Registration of Nanomaterials

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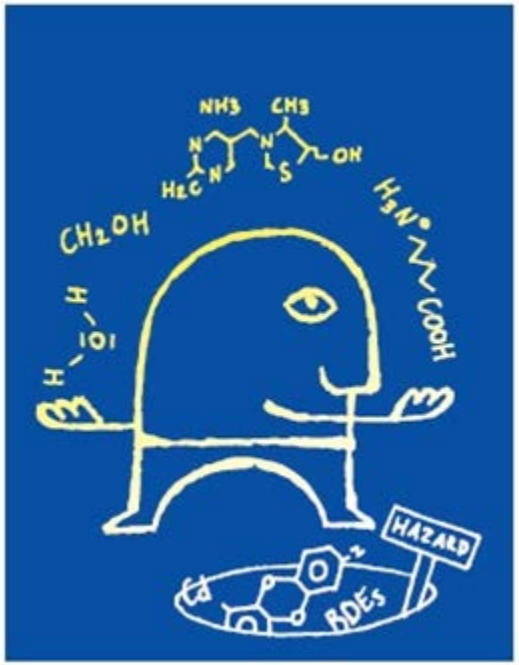


The EEB

- **Europe's largest federation of environmental organisations with 140+ member organisations.**
- Represent **15 million European citizens**, and act as the ears and voice of its members towards the **EU decision makers**.
- Goal: to enable the citizens of Europe to play their role to **protect and improve the environment in Europe**
- **European wide network & working groups**

What is REACH supposed to do?

Why is enforcement important?

Why Nano?

Is ‘no data, no market’ being enforced for NMs?

Is safety proven for NMs?

How could things be improved?

Conclusions

What is REACH supposed to do?

“to ensure a high level of protection for human health and for the environment"

The principle of REACH is that manufacturers, importers and downstream users ensure they manufacture, market or use such substances that do not adversely affect human health or the environment (Article 1(3)).

This principle is applicable to substances in whatever size or form, and for all their identified uses, which means that nano-forms are included.

Why enforcement is important

- With no enforcement there is no level playing field
- The best in sector are penalised, the worst in sector rewarded
- We should reward companies doing the right thing, not the wrong thing
- Good enforcement is essential for a ‘high level’ of protection
- Without enforcement, REACH becomes a voluntary agreement

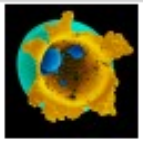
Why nano? Size Matters

- **Nanoscale materials do have special properties**:
  - All properties vary with size also toxicological properties. Low mass/above-average surface area causes an increased reactivity and potential to become toxic.

- **NMs are able to enter and persist in the body, rapidly migrate to the organs, get deep into the lungs, cross the blood barrier and placenta, enter the brain, penetrate the skin, and even some protective equipment….**

- **NMs are available and persist in all environmental compartments** (and cause harm, e.g. ozone depletion)

Why nano? Ground for concern



11 JULY 2014 | Brain Behavior

Nanoparticles may harm the brain

Drug delivery method may be toxic

Dose-Related Alterations of Carbon Nanoparticles in Mammalian Cells Detected Using Biospectroscopy: Potential for Real-World Effects

Nanosilver from Clothing Can Pose Major Environmental Problems

Gold- and Silver Nanoparticles Affect the Growth Characteristics of Human Embryonic Neural Precursor Cells

Study Says Carbon Nanotubes as Dangerous as Asbestos

Model suggests nanoparticles cross into placenta

Nanoparticles from dietary supplement drinks likely to reach environment: Potentially harmful substances

Silver nanoparticle exposure in young males affects sperm

CW. 27 February 2014 / Brazil,Risk assessment

Echoes of Autism? Inhaled Ultrafine Particles and Brain Changes in Mice

More dangerous chemicals in everyday life: Now experts warn against nanosilver

Silver Nanoparticles May Adversely Affect Environment

Silver nanoparticles in sewage sludge harmful to soil microorganisms

Commonly Manufactured Nanomaterial Induces Neurovascular Toxicity

Common Cosmetic and Sunblock Ingredient, Titanium Dioxide, May Have Potential Health Risks

Nanoparticles in tattoo ink could cause cancer

Study reveals toxic pathways for zinc oxide nanoparticles

Nanotechnology and human health:
Scientific evidence and risk governance
Report of the WHO expert meeting
10-11 December 2012, Bonn, Germany
http://www.euro.who.int/__data/assets/pdf_file/0018/233154/Nanotechnology-and-human-health-Scientific-evidence-and-risk-governance.pdf

The report concludes that "given the scientific uncertainty and still emerging evidence, and given the early indications of harm and possible adverse human health effects that have been hypothesised for some nanomaterials, a precautionary approach seems desirable."

