

A close-up photograph of a microscope's objective lenses and eyepiece, set against a blue background. The lenses are metallic and have some text on them, including "Plan" and "0.25".

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## Nanocomposites Nanotubes 2010

# Global Nano Regulation and Standards

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*24-25 March 2010, Brussels, Belgium*

[steptoe.com](http://steptoe.com)

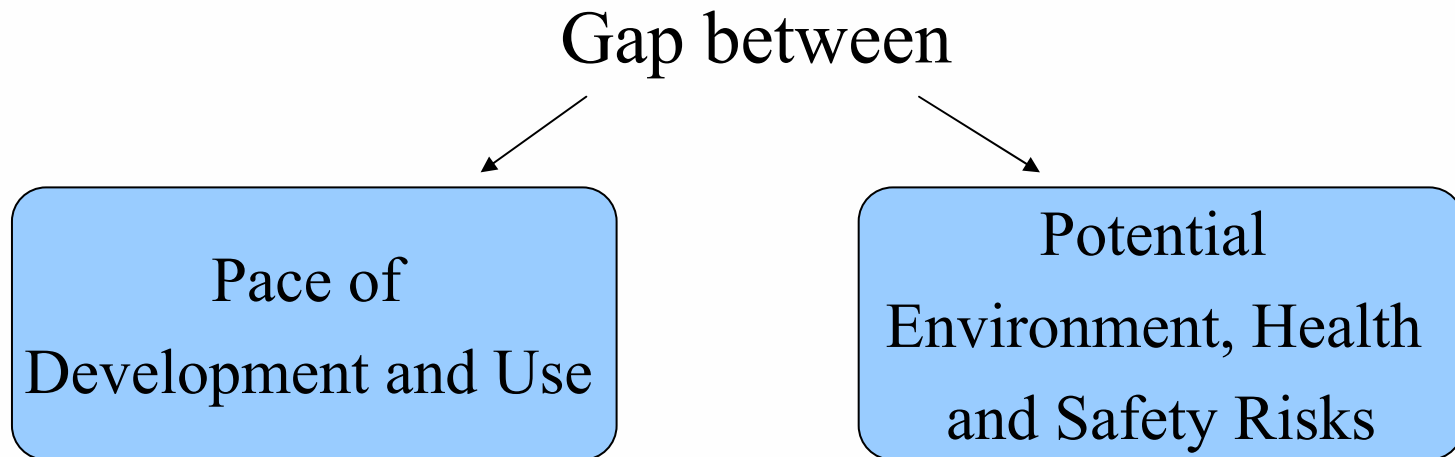
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# OUTLINE

1. Opportunities and Risks
2. Definition of “Nanomaterial”
  - The Basis for Regulation
  - Existing Working Definitions
3. Regulatory Pressure
  - US
  - EU
4. Industry Co-operation
5. The Way Forward

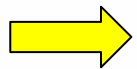
# OPPORTUNITIES & RISKS



- When nanomaterials act differently than their bulk form → new applications are made possible
- The same properties responsible for these new applications
  - **may** result in different toxicological profiles and environmental impacts
  - **may** bring uncertainty as to the applicability of existing testing methods

# EHS RISKS

- **Workers' safety issues** at product development and commercial manufacturing stages
- **Health and environmental issues** directly relating to manufactured nanoparticles themselves
- **Health and environmental issues** related to manufactured nanoparticles in different products in downstream use. Their biological and environmental fate during the entire life cycle, their persistence and transformation in waste management



**No regulatory vacuum, issues are addressed on the basis of existing regulation → Is this sufficient?**

# STAKEHOLDER INVOLVEMENT

(Courtesy: International Risk Governance Council, 2009)

