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Questions and answers on the Commission Recommendation on the definition of nanomaterial

1. Why do we need a definition of the Term "nanomaterial"?

The definition will primarily be used to identify materials for which special provisions (concerning for example risk assessment or ingredient labelling) might apply. Those special provisions are not part of the definition but of specific legislation in which the definition will be used.

Nanomaterials are not intrinsically hazardous but there may be a need to take into account specific considerations in their risk assessment. Therefore one purpose of the definition is to provide clear and unambiguous criteria to identify materials for which such considerations apply. It is only the results of the risk assessment that will determine whether the nanomaterial is hazardous and whether or not further action is justified.

Today there are several pieces of EU legislation and technical guidance documents that support the implementation of legislation, which contain specific references to nanomaterials. To ensure conformity across legislative areas, where the same materials are often used in different contexts, the purpose of the Recommendation is to provide a coherent cross-cutting reference. Therefore another basic purpose is to ensure that a material which is considered as a nanomaterial in one sector will also have the same classification if used in another. Definitions so far used in EU legislation have not been subject to the same level of detailed scrutiny as the present Recommendation. The EU co-legislators already acknowledged this when e.g. the Cosmetics Regulation was adopted, by allowing later adaptation of the definition through thecomitology procedure. The Recommendation will be used as the basis for this adaptation.

2. Are nanomaterials Hazardous ?

The Recommendation on the definition of nanomaterial concerns exclusively the defining aspects of materials within a specific size range. Some materials covered by the definition are hazardous while others are not. There is no consistent causal link between nano size alone and hazards. It has clearly been expressed by SCENIHR[1] that:

"It should be stressed that "nanomaterial" is a categorisation of a material by the size of its constituent parts. It neither implies a specific risk nor does it necessarily mean that this material actually has new hazard properties compared to its constituent parts." (final opinion 2010, p31)

[1] Scientific Committee on Emerging and Newly Identified Health Risks

3. Why not use existing international definitions?

Several countries, both inside and outside the EU, as well as international organisations, have used working definitions. All these have been carefully scrutinised. There is variability between the different working definitions and most of them are not as precise as the present Recommendation.

Most non-EU countries generally use their definitions in a different regulatory context mainly to identify individual substances on a case by case basis, which then may be subject to specific data provision or risk assessment obligations. In the EU, provisions in individual pieces of legislation (e.g. ingredient labelling, prior notification and authorisation etc.) apply directly to all producers of products containing nanomaterials. Therefore, much more precision is required to provide legal clarity.

The Commission has taken the ISO (International Organisation for Standardisation) term “nanomaterial” as the basis for its definition but has made a number of modifications which were deemed necessary to ensure its practical application in a regulatory context.

Notably the reference to "approximately" when referring to the size range is not appropriate in a legislative context. Moreover, contrary to ISO terminology, the Commission definition of “nanomaterial” is limited to materials consisting of particles (excluding non-particular materials such as proteins or micelles as present for example in mayonnaise), and excludes nanostructured materials (i.e. solid products, parts or components) with an internal or surface structure in the range between 1-100 nm, such as computer chips).

4. Is it really possible to have only one single definition?

The Recommendation offers a common understanding of the term “nanomaterial” to avoid confusion on terminology and inconsistency between different pieces of legislation. This does not mean that specific legislation needs to apply to all nanomaterials, or that there could not be legislation covering similar materials outside the definition. Since the definition is broad in its coverage, further sector specific qualifiers may be needed in order to identify more precisely those materials that should potentially be subject to specific legislative requirements or policy attention.

For example it is likely that in many cases only materials that are a designed product of a deliberate manufacturing process will be of interest (commonly referred to as "engineered" or "manufactured" nanomaterials). Thus further qualifiers will be added on a case-by-case basis, in order to target the specific materials that qualify for special attention within each regulatory sector.

Another consideration is that in certain specific sectors, like pharmaceuticals, it is established practise to refer to nano-scale being broader than 1 nm – 100 nm. The Recommendation clearly specifies that in such a situation other "nano"-terms may be needed to describe those products.

5. Why is the number distribution threshold put at 50 % when SCENIHR suggested 0.15 %?

There is no unequivocal scientific basis to suggest a specific threshold in the size distribution below which materials containing particles in the size range 1 nm – 100 nm are not expected to exhibit properties specific to nanomaterials. SCENIHR's advice was to use a statistical approach based on standard deviation with a threshold value of 0.15%.

The Commission decided to deviate from this threshold value for practical considerations. Nanoparticles are present in low quantities in most solid materials. The percentage may be significant, in particular in certain powders. Therefore, a threshold of 0.15% could include too broad a range of materials within the definition, and would have made it difficult to tailor regulatory provisions appropriately. The choice of 50 % is based on the attempt to distinguish nanomaterials which may exhibit specific novel properties from conventional chemical substances. The value will be subject to further review by 2014.

