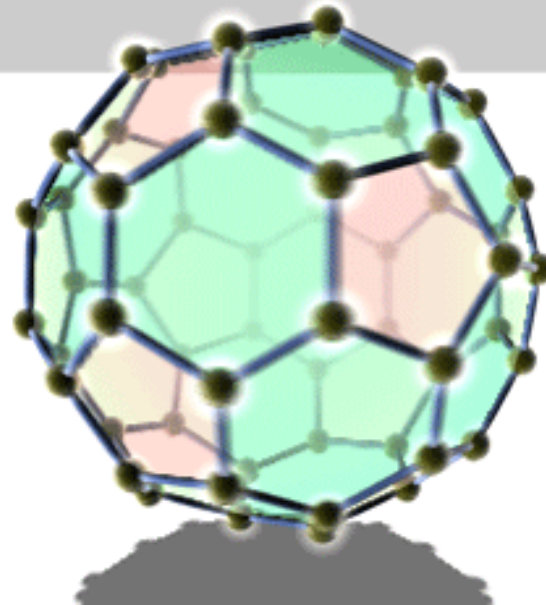


# The Need to Regulate Nanotechnologies



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# Outline of this Presentation

1. General Assessment of the Current State of the Regulatory Framework
2. Steps Towards Adequate Regulation
  - a) Standardisation as Basis for Regulation
  - b) Regulation of Nanomaterials under REACH
3. Summary/Conclusions



# The current state of affairs

## Growing number of nano consumer products on the market

- Woodrow Wilson Center: 800+ products, but total number likely to be much higher
- Applications include very sensitive areas with a high potential for consumer exposure, such as cosmetics, food, textiles, kitchen utensils, toys



## Many open questions regarding the safety and risk assessment of nanomaterials

- Initial research shows greater potential for toxicity compared to the bulk material for at least some nanomaterials, including some of the most widely used (Silver, Titanium Dioxide, Zinc Oxide, CNTs)
- Lack of standardised test methods for the assessment of nanomaterials
- Only about 5 % of nanotech research funding going into risk research
- OECD sponsorship programme just starting



## Sometimes contradictory industry communication adds to the confusion about the safety of nanomaterials

- “key technology”, “great innovative potential”, “in perfect tune with the new era of nanotechnology”
- “our products are in no way related to nanotechnology, in fact rather the opposite is the case”



# The current state of affairs

## No mandatory labelling and no mandatory registration

- products advertised as “nano” do not necessarily contain nanomaterials
- Products containing nanomaterials often not specified as such (especially in sectors with a high potential for consumer concern)
- Consumers are denied the right to choose for or against products containing nanomaterials
- Even the relevant risk-assessment authorities often do not know which products contain nanomaterials

## Little consumer awareness yet...

- About half of the population still has no clue about nano

## ...but growing interest

- Growing number of consumer and environmental groups getting involved with nano-issues
- Rising number of consumer requests
- Consumer concern greatest in food and cosmetics



# The current state of affairs

## So far only “soft” regulation/voluntary codes of conduct

- DuPont/Environmental Working Group
- UK Responsible NanoCode
- VCI, BASF
- Swiss Retailers
- German NanoDialog

## No “hard” nano-specific legislation

- No current EU or international legislation explicitly covering nanomaterials
- EU COM: existing legislation principally applicable, but adaptations might become necessary over time



# Assessment of the regulatory framework

## Regulation should ensure that:

- Nano-products undergo a mandatory pre-market safety assessment
- Consumers have a right to choose if they want to buy products containing manufactured nanoparticles

## In this respect the current regulatory framework is unsatisfactory:

- Voluntary Codes of Conduct can be important for the development of adequate risk management methodology, but are no substitute for mandatory regulation (enforcement issues)
- Some legislation might be principally applicable to first generation nanomaterials, but essential basics for the implementation are missing. Adaptations will be needed!
- REACH: existing legislation with the greatest potential to cover a wide-range of nanomaterials
- Adaptation of existing legislation alone will be insufficient, in the medium-term new legislation will need to be developed for more advanced generations of nanomaterials and –systems

As an intermediate step we call for:

**A temporary moratorium on manufactured nanomaterials in products with a high potential of exposure for consumers and the environment!**

# Standardisation

## What is „nano“?

- Most commonly defined as  $\leq 100$  nm in one dimension

BUT:

- Materials  $> 100$  nm, can also exhibit novel-properties, e.g. some CNTs bigger than 100 nm in diameter
- Aggregates and Agglomerates can exhibit nano-properties (depending e.g. on form and surface area) or degrade to nanoparticles
- Much higher bioavailability of particles up to a few hundred nanometers
- Typically, particles do not have a uniform size. Even with a medium size above 100 nm, the size range will often include smaller particles
- Materials with nano-properties could be left out of adequate regulation, if the definition is too narrow.

# Standardisation

**It is important to choose a definition that includes all materials with novel properties**

- