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NANOMATERIALS DEFINITION FACT SHEET

NOVEMBER 2014

• A legal definition of nanomaterial is essential to implement specific risk assessment and risk management measures for nanomaterials.

• Crafting a science-based legal definition is challenging because both our understanding of these new materials and the measurement and imaging technologies needed to assess them are evolving rapidly.

• A definition too large in scope could impose nano specific requirements to materials for which they are not relevant. On the other hand, a definition that is too restrictive could allow nanomaterials onto the market without subjecting them to adequate risk assessment and management measures

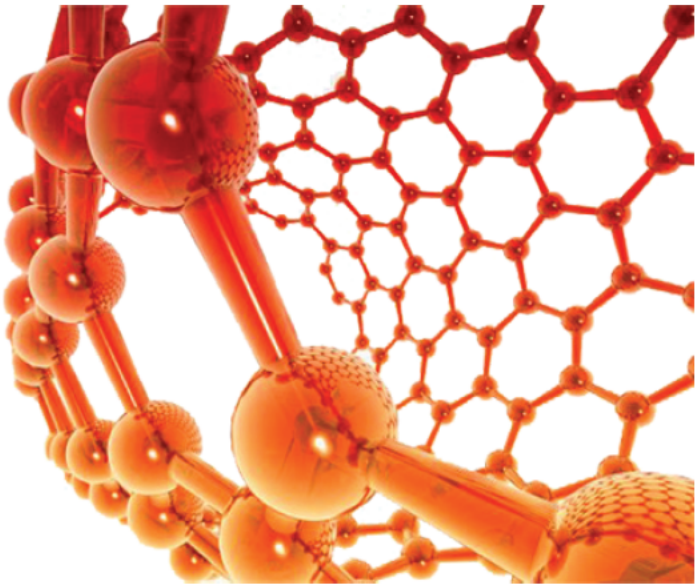
• The EU is the only jurisdiction with a horizontal legal definition of nanomaterials in place. In addition, EU sector specific legislation such as for cosmetics and biocides contain distinct definitions that are yet to be harmonized.

• The EU definition is challenged as being too broad or too restrictive by different stakeholders.

• Technical challenges to its implementation remain, and the EU Commission is currently considering revisions with assistance from the Joint Research Center.

Nanotechnology can generally be described as the synthesis, visualization, configuration and manipulation of atomic to molecular sized particles. This includes the manufacture, use and manipulation of materials at the nano scale. This innovative technology promises technical and economical advantages in diverse fields ranging from medicine, cosmetics and food processing, to energy production and storage, and electronics and textiles. Despite its promises, the use of nanomaterials come with risks and potentially harmful impacts on human health and the environment. Because voluntary options have repeatedly failed in the past, nanomaterials must be legally required to go through specific risk assessment and management procedures before being introduced to the market .

In a regulatory context, a legal definition is critical to establishing which substances and materials will be covered by the specific provisions adopted to ensure the safe development and use of nanomaterials. A definition that is too restrictive means that some nanomaterials will not be subject to the specific risk assessment and risk management provisions designed for nanomaterials, and will enter the market without being properly assessed and managed. Conversely, a definition that is too broad will include materials that do not need to be subject to the targeted risk assessment and risk management procedures designed specifically to ensure the safety of nanomaterials.



However, crafting a science-based legal definition of nanotechnology is a serious challenge because both our understanding of these new materials and the measurement and imaging technologies needed to assess them are fast evolving.

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Nanotechnology Definition Fact Sheet

Many countries and organizations have developed working definitions to identify nanomaterials based on the size of the material, its novel properties, or a combination of both. These working definitions however, often include qualifiers such as "approximately" or "in the range of," which makes them unsuitable for use in a regulatory context.

The EU is the only jurisdiction currently using legal definitions. The European Commission developed a recommendation for a definition in 2011. It is a size-based definition developed with the help of the European Commission's Joint Research Center (JRC) taking into account scientific opinions provided by the Scientific Committee on Emerging and Newly Identified Health Risk (SCENIHR), and following a lengthy public consultation. The EU Commission aimed at using this recommended definition in all EU legislation. However, because several EU legal texts were revised to include nano specific provisions and definitions before the adoption of the Commission recommendation, EU legislation still uses a variety of legal definitions (see "Practice in the EU" on page 4).

Options for Defining Nanomaterials

Size Based

This option is the most widely used around the world, mostly using a 1 to 100 nm size range. The EU has proposed a 50% threshold value of nanosize particles to establish if a material is to be considered nano.