Nevertheless, in accordance with SCENIHR's advice, even a small number of particles in the range between 1 nm – 100 nm may in certain cases justify a targeted assessment. For such cases, the Recommendation clearly specifies that where warranted by concerns for the environment, health, safety or competitiveness a threshold below 50 % may be set.

6. Why is it not specififed that only manmade materials can be nanomaterials?

The Recommendation only identifies a nanomaterial on the basis of its particle size. The justification for this choice is that properties or risks posed by a nano-sized material are not determined by the intention of the manufacturer and do not differ depending on whether the nanomaterial is natural, produced incidentally, or the result of a manufacturing process with or without the explicit intention to produce a nanomaterial. There are many naturally occurring nanomaterials and they may exhibit similar properties to those that are manufactured. From a definition point of view it is therefore not logical to omit certain types of materials on the basis of their genesis.

However, when it comes to potential legislative requirements it is expected that nanomaterials will be treated like other materials. This means that if a specific piece of legislation only addresses manufactured materials, the same limitation would also apply to nanomaterials.

7. Why not focus the definition on nano-specific properties instead of size, as this is done in other definitions, including some of the definitions in existing EU legislation and some definitions in non-EU countries?

The Commission considers that size is the only universally applicable, clear and measurable criterion which can be used to identify materials which due to their particle size may exhibit specific properties or risks, and which therefore should be characterised as nanomaterials, and for which special considerations might apply. This is also in line with the advice of SCENIHR.

Whether a specific nanomaterial indeed exhibits hazards or risks will however only appear as a result of a risk assessment.

Another reason for not referring to properties specific to nanomaterials is legal clarity. The specific properties of nanomaterials vary and it is often unclear whether such properties relate to the nano-size, to the chemical nature of the material or a combination of both. Therefore, referring to properties in the definition would render the definition subjective, as it would be unclear what properties would be meant and what thresholds would be used to distinguish nanomaterials from non-nanomaterials.

Moreover, a definition based on properties bears the risk of a circular reasoning. This is because size is relatively straightforward and clear to measure compared to other properties. Information on other properties of the material might not be available before testing but only as a result of the testing. Therefore, with a definition based on properties in general it may only be possible to identify whether a material is a nanomaterial after the testing for those properties, while one of the main purposes of the definition is to identify materials in a relatively easy and clear way for which specific testing considerations might apply

8. Why is the size range limited to 1 nm – 100 nm?

There is no clear scientific justification for setting the thresholds at 1 nm and 100 nm, as specific effects may also occur at a lower and higher size range. On the other hand, there may also be no specific effects of particles within the size range of 1 to 100 nm. Nevertheless, many of the described specific properties of nanomaterials are actually within that range. Therefore, in the absence of better arguments for other thresholds, the Commission decided to follow the most commonly applied approach, i.e. a size range between 1 and 100 nm. This is also in line with the advice from SCENIHR and other scientific bodies, as well as with the size range used in the ISO term “nanomaterial”.

9. Why must the particle distribution be measured in number and not by mass which is commonly used?

The amount of nanoparticles in a material can be determined based on mass (weight of nanoparticles to total weight of material) or based on the numbers (number of nanoparticles to total number of particles, "number size distribution"). There is a correspondence between the two measures for every material, but size and mass distribution are not directly convertible.

The Scientific Committee (SCHENIR) argued in its opinion that "*a low mass concentration of nanoparticles in a product may still represent a high number of particles and a mass based distribution can be skewed by the presence of relatively few large and thus heavy particles".* Therefore it considered number size distribution as a more relevant metric for possible effects of nanoparticles than mass concentration.

The Commission considers this reasoning as relevant and decided to follow this choice of metrics. Further work is certainly needed on the metrological aspects. The Commission intends to start work to provide practical guidance on measurement methods. This issue is also likely to be one of the subjects to be studied in further detail as part of the review planned for 2014.

10. Are aggregates and agglomerates of nanoparticles nanomaterials?

The short answer is 'yes'. Agglomerated or aggregated particles may exhibit the same properties as unbound particles. Moreover, there can be cases during the life-cycle of a nanomaterial where the particles are released from weakly bound agglomerates or under certain conditions even from more strongly bound aggregates. The definition in the Recommendation therefore includes particles in agglomerates or aggregates whenever the constituent particles are in the size range 1 nm - 100 nm.

This inclusion is in conformity with the scientific advice the Commission has received as well as the general international understanding e.g. in the works of ISO.

11. What is the purpose of including the Volume specific surface area as a metric?

At present it is possible to measure a specific surface area by mass for dry solid materials or powders with the gas adsorption method (“BET-method”). If the particle density is also known, then the 'volume-specific surface area' can be calculated and used as a proxy to identify a potential nanomaterial. In those cases the specific surface area can be used as a proxy to identify a potential nanomaterial.