			Affected stakeholders	Civil society
Actors	Regulatory bodies/industry experts	External Scientists/ Researchers	External Scientists/ Researchers	Affected stakeholders
Type of participation	Use <b>existing routines</b> to assess risks and possible reduction measures	<b>Maximise the scientific knowledge</b> of the risk and mitigation options	Involve all affected stakeholders to <b>collectively decide</b> best way forward	<b>Societal debate</b> about the risk and its underlying implications
Dominant risk characteristic	Simple	Complexity	Uncertainty	Ambiguity

As the dominant characteristic changes, so will also the type of stakeholder involvement need to change

# DEFINITION OF “NANOMATERIAL”

- Is the basis for any regulation
- No internationally agreed definition
- Clarification is needed on
  - size ranges and other relevant characteristics
  - types of physical and chemical properties particular to nanomaterials
  - thresholds
  - metrics to express thresholds
  - ...

# WORKING DEFINITIONS

- **Considerable number of working definitions**
    - International level
      - ISO
      - OECD Working Party on Manufactured Nanomaterials (WPMN)
    - European level
      - Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)
      - Scientific Committee on Consumer Products (SCCP)
      - Definitions adopted in EU law (Cosmetics, Novel Food ...)
    - National level
      - US, Australia, Canada, UK, Germany ...
- ... not based on the same “essential elements”

# DEFINITION

## International Standardisation Organisation (ISO)

- ISO/TC 229 started work on nano in 2005
- Technical Specification, providing definitions for a number of nanomaterial sub-categories → transposed by the European Standards Committee (CEN)
- Ongoing → core terms, incl. main nanomaterials definitions, expected before end of 2010
- 8 nano-terms agreed, most importantly:

***Nano-object:** material with one, two or three external dimensions in the nanoscale*

***Nanoscale:** size range from approximately 1 nm to 100 nm*

# DEFINITION

## OECD Working Party on Manufactured Nanomaterials (WPMN)

- Established in 2006
- Slightly adapted ISO working definition (awaiting formal agreement)
- WPMN working definition (agreed in 2007):

*Manufactured nanomaterials: Nanomaterials **intentionally** produced to have specific properties or specific composition.*

*Nanoscale: The **size range** typically between **1 nm and 100 nm**.*

*Nanomaterial: Material which is either a nano-object or is nano-structured.*

*Nano-object: Material confined in **one, two, or three dimensions** at the nanoscale.*

*Nanostructured: Having an **internal or surface** structure at the nanoscale.*

Note 1: The WPMN considers that fullerene molecules are included within the scope of manufactured nanomaterials.

Note 2: The WPMN considers that aggregates and agglomerates are nanostructured materials along the lines of ISO.

Note 3: Those end products containing nanomaterials (e.g. tires, electronic equipment, coated DVDs) are not themselves nanomaterials.

# DEFINITION

## Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

- Adopted several opinions on nano
- Suggested definitions (2008):

*Nanoscale: a feature characterised by dimensions of the order of **100 nm** or less.*

*Nanostructure: Any structure 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 100 nm or less.*

*Nanomaterial: Any form of a material that is composed of discrete functional parts, many of which have one or more dimensions of the order of 100 nm or less.*

- 2009 opinion → proposal to extend definition based on physical size by the addition of:

*"a limit of the specific surface area to be **above 60 m<sup>2</sup>/g of material volume** (the value of 60 m<sup>2</sup>/g corresponds to the specific surface area of 100 nm solid spheres of unit density)"*

# DEFINITION

- March 2010 → **COM requests SCENIHR to adopt a Scientific Opinion** on the scientific basis for the definition of “nanomaterial”
- Deadline May 2010!
- **Terms of reference – Advice on “essential elements” for a science based working definition, defining:**
  1. Size ranges and other relevant characteristics and corresponding metrics
  2. Characteristics
  3. Physico-chemical properties
  4. Threshold(s) at which properties identified above may be expected to occur

# EXISTING DEFINITIONS - EXAMPLES

*The term “nanoscale” is generally used to refer to the scale measured in nanometers ( $1 \times 10^{-9}$  meters). For the purposes of the Program, nanoscale is the **size range between the atomic/molecular state and the bulk/macro state**. This is generally, but not exclusively, below 100 nm and above 1 nm. Materials engineered to be in this size range can exhibit novel or enhanced properties.*