Challenges Include

- A fixed cut-off value fails to recognize that properties evolve gradually and actual threshold values for toxicity depend on the type of nanomaterial.
- Most nanomaterials are not composed of uniform particle sizes. Within each batch of substance, particles of different sizes coexist. A size-based definition must take this fact into consideration and express a definition based on a particle size distribution curve.
- Size-based definitions depend on the identification of an adequate cut-off value. Scientists agree that the 100 nm cut off value is an arbitrary, non-scientific threshold.
- Most nanomaterials can and will bind together through weak or strong bonds. These clusters of particles, called agglomerates (when weakly bound) or aggregates (when strongly bound or fused) can be larger than nanoscale but may nonetheless exhibit physical or chemical properties that are different from the properties of the bulk substance. Moreover, they may break down into their primary nanoscale particles when external conditions change.

Nano-specific Properties

This approach has been praised for only identifying the materials whose properties differ from that of the corresponding bulk material. However, challenges also abound in crafting a science-based legal definition on that basis:

Challenges Include

- Material at nanoscale could demonstrate properties that are distinct from the bulk form of the same material, but which are not unique to nanoscale materials (as they can be exhibited by other materials in the bulk form);
- Some properties of nanomaterials are not genuinely different from those of the corresponding bulk material but rather intensified due to increased surface area.
- Some toxicity mechanisms seem to depend only on the size of the material, regardless of its properties (see "Toxicity Risks of Engineering Nanomaterials" fact sheet). Such materials risk falling outside the scope of a property based definition (and hence being excluded from related legal requirements) if the focus is solely on specific properties.

Examples of existing definitions[1]

The **International Organization for Standardization (ISO)** defines nanomaterial as "a material with any external dimensions in the nanoscale or having internal structure or surface structure in the nanoscale."[2] This definition has been used as the basis for working definitions in Australia, Canada, the United Kingdom, the United States and the Organization for Economic Co-operation and development (OECD)[3], among others. In 2014 the ISO definition of Nanoscale was modified to mean the "length ranging from approximately 1nm to 100 nm."

The OECD Working Party on Manufactured Nanomaterials defines a nanomaterial as "[a] chemical that is either a nano-object or is nano-structured." A nano-object is defined, in turn, as "a material confined in one, two, or three dimensions at the nanoscale" and nano-structured means "having an internal or surface structure at the nano scale." The nano-scale is defined as "the size range typically between 1nm and 100 nm."[4]

The **United States** does not have a regulatory definition. Various agencies use working definitions focusing on key criteria. The Environmental Protection Agency (EPA) uses a working definition developed by the National Nanotechnology Initiative, a government research and development program seeking to coordinate efforts and research in areas of nanoscale technology. According to the EPA, "Nanomaterials can exhibit unique optical, mechanical, magnetic, conductive and sorptive properties different than the same chemical substances in a larger size."[5] The US Food and Drug Administration (FDA), refers to nanomaterials as "both materials that have at least one dimension in the size range of approximately 1 nanometers (nm) to 100 nm and certain materials that otherwise exhibit related dimension-dependent properties or phenomena."[6]

Health Canada, the Canadian government body tasked with regulating products and substances applies a working definition of nanomaterials as "at or within the nanoscale [meaning 1 to 100 nanometers, inclusive] in at least one external dimension, or has internal or surface structure at the nanoscale; or, it is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena."[7]

Within the **European Union**, the European Commission issued a Recommendation in October 2011 for a definition of nanomaterials to be used as "a reference for determining whether a material should be considered as a 'nanomaterial' for legislative and policy purposes in the Union."[8]

It defines nanomaterials as "**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 1nm-100nm.**"[9] The definition further provides that, where warranted by environmental, health, safety or competitiveness concerns, a lower threshold may be applied for the number size distribution.

The definition specifies that by derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered nanomaterials.
The definition also includes the use of a specific surface area by volume ratio of 60m2/ cm3 to determine whether a material is to be considered a nanomaterial. This proxy measurement can only be used to establish that a material is a nanomaterial. It cannot be used to establish that a material does not fall under the scope of the definition.

The definition is based only on size (with no reference to specific properties) and uses the number of particles as the primary means of measuring the proportion of the material in the nano range (as recommended by SCENIHR).

The Commission aims to integrate this definition into sector or product-specific legislation, adapting it where necessary, in particular by lowering the 50% thresholds when warranted by concerns for the environment, health, safety or competitiveness.[10]

The definition is currently undergoing a review process to be concluded by December 2014, as mandated by the original recommendation adopted in October 2011.

