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Legal study

Nanotechnologies and Environmental Law

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Study Approach/Outline of the presentation

0. Problem description (3 pages + annexes)
1. Analyse regulatory gaps (30)
 - EC Environmental Law
 - German Environmental Law
2. Identify regulatory options (15)
 - a) IPPC
 - b) Water Framework Directive / Waste Directive
 - c) Substance Law (ESR, REACH)
3. Policy recommendations (5)
 - regulatory multi-step concept (→ excerpt)

0. 1 Problem / Definition of Nano-materials

1) Structures of anthropological origin (e.g. particles, layers, tubes) smaller than 100 nm within one dimension

+

2) these structures must have new functions or properties which cannot be achieved in a macro-world and which are developed for new products or used in applications

0.1 Problem: Examples of use for Nano-Products

- **Nano-technologies are enabling technologies:**
wide scope of possible applications

Examples:

- Coatings (e.g. window-glass, lenses)
- Paint / varnish
- Cosmetics (sun creme)
- Detergents (e.g. Nano-Silver, anti-bacterial)
- Textiles (e.g. Nano-Silver; anti-bacterial)
- Food and Food-packaging

0.1 Problem: Risk Assessment

- **No general answer to toxicity of Nanomaterials possible due to the dependence on:**
 - Substance
 - Size of nano-material
 - Shape
 - Exposition-path (dermatological, inhalative, ingestive)
- **Proven toxic effects:**
 - Can cause Inflammation (nano-materials can pass the lung)
 - Toxic for cells
 - Able to pass into the brain
- **Methods to test nano-risks are not developed at the moment:**
 - Standardisation of the samples and measuring methods are necessary
 - nano-specific exposure scenarios are missing (indicators for exposure)

0.1 Problem: Potential Risks / Open Questions

- **Widely unknown interaction of nano-materials within the environment !**
- **Compatibility with bio-technological systems**
(e.g waste water treatment facilities)
- **Carrier function of nano-materials in the environment ?:**
 - Can they mobilize pollutants (in the sewage sludge)?
 - Can they wash out nutrients, e.g in the soil?
- **Possible effects on organisms in the water and the soil?**
- **Accumulation of nano-materials in the food chain?**

0.1 Problem: Possible focal points for emissions of Nano-materials

- **Emission of Nano-particles are possible at all stages of the life-cycle (case-by-case approach) !**
- **Important conditions for emissions and exposure are:**
 - Type of production process (open or closed system)
 - Type of the handling (liquid or solid/powder)
 - Is the nano-material embedded in a product matrix
 - Persistent structure of nano-materials?
- **Uncontrolled emissions occur with the use of varnishes, paint, sprays!**
- **Situation of emissions at the end of life of a product?:**
 - Will nano-materials be emitted into the water (ground water)?
 - What happens to nano-materials in the waste incineration?
 - Fate of nano-materials in waste disposal site or in sewage sludge?

1./2. Regulatory gaps and options

a) IPPC

subject matter	Status quo	Options
obligation to obtain a permit (incl. 'change in operation')	Art. 4/12 IPPC	
Production	„chemical processing“? / other production techniques?	Clarify: Definition /Modify: Annex I ?
Application (Downstream use)	Not nano-specific	Introduce: obligation to obtain a permit ?
waste management	Not nano-specific	ditto?
Non IPPC Installations	No regulation	ditto?
update of permit cond.	nano-specific reasons	→ Substance Law?

1./2. Regulatory gaps and options

a) IPPC

subject matter	Status qou	Options
Immission-values	Air quality Directives Not nano-specific	Link substance law: Legal assumptions (PNEC = quality standard) (<i>in Sigma?</i>)
Emission-values	Not nano-specific	- risikogesteuert → Stoffrecht - Vorsorge nach StdT/BAT?
Control of major-accident hazards	Seveso Directive: Not nano-specific	nano-specific thresholds (<i>Sigma</i>)
Monitoring	Not nano-specific	? – (<i>measuring methods available?</i>)