- Number of dimensions: For the purpose of the Program, any substance engineered with **one or more dimensions** in the nanoscale may be appropriate for inclusion in the program.*
- One-dimensional nanoscale materials: The category of “one-dimensional nanoscale materials”—that is, materials that have one dimension in the nanoscale and two dimensions larger than the nanoscale—may be divided into two: 1) Particles or 2) Films and coatings*

**US, EPA, "Stewardship program on nanomaterials", 2008**

# DEFINITIONS - EXAMPLES

*Nanoscale materials are defined as having **two or more dimensions up to 200nm.***

*And*

- *are deliberately engineered (i.e. not natural or unintentional by-products of other processes)*
- *are “free” within any environmental media at any stage in a product’s life-cycle*

**UK, Voluntary Reporting Scheme, 2006**

# DEFINITIONS - EXAMPLES

*Industrial nanomaterials are those industrial materials **intentionally produced, manufactured or engineered** to have specific properties or specific composition, and **one or more dimensions** typically **between 1 nm and 100 nm**. This size range refers to individual particle size, and does not take into account agglomeration of particles.*

**Australia, NISNAC, Survey, 2008**

*Although there is no internationally recognized definition of this type of substance, nanomaterials can be described generally as substances having **one or more dimensions** in a nanoscale range, typically **between 1-100 nanometer**.*

**Canada, Advisory Note Regarding Nanomaterials, 2007**

# REGULATORY DEVELOPMENTS



## US EPA

- TSCA (PMN and SNUN)



## EU European Commission

- Horizontal and Vertical (Application Specific) Legislation
- New EU Action Plan on Nanotechnology 2010-15



## Member States

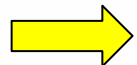
- National initiatives either on voluntary (Germany, UK) or potentially mandatory (France) basis



# US REGULATORY DEVELOPMENTS

## **Toxic Substances Control Act (TSCA), 1976**

- Central component of EPA's authority to regulate nanomaterials
- TSCA Inventory of Existing Chemical Substances → lists chemicals which have been reported to EPA
- Precautionary strategy → enables EPA to gather information and potentially issue restrictions before chemicals are widely released
- **2 tools to regulate nanomaterials**
  1. **Pre-manufacture Notice (PMN)**
  2. **Significant New Use Rules and Notice (SNUR and SNUN)**



**TSCA is under review, legislative TSCA reform proposal is imminent.**



# US REGULATORY DEVELOPMENTS

## **Pre-manufacture Notice (PMN)**

### Which chemicals are covered?

- “new” chemical substances (= chemicals not on the TSCA Inventory)

### Procedure?

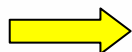
- **Notice** Manufacturers submit notice to EPA before manufacture  
Detailed information about chemical, its intended uses, human and environmental exposures (only to the extent that such information is available)
- **Risk assessment** conducted by EPA within 90 days
- **Risk management** options available to EPA
  1. Ban/restriction of chemical or use (Section 5(f))
  2. Prohibition/limitation of manufacture, processing, distribution in commerce, use, or disposal of such substance pending development of add information (Section 5(e))



# US REGULATORY DEVELOPMENTS

## Are nanoforms of existing substances considered as “new”?

- EPA, January 2008: a chemical is new or existing based on whether a substance with the same chemical structure is already listed on the Inventory
- Numerous PMN for nanomaterials have been submitted
- EPA confirmed CNTs to be new chemicals, reviewed on a case-by-case basis
  - February 2010: 30 new notices have been submitted for CNTs



**Some nanomaterials will be considered as existing, some will be considered as new, i.e. subject to PMN requirements**



# US REGULATORY DEVELOPMENTS

## **Significant New Use Notice (SNUN)**

### Which chemicals are covered?

- “existing” chemical substances (= chemicals on the TSCA Inventory)

