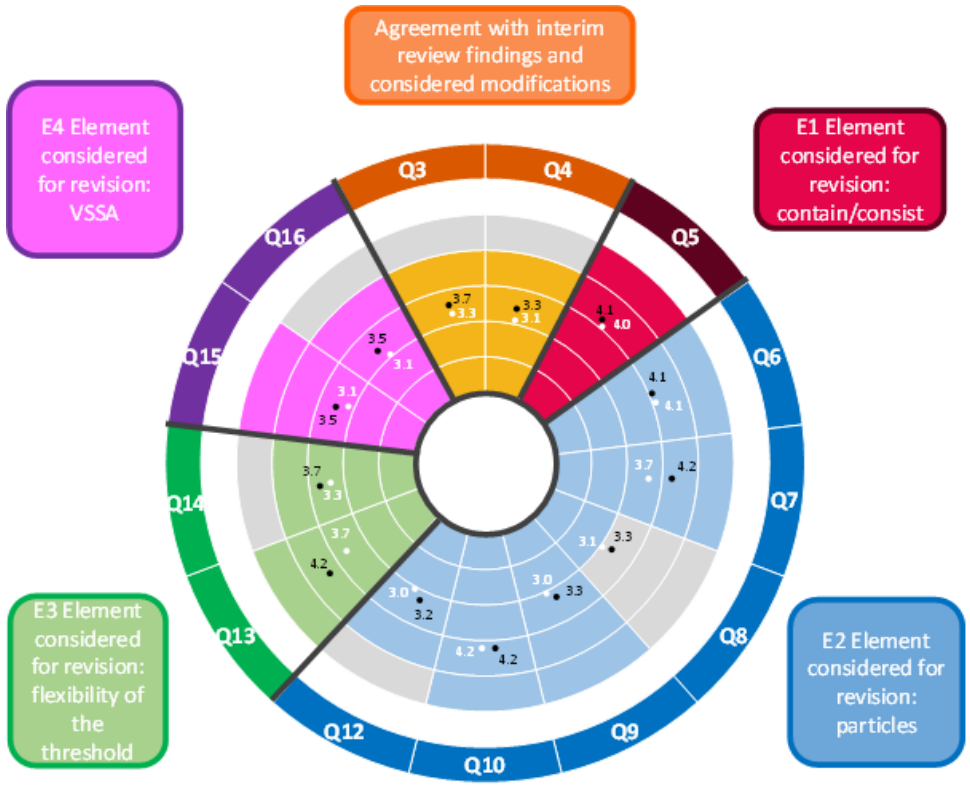

Figure 47: *Summary of Likert scale result from Part 1 and Part 2 questions. The coloured inner circle segments correspond to the modal classes; the black and white dots with numbers denote the arithmetic means and medians, respectively.*

10. ANALYSIS AND ANSWERS TO THE SURVEY QUESTIONS (PART 3)

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

Consultation question 17: "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)?"

Consultation question 18: "Do you plan to produce such materials in the near future?"

As shown in the pie chart depicted in ***Figure 48***, three-quarters of the respondents stated that the implementation of the considered changes will not affect the categorisation of their materials produced or imported. On the other hand, 11 out of the 57 respondents, or 19 %, declared that their materials will possibly become nanomaterials when the proposed changes will be implemented. Lifting out this group shows that 7 out of the 11 respondents are industry stakeholders linked to industrial chemicals (3), nanotechnology (1), food and feed (1), construction or decoration materials (1) and other (1).