1./2. Regulatory gaps and options: Waste

Subject	Status quo	Options
Waste control	<ul style="list-style-type: none"> - Existing waste codes are not nano-specific; - Criteria for waste char. (Annex III Dir. 91/689) 	<ul style="list-style-type: none"> - Introduce new waste codes for nano-materials; - generate risk information under REACH to enable waste char.
Waste incineration	Instruments exist / Thresholds not nano-specific (Dir. 2000/76/EC)	Clarify, whether nano-type is covered; if not adjust to nano-materials
Sewage sludge	-Instruments exist/ thresholds not nano-specific (Dir. 86/278/EEC)	<ul style="list-style-type: none"> - Ban of sewage sludge; - Ban or restrict the disposal of nano-materials in waste water
Waste deposit plants	Site category/ Thresholds are not nano-spec. (Dec. 2003/33/EC)	- nano-specific criteria for site category (link to REACH)

1./2. Regulatory gaps and options: Water

Subject	Status Quo	Options
Disposal direct into Water bodies from industrial activities (Art. 9 IPPC/ Art. 10, Annex VIII WFD)	-Instruments exist, but no regulation outside IPPC activities; but in German Water Law (+)	Control authorisation
Indirect Disposal indifferent sources (ubiquitarious)	- No nano-specific thresholds in the WFD	Restrictions for products or production process for priority substances (Art. 16 VI WFD)
Update Permit Conditions (Art. 13 IPPC)	Nano-specific reasoning necessary	link to substance law (PNEC)

1./2. Regulatory gaps and options: Water

Subject	Status Quo	Options
Emissions (Duty to minimize amount of pollution according to BAT)	<ul style="list-style-type: none">- Thresholds are not nano-specific;- Procedures to measure & analyse are not nano-specific	<ul style="list-style-type: none">- Minimize disposal of NM;- Develop parameters;- Develop/define BAT incl. in the Brefs
Immissions (Art. 16 WFD)	<ul style="list-style-type: none">- Thresholds are not nano-specific;- Procedures to measure + analyse are not nano-specific	<ul style="list-style-type: none">- Develop parameters & methods to analyse;- Include nano-materials in Water Management Plans

1./2. Regulatory gaps and options

c) Substance Law/REACH

Survey

1. Approaches

- a) Existing Substances Regulation
793/93/EEC
- b) “New Substances Directive” →
Council Directive 92/32/EEC = 7th
amendment of Directive 67/548/EEC
→ nat. implementation measures



„Nano“ =
Existing vs New
Substance ?

c) REACH

2. Regulatory options

3. Recommendations

1. Regulatory approaches in Existing Chemicals Legislation

a) Existing Substances Regulation (793/93)

- **Art. 7 par.1 ESR:**
obligation to update substance information spontaneously, in particular on
(a) new uses of the substance which substantially change the type, form, magnitude or duration of exposure of man or the environment to the substance
- **Use of substances in Nano dimensions**
= extremely small particle size (blood-brain barrier)
= specific surface/volume
= extreme surface energy
- **= new use (+)**

1. Regulatory approaches in Existing Chemicals Legislation

a) Existing Substances Regulation (793/93)

- **Update obligation acc. Art. 7 par.1 only refers to substances produced in amounts of min. 10 t per year and manufacturer**

Art. 7 par. 1 ESR

“Manufacturers and importers who have submitted information on a substance in accordance with Articles 3 and 4”

- obligation acc. Art. 3: quantities exceeding 1 000 t per year
- obligation acc. Art. 4: quantities exceeding **10 t** per year

1. Regulatory approaches in Existing Chemicals Legislation

a) Existing Substances Regulation (793/93)

■ **Update obligation acc. Art. 7 par. 2 ESR**

„Any manufacturer or importer of an existing substance who acquires knowledge which supports the conclusion that **the substance in question may** present a **serious risk to man or the environment** shall immediately report such information to the Commission and to the Member State in which he is located. “

■ **independent from quantities? (industry)**

■ **YES**

1. Regulatory approaches in Existing Chemicals Legislation

a) Existing Substances Regulation (793/93)

- **Regulatory situation of substances in Nano dimension under the ESR**
 - **No obligation to notify beneath tonnage thresholds of **10 t per year and manufacturer****
 - **Substance properties are no subject to a general systematic survey (voluntarily: occupational health, product liability, etc.)**
- **Only in the case of Art. 7 par. 2 ESR**
“acquired knowledge of possible serious risk to man and the environment”
→ **Immediate report to the commission**

1. Regulatory approaches in Existing Chemicals Legislation

b) “New Substances Directive” (92/32/EEC)