### Procedure?

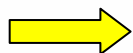
- **Significant New Use Rule (SNUR)** → EPA rulemaking to require submission of notice prior to manufacture  
“use” → widely interpreted by EPA, incl. any manner of manufacturing, new exposure levels etc.  
“significant new use” → takes into consideration ALL relevant factors, not a matter of commercial importance but of health and environmental risks/impacts (examples in Section 5(a)(2))
- **Notice, risk assessment, risk management:** same requirements/options as for PMN



# US REGULATORY DEVELOPMENTS

## **SNURs issued on nanomaterials to date**

1. 2 SNURs for siloxane-modified nanoparticles (P-05-673, P-05-687 73 Fed. Reg. 65743)
2. Proposed SNUR for **multi-walled CNTs** (Fed. Reg. Vol. 75, No. 22 / Wednesday, February 3, 2010 / Proposed Rules)



**EPA can use SNURs to subject existing substances to same notice requirements as new substances**

## **CNT – Issues arising from case-by-case approach**

- How does EPA distinguish between different multi-walled CNTs?
- Difficult for companies to determine whether their CNT is the “same” as one of the CNTs that is subject to a SNUR
  - “Same”: SNUN, complying with SNUR
  - Different: PMN



# EU REGULATORY DEVELOPMENTS

## European Commission

Communication, 2008: Regulatory Aspects of Nanomaterials

*“current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework”*

## Existing Regulatory Framework:

### Horizontal Legislation:

- General Product Safety and Product Liability Legislation
- Chemicals Legislation (REACH and CLP)

### Vertical (Application Specific) Legislation: (not nano-specific)

- Food / Novel Food / Food-contact / Cosmetics / Medical Devices etc.



## **New EU Action Plan on Nanotechnology 2010-15**

### Aims

1. Addressing *technological and societal challenges* of next 5 years
2. Strengthening the *research and innovation* efforts
3. Emphasis on *sustainable development, competitiveness, health, safety and environmental issues*.

→ Public consultation ended 19 February



# EU REGULATORY DEVELOPMENTS

- **SCENIHR (Scientific Committee of Emerging and Newly Identified Health Risks)**

*Risk Assessment of Products of Nanotechnologies* (January 2009)

“While risk assessment methodologies for the evaluation of potential risks of substances and conventional materials to man and the environment are widely used and are generally applicable to nanomaterials, specific aspects related to nanomaterials still require further development.”

- **CASG-nano Workshop** on Early Harvest of Research Results on Nanosafety 14-15 April 2010 in Ispra, Italy



# EU REGULATORY DEVELOPMENTS

## European Parliament (EP) *Resolution* (24 April 2009)

- “Calls on the Commission to **review all relevant legislation within two years** to ensure safety for all applications of nanomaterials [...]” (Point 5)
- “Stresses that such review is not only **necessary to adequately protect human health and the environment**, but also to **provide certainty and predictability** to economic operators as well as public confidence” (Point 6)

## EP Requirements re REACH:

1. Registration of nanomaterials (NM) also **< 1 tonne/year**
2. Consider **all NMs new substances**
3. Submit CSR with **exposure assessment** for all registered NM
4. **Notification** for all NMs placed on the market (as such, in preparations or in articles)



# EU REGULATORY DEVELOPMENTS

**European Commission believes REACH to be appropriate, with possible modifications..**

- **CASG Nano (1/2 July 2008):**

Substance identification is based on chemical structure and purity supported by analytical data. Other potentially relevant parameters (particle size, geometry etc.) may need to be determined to differentiate the “nanofoms” of a substance; however the existence of different properties in itself does not define a substance as “new” (in line with the US EPA, so far..)

- **CASG Nano (7/8 July 2009)**

“REACH provisions require manufacturers and importers to supply data on their substance, its classification and labelling, handling, exposure control, personal protection transport etc. to users via Safety Data Sheets (SDS). This fundamental requirement of communication in the supply chain also applies to manufactured and/or imported nanomaterials regardless of their volume.”



