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


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: Titandioxide in bulk ≠ Titandioxide in nano format

→ Different approaches of self-responsibility


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
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