= 7th amendment of Directive 67/548/EEC

→ nat. implementation measures

- **Art. 7, 8, 13 par. 2:**
obligation to notify any new substance placed on the market in quantities of more than 10 kg per year per manufacturer
- **Carbon nanotube, single-walled as produced, 10 – 40 % diameter x length 0,7 – 1,2 nm x 2 – 20 µm**
Price 1 g: 250,70 € (www.sigma-aldrich.com)
- **Substance specific approach may be problematic**

1. Regulatory approaches in Existing Chemicals Legislation

b) “New Substances Directive” (92/32/EEC)

Above the quantity threshold of 10 kg:

(Art. 8 par.1)

- **a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment, and containing all available relevant data for this purpose.**
- **Regulatory situation of substances in Nano dimension under the Directive 92/32/EEC:
Regulated in case of exceeding the quantity threshold.**
- **New challenge: test methods.**

1. Future Regulatory approach

c) REACH

■ New Substances

Obligation to register substances in quantities from **1 t per year and manufacturer**

■ Existing substances

→ Phase-in-substances (Art. 3 No.19 REACH)

→ quantity-/danger related transitional periods (Art. 23 par.3 REACH)

→ Registration only within **11** years after EIF

- substances in quantities below **100 t/year/manuf.**
- not very toxic to aquatic organisms (R 50/53)
- not CMR

1. Future Regulatory approach

c) REACh

Definition of Nano substances as Existing Substances

1. → Phase-in substances (possibly long transitional period)
2. → Not even update obligation acc. Art. 22 REACh:

“Following registration a registrant shall be responsible ...”

Art. 24: A **notification** in accordance with Directive 67/548/EEC shall be regarded as a registration for the purposes of this Title.

But: Existing substances are not notified!

ESR shall be repealed 1 year after REACh EIF.

→ Potential GAP for 10 years (not nano specific) ?

1. Regulatory approaches in Chemicals Legislation

Specific impact of defining substances in Nano dimension as Existing Substances or New Substances also under REACH

Allocation of substances according to the “**EINECS principle**“ **European Inventory of Existing Commercial Substances**

- **Substances listed in here are Existing substances by definition**
→ any other substance is a New Substance
- **In EINECS:**
substances introduced between
1st Jan.1971 and 18th Sep. 1981
- **Number: 100.195**

1. Regulatory approaches in Chemicals Legislation

Specific impact of defining substances in Nano dimension as Existing Substances or New Substances also under REACH

Working Group on Nano materials as published in the Manual of Decisions (Dir. 67/548/EEC) 07/2006, chapter 5.1.3

„It was agreed that the decisive criterion whether a nanomaterial is a new or existing substance is the same as for other substances, i.e. whether or not the substance is on EINECS.“

Thus, substances in nanoform which are in EINECS (e.g. titaniumdioxide) shall be regarded as existing substances.

Substances in nanoform which are not in EINECS shall be regarded as new substances.

→ New appearances (Nano dimension) of Existing Substances may not be “detected by the legislative system”.

1. Summarising the Regulatory approaches:

„Perception“ of Substances in Nano dimension as

- Existing Substance: from 10 t
- New Substance: from 10 kg
- Under REACh: from 1 t

Problem:

No guarantee of “Nano specific” perception, maybe REACh (concept of use and exposure categories).

Focus on specific Nano dimension and their characteristic properties (e. g. eco toxicity of Titanium dioxide) ?

1. Regulatory approaches:

Existing obligations only come into effect unless there are exemptions

- **Exempted from “the” ESR obligations:**
substances included in Annex II
(e. g. Carbon, in Nano dimension “Carbon Black”),
- **Transfer of all exemptions to REACH as**
→ Annex IV REACH

Acc. to Art. 2 Abs. 7 a) REACH:

“as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties” (“before Nano”)

2. Regulatory options

Consideration of substances in Nano dimension as

a) **Self-contained, single substances**

- **Because of unique (→ Nano specific) properties (e. g. eco-toxicity of Titanium Dioxide)**
- **If a Chemical shows different properties in Nano dimensions than in other dimensions, the Nano dimension would be a single substance (e. g.: Titanium Dioxide , **Titanium Dioxide Nano**)**
- **A **New Substance****
 - **Current legislation: notification from 10 kg**
 - **REACH: registration from 1 t**

2. Regulatory options

Consideration of substances in Nano dimension as

a) **Self-contained, single substances**

Supported by

- **Suggestion of SCENHIR:
self-contained CAS No.'s for substances in Nano
dimension**
- **Formation of SIEFs under REACH:
Manufacturers/Importers of „Nano materials and Non-
Nanomaterials” will not be together in the same SIEF**

2. Regulatory options

Consideration of substances in Nano dimension as

a) **Self-contained, single substances**

Question:

Are the quantity thresholds (10 kg, 1 t) proportional ?

