Regulatory definition of nanomaterial and implementation issues

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Serving society
Stimulating innovation
Supporting legislation

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Commission structure

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The Mission of the Joint Research Centre

To provide customer-driven scientific and technical support for the conception, development, implementation and monitoring of EU policies.

As a service of the European Commission, the JRC functions as a reference centre of science and technology for the Union.

Close to the policy-making process, it serves the common interest of the Member States, while being independent of special interests, whether private or national.

Nanomaterials and EU legislation

- No specific legislation on nanotechnology or nanomaterials in EU
- Recently adopted EU legislation specifically addresses nanomaterials (cosmetics, food, biocides)
- Legislation on chemicals, food and consumer products in principle applies to nanomaterials even if it does not specifically address them

<table>
<thead>
<tr>
<th>Horizontal Legislation</th>
<th>Product Legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemicals Legislation</td>
<td>General Product Safety</td>
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<tr>
<td>(REACH)</td>
<td>Cosmetic Products</td>
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<tr>
<td>Worker Protection</td>
<td>Food Legislation</td>
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<tr>
<td>Environmental Legislation</td>
<td>Biocidal Products</td>
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<td></td>
<td>Plant Protection Products</td>
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<tr>
<td></td>
<td>Medicinal Products and Devices</td>
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</tbody>
</table>

Nanomaterial Definition: Why?

**PROS**
- Societal demands for regulating NM
- Political requirements, e.g. European Parliament
- Principles of European Regulation - Need to define what has to be regulated
- Removing uncertainties for industry and regulators how to deal with NMs
- Assuring equal treatment of NMs in different types of legislation
- Enforceability of legislation

**CONS**
- Large variety of NMs
- Many attributes of possible significance (size, surface area, …)
- No scientific evidence for strict limits regarding phys-chem properties
- Experimental difficulties – lack of validated methods
- Size distributions/mixtures
- Nanomaterial ≠ harmful substance

Relevance of the Definition Recommendation

- Safety Testing
- Labeling
- Consumer Information
- Trade
COMMISSION RECOMMENDATION of 18 October 2011
on the definition of nanomaterial (2011/696/EU)

2.

‘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 nm-100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.


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COMMISSION RECOMMENDATION cont’d

3.

By derogation from point 2, fullerences, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

4.

For the purposes of point 2, ‘particle’, ‘agglomerate’ and ‘aggregate’ are defined as follows:

a) ‘particle’ means a minute piece of matter with defined physical boundaries;
b) ‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
c) ‘aggregate’ means a particle comprising of strongly bound or fused particles.

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COMMISSION RECOMMENDATION cont’d

5. Where technically feasible and requested in specific legislation, compliance with the definition in point 2 may be determined on the basis of **the specific surface area by volume**. A material should be considered as falling under the definition in point 2 where the specific surface area by volume of the material is greater than 60 m²/cm³. However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with the definition in point 2 even if the material has a specific surface area **lower than 60 m²/cm³**.

Recital 12

Agglomerated or aggregated particles may exhibit the same properties as the unbound particles. Moreover, there can be cases during the life-cycle of a nanomaterial where the particles are released from the agglomerates or aggregates. The definition in this Recommendation should therefore also **include particles in agglomerates or aggregates** whenever the **constituent particles** are in the size range 1 nm-100 nm.
Nanomaterial Definition in Legislation

**Horizontal Legislation**
- Chemicals Legislation (REACH)
- Worker Protection
- Environmental Legislation:
  - Integrated Pollution Prevention and Control
  - Major-accidents, Seveso II Directive
  - Water
  - Waste

**Product Legislation**
- General Product Safety
- Cosmetic Products
- Biocidal Products
- Food Legislation
- Medicinal Products and Devices
- Plant Protection Products
- Electronic Industry
- Aerosol Dispensers
- ... 

Different definitions, not yet harmonized

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Regulation (EC)1223/2009 on Cosmetic Products

- First EU legal instrument to introduce rules on nanomaterials
- **Notification** obligation to European Commission (from 01/2013) Pre-market notification of products with nanomaterials
- **Labelling** obligation for nano ingredients (from 11 July 2013)
- **Specific nano-definition**

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Definition of Nanomaterial for Cosmetics

Cosmetic Products Regulation (EC) 1223/2009

"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"

Legally binding!

- Takes into account risk considerations
- Can be adapted to technical and scientific progress and to definitions subsequently agreed at international level
- Different from the EC Recommendation

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Definition of Nanomaterial for Cosmetics

COM definition of 'nanomaterial' was analysed by a SANCO Expert Working Group with MS representatives

Discussions took place on:

- 50% threshold (impact, realistic?)
- Intentionally manufactured, incidental
- Insoluble, biopersistent
- Primary or secondary particle size in the nano-scale (1-100 nm)
- External or internal structures in the nano-scale
- Additional parameters, such as the use of volume specific surface area
- Functionality (or a nano-specific property)

The WG agreed on a new proposal

- Adoption currently discussed by relevant committees

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A technical consideration of the definition

COMMISSION RECOMMENDATION on the definition of nanomaterial

"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 nm - 100 nm.