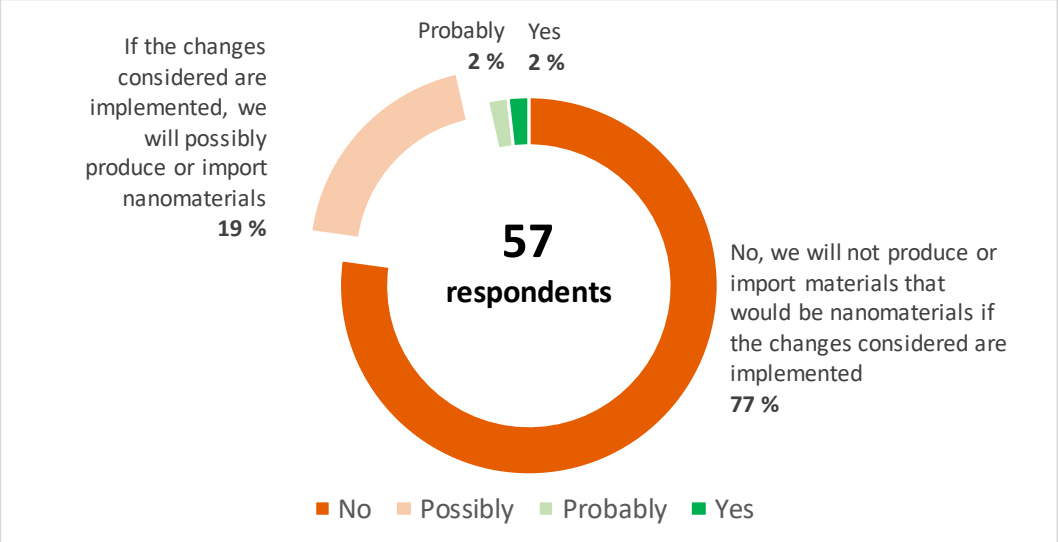

Figure 48: *Impact of implementation of changes considered on material categorisation.*

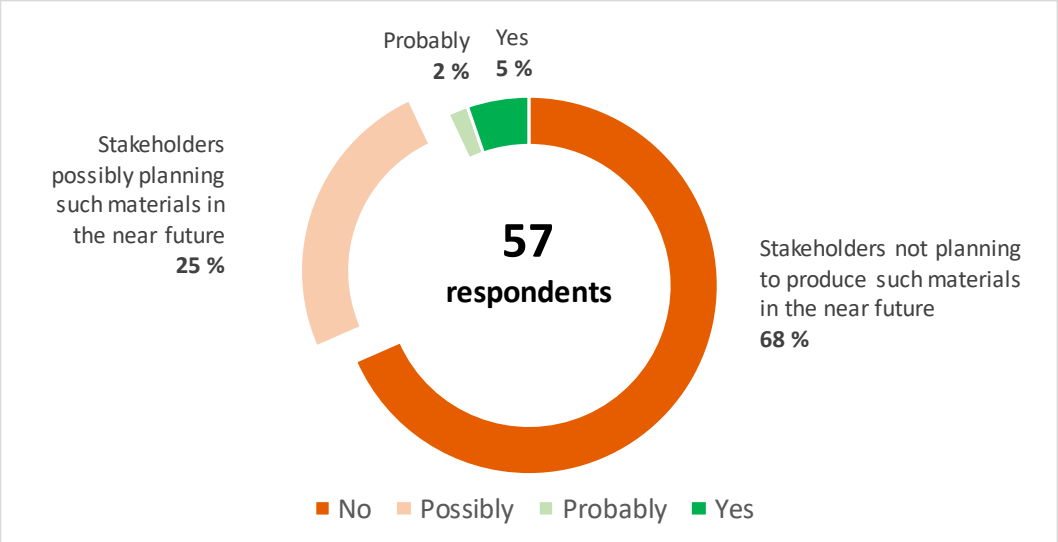

Figure 49: *Impact of implementation of changes considered on production of future materials.*

On the question whether stakeholders plan to produce such materials in the near future, 39 respondents, or 68 %, confirmed negatively while 14 respondents (or 25 %) replied that the production of such kind of materials will be possibly planned in the near future (**Figure 49**). In line with the previous question, the latter group consisted mainly of industry (10) and public research organisations (4). The industry stakeholders were mainly linked industrial chemicals (5), food and feed (2), product safety (1) and other (1).

When the respondents selected 'yes' or 'probably', the respondents were invited to identify and describe their material(s) (***Table 3***). In total, seven candidate nanomaterials were identified by four respondents. Platelet-like materials are clearly represented within this group.

Table 3*:* Candidate nanomaterials identified by the respondents

Name/de-scription	**Volume (present or planned, in tonnes/year)**	**Criterion relevant for the inclusion (2b/fibre, 2c/platelet or another criteria)**	**Particle dimensions or other relevant feature**	**Use(s)**	**Do you presently consider them as nano-material?**
Pearlescent pigment	> 10	Change of unbound state	(1-100) µm	Cosmetic	No
Silica	> 10	VSSA	>1 µm	Cosmetic	No
Graphene	< 0.1	One dimension in the nanometre range	Particle dimension only	Develop-ment in general	Yes
Few layer graphene and graphene nano-	2-3 (present) 10-100 (planned)	2c/platelet	Lateral sizes (2-5) µm Thicknesse (1-10) nm	Additives for polymer systems, coatings, lubricants,	Yes

