

# Nano and REACH workshop

"Update on the Commission's work  
on a definition for nanomaterials"

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# What has been adopted so far?

- The (EC) Regulation Nr 1223/2009 (EC) on Cosmetics reads:
  - ‘nanomaterial’ means an **insoluble** or **biopersistent** and **intentionally manufactured** material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm;
- RoHS Directive (recast 2010):
  - “...substances of very small size or internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure” (recital text)

# SCENIHR opinion (December 2010)

- (from the executive summary) “The scientific opinion concluded that:
  - Whereas physical and chemical properties of materials may change with size, there is no scientific justification for a single upper and lower size limit associated with these changes that can be applied to adequately define all nanomaterials.
  - There is scientific evidence that no single methodology (or group of tests) can be applied to all nanomaterials.
  - Size is universally applicable to define all nanomaterials and is the most suitable measurand. Moreover, an understanding of the size distribution of a nanomaterial is essential and the number size distribution is the most relevant consideration.”

# The draft Definition of a nanomaterial (public consultation Oct – Nov 2010)

- **Nanomaterial:** means a material that meets at least one of the following criteria:
  - consists of particles, with one or more external dimensions in the size range 1 nm - 100 nm for more than 1 % of their number size distribution;
  - has internal or surface structures in one or more dimensions in the size range 1 nm – 100 nm;
  - has a specific surface area by volume greater than 60 m<sup>2</sup>/cm<sup>3</sup>, excluding materials consisting of particles with a size lower than 1 nm.
  - **Particle:** means a minute piece of matter with defined physical boundaries (ISO 146446:2007)

# Public consultation

<b>Public bodies</b>	<b>14</b>
<b>Business</b>	<b>132</b>
<b>Academia</b>	<b>19</b>
<b>Third countries (Outside the EU but can be from either of the other categories )</b>	<b>14</b>
<b>Non governmental organisations (including labour and worker unions, environment, consumer and human right groups and others)</b>	<b>8</b>
<b>Others (including standardization bodies and private citizens)</b>	<b>8</b>

# Public consultation

<p><b>Too broad</b></p> <p><b>Regular review</b></p> <p><b>Hazardous material (in public perception)</b></p> <p><b>Use of other definitions</b></p> <p><b>A single definition (is it feasible?)</b></p> <p><b>Man-made material</b></p> <p><b>Size and other properties</b></p> <p><b>The size range 1 nm – 100 nm (too broad or narrow)</b></p>	<p><b>Distribution particles vs. mass</b></p> <p><b>Why one dimension?</b></p> <p><b>Internal or surface structure vs. aggregates and agglomerates</b></p> <p><b>Volume specific surface area as a metric</b></p> <p><b>Material/Substance/Particulate material</b></p> <p><b>"Nanomaterial" vs. "Containing Nanomaterial"</b></p> <p><b>Measurement and standards</b></p>
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# Next step

- Prepare a Commission Recommendation defining the term “nanomaterial”
- Based on:
  - SCENIHR;
  - Input from the public consultation and;
  - Policy decision

*Thank you for your attention !*