Plastic nanoparticles also harm freshwater organisms

Posted: 17 Oct 2014 06:29 AM PDT

Organisms can be negatively affected by plastic nanoparticles, not just in the seas and oceans but in freshwater bodies too. These particles slow the growth of algae, cause deformities in water fleas and impede communication between small organisms and fish.

Why nano? Wide exposure while unknown what is in the market

"**There is a general lack of knowledge about the characteristics of nanomaterials in relation to environmental and population exposure**" *SCENIHR*

- **Medicines**
- At least 96 **food** items (probably more) sold in grocery stores contain nanoparticles. *Friends of the Earth*
- **Consumer products:** NMs are widely used in a variety of sectors and in numerous products.
- **Biocides and pesticides**
- **No labeling for most consumer products**

Is no data no market being enforced for NMs?

NMs were allowed in the market in the first place since 20 years without basic data being submitted by industry.

Direct employment estimated at 300,000-400,000 t/y in EU

Most NMs are NOT registered

- 3,000 NMs estimated in the EU market
- CEFIC announced that 80-90% of all existing NMs should have been registered by the first registration deadline of 2010
- However, **only 9 substances registered as nano**!

Is safety proven for NMs?

Most NMs registration dossiers are NOT compliant

- Inadequate or total lack of characterisation of NMs
- Characterization of the Nanoform is very first step to RMM
- Lack all relevant scientific information in dossier
- NM and bulk substances joint registration with the same risk assessments
- Only 3 decisions so far for NMs

Non compliant company name is secret and enforcement activities performed unknown

Is safety proven for NMs?

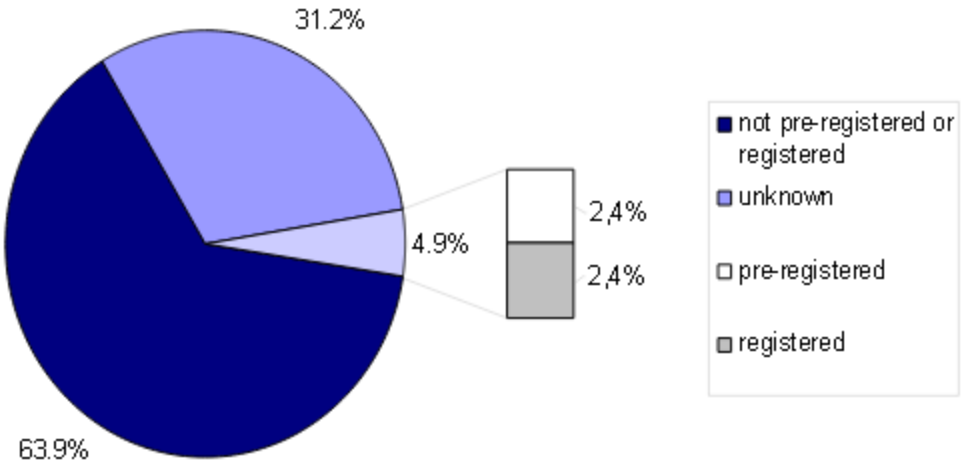


Fig. 2: Percentage of nanomaterials within the study being pre-registered or registered in accordance with REACH

- < 5% of NMs (pre)registered
- Only one company registered as nano
- large gaps in knowledge re possible negative effects on humans and environment

50% companies carry out safety assessments before marketing and of these approx. only a half use nano-specific test methods.

http://sofia-darmstadt.de/fileadmin/elni/dokumente/Archiv/2012/Heft_2/elni2012-2_AC-Schenten-Fuehr-open.pdf

How could things be improved?

First step is **revocation of registration numbers** when info is insufficient or inadequate: no data, no market

Enforcement authorities should ensure a well functioning legal framework:

- Collects all necessary data (and incite the production of such data where it does not yet exist): REACH
- Ensures risk management measures are implemented (sectoral regulation, workplace measures, and REACH)
- Identifies all potential exposure pathways
- Allows authorities to react effectively in case of identified problem (traceability mechanism)

Conclusions

- **Potential risks of NMs must be regulated**
- **REACH can only work if it is enforced** (it's not voluntary agreement)
- Enforcement authorities must ensure that industry provides **sufficient information** about the NMs they produce and that they are **safe to use.**
- Enforcement must be **visible and transparent** (transparency provides extra pressure for action)
- Regulators must **monitor, and ACT when things go wrong**

Thank you for your attention!

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An international non-profit association