Implementation Issues: Size Measurement

- Constituent particles – agglomerates - aggregates
- Validated size measurement methods
  - Sample preparation
  - Measurement techniques
  - Evaluation and interpretation of data (number size distribution)
- Development of guidance

Related Problem
Nanomaterials in complex matrices (food, cosmetics, …)
Example: Size Measurement SiO₂ by TEM

Material:
- Precipitated SiO₂ (NM 200)

Issues:
- Representative sample
- Dispersion
- Sample preparation
- Statistical evaluation

Number of particles (agglomerates/aggregates) within size limits

<table>
<thead>
<tr>
<th>Size Limit</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100 nm</td>
<td>88.7%</td>
</tr>
<tr>
<td>&lt;50 nm</td>
<td>69.8%</td>
</tr>
<tr>
<td>&lt;10 nm</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

From: Report EUR 26046 EN

Example: Size Measurement SiO₂ by TEM

Material:
- Pyrogenic SiO₂ (NM 203)

Issues:
- Representative sample
- Dispersion
- Sample preparation
- Statistical evaluation

Size and number of constituent particles within size limit

<table>
<thead>
<tr>
<th>Feret Min</th>
<th>Feret max</th>
<th>Feret mean</th>
<th>Size Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.8 nm</td>
<td>15.6 nm</td>
<td>13.5 nm</td>
<td>&lt; 100 nm</td>
</tr>
</tbody>
</table>

100%

From: Report EUR 26046 EN
Control of products containing nanomaterials

Implementation of labelling requirements for nanomaterial ingredients

- Regulation (EC) No 1223/2009 on cosmetic products
- Regulation (EC) No 1169/2011 on the Provision of Food Information to Consumers

- No hazard labelling
- Consumer information

Principal Challenge

Validation of analytical methods for the detection and characterisation of nanomaterials in food and cosmetics

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Quality assurance tools

International Harmonisation and Standardisation

Standardisation Bodies
CEN TC 352 Nanotechnology
ISO TC 229 Nanotechnology
ISO/REMCO (reference materials)

OECD Working Party on Manufactured Nanomaterials
Safety Testing of a Representative Set of Manufactured Nanomaterials
Manufactured Nanomaterials and Testguidelines
The Role of Alternative Methods in Nanotoxicology

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Certified Reference Materials

Development and certification of reference materials
- including interlaboratory comparisons of measurement techniques, validation of methods
- identification of standardisation needs for crucial parameters defined via measurement procedures

Cooperation & networking
- Member States' expert laboratories, other reference material producers (NIST – USA, BAM – DE, etc.)

ERM®-FD100 Colloidal silica in water - monodispersed
ERM®-FD304 Colloidal silica in water - polydispersed

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Quality assurance tools

**Representative Test Material (RTM):**

A material from one batch, which is sufficiently homogeneous and stable with respect to one or more specified properties, and which implicitly is assumed to be fit for its intended use in the development of test methods which target properties other than the properties for which homogeneity and stability have been demonstrated.

Database

**Nanomaterials**

- OECD list of representative NMs
- OECD sponsorship programme
- European NM Repository

**Projects hosted today**

- OECD WPMN
- FP 7 Projects
- National projects
- Institutional projects
Review of the EC Definition Recommendation

Review due by December 2014

Items under consideration

• Identification of the main implementation challenges
• Stakeholder opinions
• Availability of guidance and measurement systems
• Needs for standardisation, reference materials, etc.
• Available information on size distributions
• Difficulties related to the determination of number based particle distributions, implication of thresholds
• Constituent particles – agglomerates - aggregates
• Nanostructured materials

JRC Work on Nanomaterials

General scientific advice to policy makers
Definition, safety assessment, analysis

Safety assessment of nanomaterials
• Standardised protocols for toxicity testing
• Research on protein-nanomaterial interaction and cell barriers
• Repository of representative nanomaterials and NanoHub database

Detection and quantification of nanomaterials
• Developing methods for detection in food and consumer products
• Validating fit-for-the-purpose analytical methods
• Providing certified reference materials
Size Distribution

Median size: 270 nm
Mean size: 372 nm

Number fraction < 100 nm: ca. 10%

Equal number: \( N_1 = N_2 \)
Mass ratio: \( \frac{M_2}{M_1} = \left(\frac{R_2}{R_1}\right)^2 \)