The use of different definitions across various jurisdictions poses a serious challenge to regulatory efforts because it leads to legal uncertainty and differing regulatory approaches for the same nanomaterial. For example, the use of different definitions in various regulations means that a substance may be considered a nanomaterial and subject to specific requirements when included in a certain type of products (e.g.: biocide) but be considered a bulk substance, not subject to specific nano safety assessment in another application (e.g.: Cosmetics). Similarly, a material could be considered a nanomaterial in certain jurisdictions (e.g.: in the EU) while being treated as a bulk material in others (e.g.: the US).

Practice in the EU

Several definitions used in a variety of instruments

In addition to the EU Commission recommendation for a definition of nanomaterials adopted in 2011, several sectoral EU regulations include distinct definitions.

Regulation (EC) No 1223/2009 on Cosmetic products (The Cosmetic Regulation) defines a nanomaterial as "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100nm."[11] This definition differs from the Commission recommendation in that it only includes insoluble or biopersistent materials and does not refer to a particle numbers distributions.

The EU biocide regulation defines a nanomaterial as "a natural or manufactured active substance or non-active substance 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 1-100nm."[12] This definition is the only one based on the Commission recommendation, and thus differs greatly from the definition used in other sectoral regulations.

The Regulation on the provision of food information to consumers defines nanomaterials as "any intentionally produced material that has one or more dimensions of the order of 100nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100nm but retain properties that are characteristic of the nanoscale."[13]

The directive on medical devices is currently being revised. At the time of writing, the text has been approved by the EU Parliament and is being reviewed by the EU Council. The current proposal includes a definition of nanomaterials modeled on the EU Commission recommendation: *"'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 1-100 nm. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials."*[14]

Controversies regarding the Commission's recommendation for a definition

The definition recommended by the Commission has generated a lot of controversy and debate. Several actors, in particular from industries potentially subject to regulation, contend that the definition is too expensive to implement as it requires the use of multiple and expensive measurement techniques for each batch of the material. They also argue that the definition uses inappropriate thresholds and is consequently overbroad. Industry opponents argue that certain potentially covered materials should not fall under the definition, either because they do not exhibit any nano specific properties or because they have been on the market for many years without being defined as nanomaterials.

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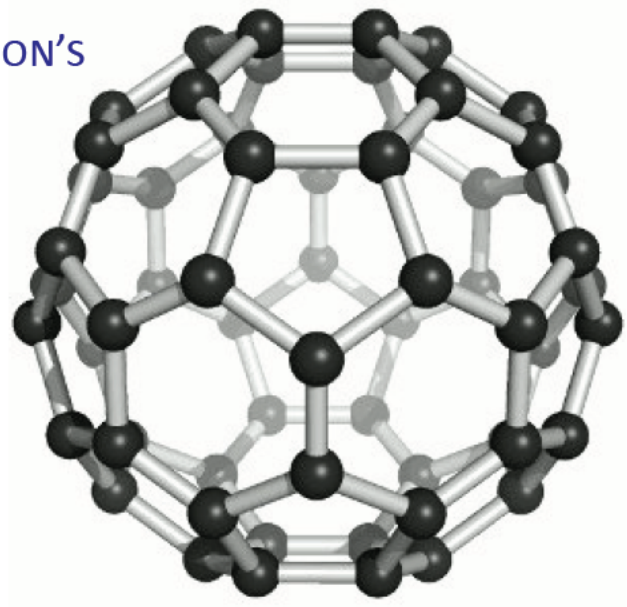

Controversies regarding the commission's recommendation for a definition

Industry generally demands that:
· The measurement unit be switched from particle number to mass; and
· The 50% threshold be raised to a much higher percentage (up to 90% of particles in the nanoscale range for a material to be recognized as a nanomaterials).

By contrast, other stakeholders contend that, as a result of political compromise, the definition is too narrow to cover all materials that should be subject to specific risk assessment and management measures. As evidence, they cite SCENIHR's opinion stating that the percentage of particles in the nano range should be as low as 0,15% for a material to be considered a nanomaterial. Supporters of a larger scope definition (including a large portion of civil society, and many scientists and scientific institutions) also argue that specific adverse effects have been demonstrated for particles as small as 0.3 nm and as large as 300nm that the definition should therefore use this particular size range and include materials that fall outside of this size range but that still exhibit unique properties.[15]

Current tensions around the definition center mainly on the use of particle numbers as the main unit, the size range and percentage of particles within this range to be used.