## **REACH Implementation Projects on Nanomaterials (RIP-oN)**

→ **3 different topics**

1. Substance Identification
2. Information requirements
3. Chemicals Safety Assessment

RIP-oN 1 on Substance Identification (kick-off Oct 2009)

→ **4 case studies**

- CNTs
- Nano-silver
- Nano-TiO<sub>2</sub>
- Nano- CaCO<sub>3</sub>



## CASG Nano Timelines

<i>Work programme</i>	<i>Start/Deadline</i>
<b>RIP-oN1 Substance Identification</b>	<b>Oct 2009 / Jan 2011</b>
1. Case study CNT	“ / June 2010
2. Case study Nano-silver	“ / tba
3. Case study Nano-TiO <sub>2</sub>	“ / tba
4. Case Study CaCO <sub>3</sub>	“ / tba
<b>RIP-oN2 Information Requirements</b>	<b>Jan 2010 / March 2011</b>
<b>RIP-oN3 Chemical Safety Assessment</b>	<b>Jan 2010 / March 2011</b>
<b>Alternative testing methods for NMs</b>	<b>Nov 2008 / Dec 2010</b>
<b>Advice on REACH guidance</b>	<b>June 2011 / tba</b>



## Regulatory developments:

### 1. Cosmetics

- **Cosmetics Regulation (EC) No 1223/2009:** establishes a definition for nanomaterials as “*insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure on the scale of 1 to 100 nm*”
- while “moving” definition; it may create difficulties in interpretation and enforcement
- Notification requirement: Intention to place a product containing nanomaterials on the market must be notified to the Commission 6 months in advance (no obligatory assessment by the SCCS)



## 2. Food Contact Legislation

- No explicit reference to nanoparticles, **BUT:**
- **Draft PIM:** specifically mentions “*substances deliberately engineered to particle size which show discrete functional physical and chemical properties*”
- **EFSA** has published a positive opinion on TiN nanoparticles in PET bottles. Basis of no concern: lack of any detectable migration into food, **BUT:** Commission doesn't act on this opinion to include TiN in the positive list of permitted food contact additives

**... other implicit references in legislation on active and intelligent packaging, recycled plastics etc.**

# INDUSTRY PARTICIPATION

## **EP Resolution of 24 April 2009, Point 10:**

“Calls for the application of a **duty of care for manufacturers** that wish to place nanomaterials onto the market; and calls on them to adhere to the European code of conduct for responsible nanosciences and nanotechnologies research”

# INDUSTRY PARTICIPATION

- Possible industry participation to the Commission's agenda where nanotechnology can play a key role in:
  - Innovation
  - Sustainable Consumption and Production Package
- Common industry platform to support :
  - ✓ Knowledge pooling: to contribute to the wealth of reliable data; a common interest for “good” regulation should drive cooperation
  - ✓ Best practises for safety: The interest of responsible industry to place safe products on the market drives towards minimized individual risk; self-policed voluntary industry standards

# Nanofutures



- “Nano-Hub”: Industry-driven initiative for the sustainable development of nanotechnologies via cooperation for addressing horizontal issues (safety, regulation communication, etc.)
- Multi-sectoral, cross-ETP integrating platform
- Objective: Co-ordinate research efforts, address all horizontal issues, ensure societal acceptance
- Openness: open to EU industry, SMEs, NGOs, financial institutions, research institutions, universities, civil society
- Close co-ordination with European Commission (DG Research)

Further information at <http://www.minamwebportal.eu/index.php?m1=Public-Area>

# WAY FORWARD

## **Proper regulatory governance:**

- including all viable regulatory options; voluntary measures and mandatory requirements;
- based on international consensus (to avoid trade disputes)
- based on internationally agreed “essential elements” for definitions
- based on internationally agreed test methods to support safety
- based on societal consensus (open dialogue)



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**THANK YOU**

**for your Attention.**

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