

Nanomaterials and REACH
Cefic REACH Implementation workshop XI



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Nanomaterials are covered by REACH

- REACH is about chemical substances **and applies to all forms of substances**
- CLP Regulation refers to substances **in their forms or physical states** as placed on the market
- However registrant must ensure **safety of all included forms** and provide adequate information to address the relevant forms.





Definition of Nanomaterials (1)

"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 %.

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

Definition of Nanomaterials (2)



"particle", "agglomerate" and "aggregate" are defined as follows:

- "Particle" means a minute piece of matter with defined physical boundaries;
- "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;
- "Aggregate" means a particle comprising of strongly bound or fused particles.

<http://ec.europa.eu/environment/chemicals/nanotech/index.htm#definition>

Nanomaterials definition – Cefic interpretation



1. The scope covers substances and mixtures **only if the mixture contains particles**
2. Particles means a minute piece of matter **of a solid substance**
3. The 50 % threshold applies to **constituent (primary) particles**
4. VSSA may be a **proxy for size measurement** where technically feasible and requested in specific legislation.
5. **Size measurement** (not necessarily size distribution) always prevails.
6. Products containing nanomaterials **are not nanomaterials.**



Measurement techniques

- **Currently investigated by JRC to ensure standardisation**
- **However no straightforward analytical method can fit the purpose and technical adaptation are still challenging!**
- **ECHA recognised that a **matrix of analyses** could be used to characterise nanomaterials and their aggregates or agglomerates e.g.:**
 - **TEM/SEM**
 - **Light scattering (e.g. dynamic, laser...)**
 - **Any other based on expertise (e.g. centrifugal particle sedimentation, X-Ray Fluorescence...)**



Guidance Documents

In 2012 guidance documents have been updated to take into account nanomaterials:

- Information requirements and chemical safety assessment**

<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>





Guidance Documents

Areas to be taken into account when updating dossiers:

- **ID and physico-chemical properties (more description, sample preparation, justification for grouping)**
- **Justify appropriate metrics, route of exposure**
- **Acute toxicity and gene mutation specific focus**
- **Address solubility and waiving**
- **Use and exposure specific to nanoform to be identified**

NB: IUCLID 5.4 updated to include options referring to nanoforms under each robust summary dossier and endpoint.

Safety Data Sheet



From Annex II and related guidance document – specific elements relevant to nanomaterials:

- **Section 3:** chemical identity incl. Information on surface chemistry
- **Section 9:** appearance incl. granulometry (size, size distribution, agglomeration and aggregation state, morphology, surface area...)





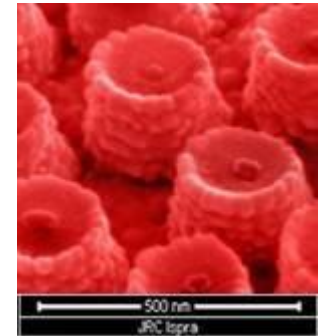
ECHA Activities

- **Evaluation of Nanomaterials under REACH registration dossiers led to requests for information either through Art. 36 or Art. 41**
- **Set up of GAARN (Group Assessing Already Registered Nanomaterials) to discuss informally about 3 cases and derive best practice**
- **Proposal for a Nanomaterial Working Group (in parallel to PBT WG) to cover scientific and technical issues related to nanomaterials under REACH – reports back to CASG Nano and CARACAL**

JRC Activities



- Nanohub (+ web platform?)



- **Standardisation of measurement techniques**
- **Evaluation of REACH dossiers (25) containing nano-elements and proposal for options (21) to improve information provided (some options already in ECHA updated guidance) – impact assessment of options on-going**



Other Commission Activities

- **2nd Review Regulation to cover nanomaterials under REACH and CLP + safety information on nanomaterials – expected to be released by July 2012**
- **REACH Review to propose for Annex changes (adaptation to nanomaterials) to be agreed by comitology**
- **Additional studies on definition implementation, read across, QSAR...**



Cefic Activities

- Further explanations on definition
- Read across discussions
- Communication material (Q/A internal and public versions)
- Strategy on nanomaterials (PPS and R&I involvement):
 - Advocacy materials with regulatory purpose
 - Safety stories for specific sectors of applications (based on exposure information)
 - Communication on testing and assessment strategies; explain how they are put in place or used
 - Compelling stories on safety of existing nanomaterials (to differentiate from asbestos)
 - Examples of future benefits
 - Coalition with the value chain