- **No, unless effects to man and the environment underneath these thresholds are known**
- **→ reduction of quantity thresholds regarding the precautionary principle of Art. 1 par. 3 REACH**

2. Regulatory options

Consideration of substances in Nano dimension as

b) **“Exemptions from Chemicals Legislation”**

due to their extremely small particle size leading to Nano specific properties

- **Chemicals Legislation (ESR, 67/548/EEC, REACH)**
“Obligations from this regulation / directive do not apply for substances in Nano dimensions “.
- → consistency to some extent
e. g. Re-exemption of Carbon
→ quantity related obligations from the ESR
- → Implementation of a
“Nano specific substance regulation module” ?

2. Regulatory options

Consideration of substances in Nano dimension as

b) **Exemptions from Chemicals Legislation and Nano specific substance regulation module:**

Embodiment of this module?

- In any case: within the frame of Chemicals Legislation, substances in Nano dimension = substances alternatives outside Chemicals Legislation are not appropriate for the addressees
- **Possibility at first:** Voluntary Reporting Scheme (UK)
Coordinative support by Industry associations possible.
- **“Code of good practise“ ?**
Regularly reporting obligations (authorities and public)

3. Recommendations:

- **“Nano specific” consideration of substances: distinction between a chemical in Nano dimension and other dimensions in order to enable the perception of distinct properties and resulting distinct risks.**
- **Where possible consideration of long time experiences with substances in Nano dimension (Carbon Black) !**
- **No global exemptions from legal obligations; exemptions only if “Nano” specific test results lead to the consideration of “minimum risk”**

3. Recommendations:

- **No hidden shift of chemicals legislation aspects (original substance legislation) into the field of occupational health legislation (secondary substance legislation)**
 - **E. g.**
 - **Obligation to provide Safety Data Sheets (SDS) exists with regard to **dangerous substances****
 - **Knowledge about the danger potential of a substance only results from the application of chemicals legislation (**output**)**

3. Policy recommendations (Step 1)

Step 1: Initial measures - problem of information

a) Communication requirements :

- Clarification: on a voluntary basis or mandatory?
 - In the latter case: modification of REACH.
- If required, adaptation of the definition of substance.
- Subject of Notification (Who? What? When? To whom?: threshold values, properties of substances, [provisional] testing programme) → UK-approach

b) At the same time:

- Standardization of nomenclature
- Testing procedures and monitoring methods

3. Policy recommendations (Step 2)

Step 2: Systematization and assessment

- a) Develop mechanisms for the gaining, merging and assessment of information (administrative or civic: discourse on risk in which institutional context?).
- b) Definition of (provisional) measures to cope with risk (based, for instance, on classification of the application/release of nano materials according to the "traffic-lights principle"):
Green / Yellow / Red
- c) Prepare and test support for stakeholders in implementation of a)/b).

3. Policy recommendations (Step 3)

Step 3: Further regulation requirements?

- a) Depending on the results of Step 2, decisions on further regulative elements could be taken.
- b) Continuance of activities mentioned under 1 b)
 - participation of civic stakeholders
 - context of international standardization organizations
- c) Overcoming problems at the interface between
 - toxic substances law and
 - other sectorial regulations (IPPC, WFD and waste law)

3. Policy recommendations (Steps 4 + 5)

Step 4: Implementation and monitoring of RMM

Establishing a risk-adequate concept for determining and controlling the undesirable effects of nano-materials:

- a) Incorporation in
 - non-statutory/administrative regulations
 - standards and norms, such as ISO/OECD, CEN others
- b) Monitoring: toxicological and ecotoxicological

5. Modification of the regulative framework

Observation of technical developments etc.

→ adaptation of the regulative framework.

Thank You for Your Attention

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