Remaining technical challenges in implementing the EU recommended definition of nanomaterials

The EU definition is under revision at the time of writing and the EU JRC is expected to publish its recommendation by the end of 2014. In September 2014, JRC published a progress report taking stock of the feedback collected from stakeholders through a public consultation undertaken in 2013.

The report indicates that the JRC received "rather diverse" comments on analytical challenges and indicates that the "lack of standardized, validated analytical methods is probably seen as the major drawback as regards the implementation of the definition."[16] The report highlights three main areas of concerns:

- The Commission's definition is based on a minimum external dimension, yet most non-microscopy-based particle size techniques measure spherical diameters. The report states that "this is an important obstacle for the assessment of materials for which the particle's shape deviate from spherical";
- The definition requires counting particles, even when they are clustered together as aggregates. Most aggregates cannot be disaggregated or dispersed without damaging constituent particles. The report thus recommends that "best practices" for dispersing particles be developed; and
- Analytical techniques may not be capable of assessing whether over 50% of particles fit within the size limits. Most common commercial particle size analysis instruments determine the particle size distribution of materials based on mass or volume fractions, which then need to be converted into a number distribution. The report observes that the accuracy of this conversion is "questionable."

Finally, measuring nanomaterials is further complicated by the fact that measurement results can be impacted by changes that occur within the lifecycle of nanomaterials.

ENDNOTES

[1] A comprehensive list and comparison of definitions used can be found in JRC Reference report : *Considerations on a definition of nanomaterials for regulatory purposes*, Lövestam, Rauscher, Roebben, Sokull Klüttgen, Putaud and Stamm, 2010. Available at http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf Scientists from industry also published their own assessment of existing definitions at: http://nanotechnology.americanchemistry.com/Nanotechnology/Panel-Activities/Nanotechnology-Definitions/Nanotechnology-Panel-Presents-at-Society-of-Toxicology.pdf

[2] National Institute for Public Health and the Environment, Ministry of Health, Welfare and Support (2012) *"Interpretation and implications of the European Commission Recommendation on the definition of nanomaterial"* RIVM Letter Report 601358001/2012 E.A.J Bleeker et al. accessed online 18th August 2014 http://www.rivm.nl/dsresource?objectid=rivmp:181801&type=org&disposition=inline#page=1&zoom=auto,537,848, p. 12

[3] See fact sheet on OECD work on Nanomaterials available at: http://ciel.org/Publications/Nano_OECD_Nov2014.pdf

[4] JRC Reference report : *Considerations on a definition of nanomaterials for regulatory purposes*, Lövestam, Rauscher, Roebben, Sokull Klüttgen, Putaud and Stamm, 2010. Available at http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf p. 14

[5] EPA (2012) Questions About Nanotechnology, accessed online 21st August 2014 http://www.epa.gov/research/nanoscience/questions.htm

[6] FDA *Guidance for Industry Considering whether an FDA - Regulated Product involves the application of Nanotechnology* (June 2014) p.3, available at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm401695.pdf

[7] Health Canada (2011) Policy Statement on Health Canada's Working Definition for Nanomaterial, accessed online August 21st 2014 http://www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php (Accessed 10/29/2014). It should be noted that Health Canada's working definition is established by a policy statement that works within existing regulatory frameworks but does not itself provide additional regulatory authority.

[8]Commission Recommendation of 18 October 2011 on the definition of nanomaterial http://ec.europa.eu/research/industrial_technologies/pdf/policy/commission-recommendation-on-the-definition-of-nanomater-18102011_en.pdf p.1

[9] European Commission (2011) "What is a 'nanomaterial'? European Commission breaks new ground with a common definition, European Commission Press release 18th October 2011 http://europa.eu/rapid/press-release_IP-11-1202_en.htm?locale=en

[10] Commission Recommendation of 18 October 2011 on the definition of nanomaterial http://ec.europa.eu/research/industrial_technologies/pdf/policy/commission-recommendation-on-the-definition-of-nanomater-18102011_en.pdf

[11] Art 2.1.(k) of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

[12] Art 3.1.(z) of Regulation (EU) No. 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:FULL:EN:PDF p.11

[13] Art 2.2.(t) of Regulation (EU) No. 1169/2011 of the European Parliament and Council of 25 October 2011 on the provision of food information to consumers, accessed online 22nd of August 2014, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF page 26

[14] Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009.

[15] See for example: Friends of the Earth Australia (2008) Discussion paper on nanotechnology standardization and nomenclature issues.

[16] 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* (2014) p. 38 available at https://ec.europa.eu/jrc/sites/default/files/jrc_nm-def_report2_eur26744.pdf