

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 m²/cm³, 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

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

Public consultation

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