platelets				cementitious additives, printed electronics, energy storage applications	
Hexagonal boron nitride nano-platelets	0.05 (present)	2c/platelet	Lateral sizes (2-5) μm Thicknesse (1-10) nm	Thermal manage-ment, composites	Yes
Transition metal dichalco-genide nano-platelets	0.05 (planned)	2c/platelet	Lateral sizes (2-5) μm Thicknesse (1-10) nm	Lubricants, semi-conductors	Yes
Graphene dispersions	0.2 [CBI]	VSSA	(30 x 500) nm	Formu-lations	Yes

Consultation question 19: "Linked to the use listed above, which EU or national regulations with nanomaterial specific provisions do you see being applied to the material(s)?"

The four respondents who identified candidate nanomaterials (***Table 3***) and one additional respondent (who did not identify any material or materials) selected multiple regulations (***Table 4***).

Table 4*: Candidate nanomaterials identified by the respondents*

Name/description	**REACH**	**Biocides**	**Cosmetic products**	**Food and feed legislation, food contact materials**	**Medical devices**	**Pharmaceutical products**	**Ecolabel**	**Other EU Regulation**	**National regulation**
Pearlescent pigment	X		X						X[1)]
Silica	X		X						X[1)]
Graphene	X								
Few layer graphene and graphene nano-platelets	X	X		X		X	X		

Hexagonal boron nitride nano-platelets	X	X		X		X	X		
Transition metal dichalco-genide nano-platelets	X	X		X		X	X		
Graphene dispersions	X	X							
Undefined material		X	X	X	X	X	X		

[1)] French R-nano register, after Decree no. 2012-232

Consultation question 20: "What will be impact of the material(s) as nanomaterial on the placement on the market, innovation?"

From the stacked bar chart shown in ***Figure 50***, it is generally perceived by the respondents that categorizing materials as nanomaterials will most likely not boost innovation and/or competitiveness, but can rather have an opposite effect. The categorisation as nanomaterial will not be the leading cause to withdraw from the market, although there is a strong feeling that it can be, at least occasionally, a contributing factor.

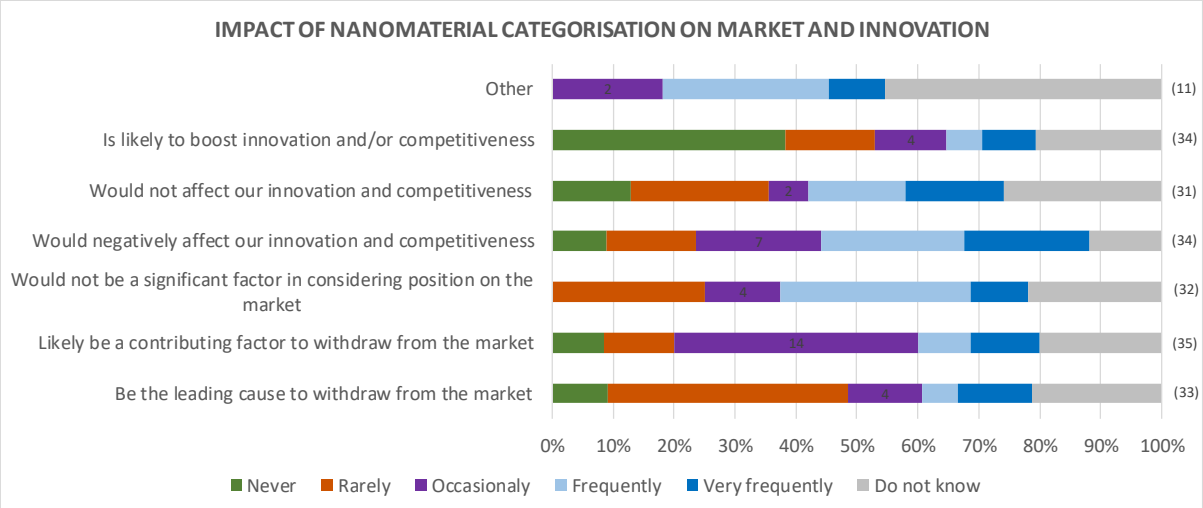

Figure 50: *Impact of nanomaterial categorisation on the placement on the market and on innovation. The numbers shown within parentheses represent the number of respondents within each group.*