Examples of safe uses and benefits under request



Practical examples

- **REACH registration (e.g. MWCNT)**
- **Risk assessment paradigm (DECHEMA-VCI report)**
- **Federchimica study on TiO₂ (nano vs bulk registration)**

Multi-Walled Carbon Nanotubes (MWCNT), synthetic graphite in tubular shape

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General Information

Classification and Labelling

Manufacture, Use & Exposure

Physical and chemical properties

Environmental fate and pathways

Ecotoxicological Information

Toxicological information

Guidance on safe use

Reference substances

Multi-Walled Carbon Nanotubes (MWCNT), synthetic graphite in tubular shape

Multi-Walled Carbon Nanotubes (MWCNT), synthetic graphite in tubular shape

Multi-Walled Carbon Nanotubes (MWCNT), synthetic graphite in tubular shape

General information

Reference substance name Multi-Walled Carbon Nanotubes (MWCNT), synthetic graphite in tubular shape

Reference substance information

IUPAC Name Multi-Walled Carbon Nanotubes (MWCNT), synthetic graphite in tubular shape

Molecular and structural information

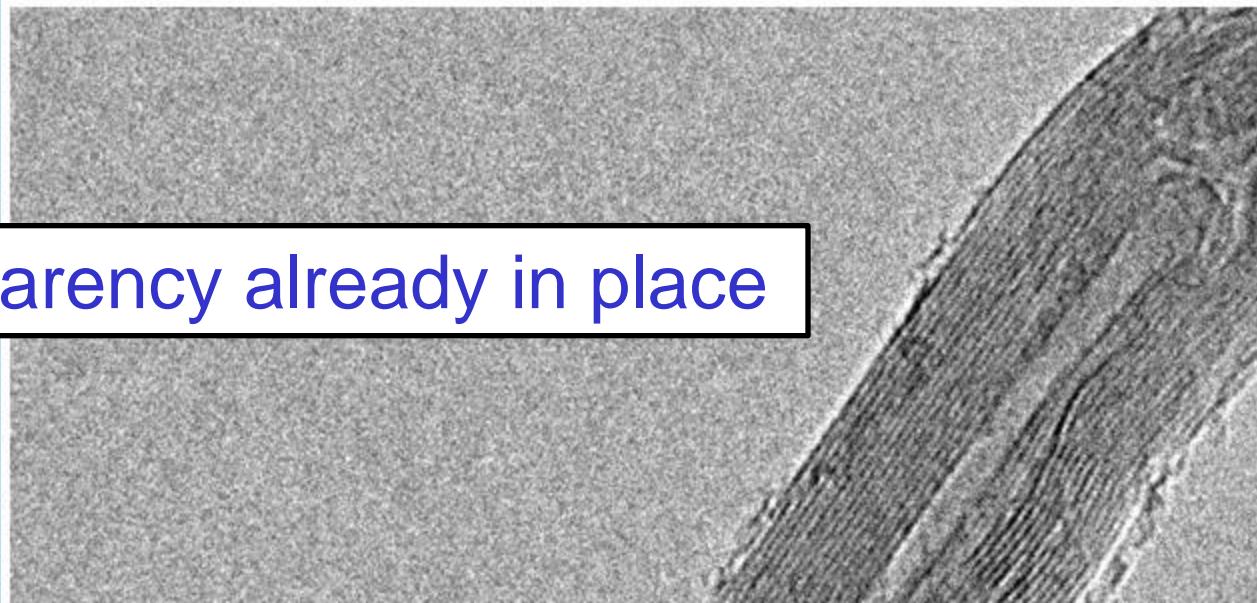
Molecular formula C

Molecular weight range ca. 7.0E7

SMILES notation C

InChI InChI=1/C

Structural formula



Full transparency already in place



Risk assessment paradigm

- **Nano**
doesn't
mean toxic!
- **OECD**
methods fit





Evaluation of literature studies on nanosized TiO₂ fulfilling the requirements of the current REACH registration

Adopted strict criteria to select only the studies that met scientific standards.

In conclusion:

- **available standard methods are suitable to obtain hazard information about nanoparticles**
- **Nanosize seems not to affect the final toxicological outcome more than bulk**
- **Effects appear to be related to the chemical structure and may be shape more than size**