

**Conference**  
**Nanomaterials (NM) on the market:**  
**What regulators need to know**  
Brussels, 9th October 2009

Does REACH provide the necessary answers?  
What is and is not covered by REACH?

based on the legal study (2006)  
Nanotechnologies and Environmental Law

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# Outline of the presentation

*Does REACh provide the necessary answers?  
What is and is not covered by REACh?*

1. What is a substance ?
2. What is a new/non-phase-in substance?
3. Are the tonnage thresholds appropriate?
4. Are the information obligations appropriate?
5. Are the basic obligations appropriate?
6. Answers
7. Policy options

# Survey: legislative developments in EC substance law

**Existing Substances Regulation**  
793/93/EEC

“New Substances Directive” → Council  
Directive 92/32/EEC = 7th  
amendment of Directive 67/548/EEC

REACH

„Nano“ =  
Existing vs New  
Substance ?

„Nano“ =  
phase-in vs non-phase-in  
Substance ?

# 1. What is a substance (under REACH)?

**Art. 3 No. 1: substance:** means a chemical element and its compounds in the natural state or **obtained by any manufacturing process**, including any additive necessary to preserve its stability and any impurity deriving from the process used ...

**Legal definition ≠ definition of chemists**  
→ no consistent approach in EINECS

# 1. What is a substance (under REACH)?

## How to apply Art. 3 No. 1 to nanomaterials?

Interpretation in the light of Art. 1 (1) and (3):

- **high level of protection**
- the **free circulation of substances** on the internal market
- while enhancing **competitiveness** and **innovation**.
- based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that **do not adversely affect human health or the environment** → **Self-responsibility**
- Its provisions are underpinned by the **precautionary principle**.

# 1. What is a substance (under REACH)?

## **How to apply Art. 3 No. 1 to nanomaterial?**

What is fascinating about nano?

The (nano) specific properties  
(surface/volume extreme surface energy)

→ new effects on human health and environment

Example: Titanium dioxide in bulk  $\neq$  Titanium dioxide in nano format

→ Different approaches of self-responsibility

**Problem:** Manual of Decisions/CA Paper (CA-SG Nano)

**Recommendation:** NM = distinct substance

Advantage: registrants of NM are not in the same SIEF as  
registrants of the bulk form

## 2. What is a new/non-phase-in substance?

Art. 3 No. 20: phase-in substance: means a substance which ...

a) is listed in EINECS (...)

**Problem:** Manual of Decisions/CA Paper (CA-SG Nano)

### **Recommendation:**

only those NM which are explicitly listed as NM

→ other substances: no phase-in privileges

### 3. Are the tonnage thresholds appropriate?

The tonnage thresholds were designed for bulk material

nanometer =  $10^{-9}$  meter

→ not adequate for NM

#### **Recommendation:**

- return to the 10 kg threshold of the “old” New Substances Directive (instead of 1000 kg)
- adjust the other thresholds accordingly



## 4. Are the information obligations appropriate?

- Art. 22 REACh update obligation:  
“Following registration a registrant shall be responsible ...”
  - The information requirements of Art. 7 ESR are no longer applicable
- Gap in information obligations until a NM is registered

### **Recommendation:**

- Adjust the registration mechanisms to NM
- Introduce nano specific information requirements

## 5. Are the basic obligations appropriate?

- Art. 14 (6) and Art. 37 (5) stipulate a  
**“duty of care”** (Annex VI)  
“ ... shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment,”
- NM effects are covered in general,  
but specific tests etc are necessary (SCENIHR)
- **Recommendation:** Encourage nanospecific approaches of self-responsibility

## 6. Answers

*What is and is not covered by REACh?*

- NM are covered by REACh – in general ...

*Does REACh provide the necessary answers?*

*Does REACh stimulate to address the appropriate questions?*

- Not really ...

## 5. Policy options

1. What is a substance ?
2. What is a new/non-phase-in substance?
  - Option a: Within the REACh framework (MB)
  - Option b: Add a nano chapter to REACh
3. Are the tonnage thresholds appropriate?
  - Option a: Add a nano chapter to REACh
4. Are the information obligations appropriate?
  - Option a: Partly solved by 3a + nano specific testing
5. Are the basic obligations appropriate?
  - After 2b, 3a + 4a: YES!

# Thank You for Your Attention

Further Information:

[www.sofia-research.com](http://www.sofia-research.com)

[www.elni.org](http://www.elni.org)

## Legal appraisal of nano technologies

Existing legal framework, the need for regulation and regulative options at a European and a national level

<http://www.umweltdaten.de/publikationen/fpdf-l/3198.pdf>