New scientific knowledge may expand the possibility to use this and other methods to other types of materials in the future. There can be a discrepancy between the measurement of the specific surface area and the number size distribution from one material to another. The measurement of the specific surface area is also sensitive to the measurement method used. It is therefore specified in the Recommendation that results for number size distribution should prevail and it should not be possible to use the specific surface area to demonstrate that a material is not a nanomaterial.

12. Why does the definition only cover particulate materials and exclude nanostructured materials?

The Recommendation only concerns particulate nanomaterials. It is equally applicable to particles in an unbound stage as well as when they are aggregated or agglomerated.

The Commission did not include other types of nanostructured materials such as nanoporous or nanocomposite materials that are used in some sectors as there is currently not sufficient evidence to guide what materials should be included. Together with all other apects of the definition, this will also be subject to the review the Commission intends to report on by December 2014.

13. What about nanomaterials in products?

The Recommendation's scope covers nanomaterials when they are substances or mixtures, but implicitly not when they are final products. This limitation is equal to that introduced by ISO. This means that if a nanomaterial is used amongst other ingredients in a formulation the entire product will not become a nanomaterial.

14. Can the definition be used without measurement and standards being available?

Guidance and standardised measurement methods as well as knowledge about typical concentrations of nanoparticles in representative sets of materials should be developed where feasible and reliable to facilitate the application of the definition in a specific legislative context. The Commission will put emphasis on these aspects as a matter of priority. However, use of the definition should not wait the outcome of this work and a pragmatic case-by-case approach will be workable already today. In fact it should be an iterative process where practical experience will form an important aspect of the further development of methods and standards.

15. Why is the definition so broad and what about economic impacts?

The breadth of the definition is a deliberate choice flowing from its exclusive focus on size. It is imperative to underline that materials covered by the definition are not more hazardous as such than larger but otherwise identical materials. Whether a nanomaterial is hazardous will only be determined as part of a risk assessment.

When the definition is applied, further qualifiers and specifications may be needed to limit the scope to only those materials of interest to each sector.

A definition will not come at any direct economic costs. It is simply a categorisation of certain materials based on their size.

16. Will the definition be subject to future reviews?

Large parts of the nano-technology sector are rapidly developing and it is therefore expected that the market developments will require the Commission Recommendation to be reviewed at certain intervals.

Moreover, there are a number of methodological issues and questions of scope which could not be fully answered in the preparatory work for the definition. For example, the Recommendation does not address nano-structured materials. Firstly, it is unclear whether the specificities of such materials warrant the same or similar considerations as for nanomaterials covered by the definition in the Recommendation. Secondly, in a way similar to particles, a wide range of solid materials have to a certain extent nanostructures, and it is unclear what cut-off values could be used to distinguish nanostructured materials from non-nanostructured materials. It is therefore envisaged that the scope of the Recommendation be reviewed by December 2014 to ascertain whether these types of materials should be included.

Another important aspect concerns the 50 % threshold which will be reviewed in light of the latest scientific knowledge and of the practical implementation experience.

17. How will the Commission engage stakeholders in the definition?

The Commission fully agrees on the need to maintain an open dialogue with all stakeholders and the international community. The public consultation and a number of subsequent events to which the Commission has engaged in vital discussions on the content of the definition as well as its future application demonstrate this commitment.

The Commission finds it important to discuss how it can be applied in different sectors and how systematic information that can feed into the 2014 Review, can be generated.

18. will the Commission propose new legislation on nanomaterials/revise existing Legislation?

The Commission has received scientific advice stating that nanomaterials require a case by case assessment. Whether this is the case today is being reviewed by the Commission. For example the adequacy of REACH and the data submitted in the REACH dossiers are currently being reviewed. The Commission will present its conclusions in a comprehensive regulatory review in the beginning of 2012. Moreover, there are plans to make a new proposal on Novel Foods which will also address nanomaterials. There are also various files in co-decision where amendments to include provisions on nanomaterials are being discussed. In addition, the Commission will also present information on nanomaterial types and uses, including safety aspects, as promised to the European Parliament.

19. Why did the Commission use the legal instrument of a Commission Recommendation, and how will this be implemented in specific Legislation?

The legal instrument of a Commission Recommendation was chosen following the positive experience with the definition of small and medium-sized enterprises, which is also a Commission Recommendation. As the definition as such does not contain any direct obligations for Member States and economic operators, its implementation will happen through various pieces of specific legislation. The Commission intends to use the definition in new proposals and update existing legislation where this is foreseen by the legislator. As indicated in the Recommendation, the definition can be applied in a flexible way through adaptations of the scope of provisions in specific legislation. In case of specific concerns related to the environment, health, safety or competitiveness, a lower threshold for the number size distribution of nanoparticles may also be used.