

Survey on experiences made during the implementation of the EC recommendation of a definition of nanomaterial

Identification and general information about your organisation	
Please give the name of the organisation for which you reply to this survey. -open reply-(compulsory)	
Japan Business Council in Europe	
Please provide your name and your position in the organisation. -open reply-(compulsory)	
Akihito Nakai, Secretariat	
Please provide your email address for correspondence. -open reply-(compulsory)	nakai@jbce.org
What is the type of your organisation? -single choice reply-(compulsory)	Industry or trade association
In which country is your organisation principally based? -single choice reply-(compulsory)	Belgium
Your experience in the implementation of the definition	
How would you describe your organisation's general experience with the implementation of the EC recommendation of a definition of nanomaterial?	
<i>Please see the link to the background documents at the top of the page.</i> -open reply-(compulsory)	
Japan Business Council in Europe, namely JBCE consist of memberships from upstream to downstream in various fields such as chemical, automotive, ICT, household appliance, medical, cosmetic, analytical equipment etc. Many of our memberships have unclear points for how they can assure whether their substances or mixtures are met with EC nanomaterial definition or not in conflicted measurement methods and consideration of measurement cost. We have close communication with Nanotechnology Business Creation Initiative, namely NBCI and they have much knowledge about how challenges in practical situation there are to specify with reliable evidence whether or not EU nanomaterial definition is met.	
Is the wording of the EC definition of nanomaterial clear and unambiguous? -single choice reply-(compulsory)	No
Please explain why you do not consider the wording as clear or unambiguous. -open reply-(compulsory)	
Generally speaking, it is almost clear. However, the scope of the definition should be limited to single and particle-like material. The definition should clearly describe that the following cases are excluded ; - mixture as such - composite material - Non-particle materials, such as nano-size thickness film and nano fiber of which one or two dimensions are millimeter range	
Is it clear to which materials the EC definition of nanomaterials applies? -single choice reply-(compulsory)	No
Please explain why it is not clear to which materials the EC definition of nanomaterials applies. -open reply-(compulsory)	
We can indicate some examples for materials that EC definition is possibly applied, but we can't say 100 % sure because there is always exceptional case. In addition, we can't measure size distribution with reliable evidence by state-of-art technics for primary particle although SEM or TEM can see particles directly for limited number.	
Are the individual elements (terms, thresholds, etc.) of the EC definition clear? -single choice reply-(compulsory)	No

Please identify the elements that are unclear and give reasons. -open reply-(compulsory)

It is almost clear, but there are some practical difficulties when measuring. We will make separate contribution because we need to take more time. We would like to say that it is important to avoid confusion between EC definition and ISO TC229 standard that the terms should not be identical if its meaning, scope, range etc. differ in both definitions.

Are you satisfied with the "Questions and Answers" section provided by the European Commission?

No

Please see the link to the background documents at the top of the page. -single choice reply-(compulsory)

How could the "Questions and Answers" section be improved?

-open reply-(compulsory)

We would like you to improve "term of particles" because we can't measure primary particles in practical situation.

Are you aware of any guidance on the implementation of the definition, other than the "Questions and Answers" section provided by the European Commission? -single choice reply-(compulsory)

Yes

Please specify the guidance(s) that you are aware of.

-open reply-(compulsory)

As you may know, ISO/TC229 are now discussing about "the tiered approach identifying nanomaterials and not nanomaterials to the definition"

Is the guidance clear? -single choice reply-(compulsory)

Yes

Has your organisation been facing issues in implementing the definition's specification on size distribution?

Yes

-single choice reply-(compulsory)

Please describe these issues in more detail. -open reply-(compulsory)

Actually, our answer should be " No ", but it is under the condition that size distribution includes mathematical / statistical calculation.

Does your organisation make use of size distribution measurements of particulate materials? -single choice reply-(compulsory)

Yes

Please list the methods which were used for these measurements.

For each method listed, please identify the material(s) for which the method is used.

-open reply-(compulsory)

SEM,TEM,DC,DLC,LD,IG, DLS, SLS, SAX, DMA etc. Needless to say, it is needed to choose appropriate measurement method in accordance with sample conditions.

Which of these methods are used by your organisation in-house? -open reply-(compulsory)

We could not collect the information in time. Nevertheless we will make our contribution by separate paper later.

Are there borderline cases, i.e., materials for which it was difficult to decide whether they are nanomaterials according to the EC definition? -single choice reply-(compulsory)

Yes

Please describe such borderline cases. -open reply-(compulsory)

If generally speaking, our answer should be " No ", but if concretely speaking, it might be affected in specific case by measurement condition like size of parent population.

Are you aware of measurement methods that have recently been developed or improved in a way that makes them a likely candidate method to help you implement the EC definition of nanomaterial in the near future? -single choice reply-(compulsory)

No

What level of resources do you use for the implementation of the EC definition of nanomaterial (e. g., manpower, instrumentation, consultancy, etc.)?

Please add also a quantitative estimate of the most significant costs (person hours, instrument time, consumables etc.) for the type of material(s) that is (are) relevant for your organisation. Please specify the material(s). -open reply-(optional)

We could not collect the information from our memberships in time. Nevertheless we will make our contribution by separate paper later.

Would you consider pragmatic solutions such as measurements of other, related material properties (e. g., specific surface area), and/or provision of information about the manufacturing process be acceptable as a substitute for size measurement for specific regulatory purposes?

-single choice reply-(compulsory)

Yes

If yes, please specify and give reasons. -open reply-(compulsory)

You can refer to "the tiered approach identifying nanomaterials and not nanomaterials to the definition" in TC229 and SSA measurement will be developed in this tiered approach. We can provide more information of some parameters to ensure nanomaterial property, but we could not be in time in this consultation. Nevertheless we will make our contribution separately.

Do you propose any change to the EC definition? -single choice reply-(compulsory)

Yes

Please specify and/or give reasons for your answer to the previous question.

-open reply-(compulsory)

The definition should be shared internationally. It's difficult to identify primary particles, so we should identify using " actual dispersion technique". It should be set "exception" as remarks, for example thin film, long fiber...

Here you can add any additional comments which you feel would be of particular use in the review process of the EC definition of nanomaterial. -open reply-(optional)

With regard to D. provision of measured particle size distributions, we guess that our several memberships can provide, but we could not say " Yes " because we could not confirm it in time for deadline of this consultation.

Additional questions

Other than the EC definition of nanomaterial, are there any other relevant 'nanomaterial' definitions in the area (geographical or sectorial) relevant for your organisation? -single choice reply-(optional)

No

Which recent scientific publications are particularly relevant for the implementation and review of the EC nanomaterial

definition? (Max. 10 publications)

-open reply-(optional)

For which matrices (consumer products, food and feed, cosmetics, biocides, substances, etc.) do you envisage or predict a future need to determine the nanomaterial fraction (i.e. volume or mass percentage of nanomaterial in the matrix, but not the size distribution) by in-situ measurements?

-open reply-(optional)

Provision of measured particle size distributions

Do you have reliably measured particle size distributions for materials with a large fraction of fine particles that provide a basis to decide whether or not the material should be classified as nanomaterial?

No

-single choice reply-(compulsory)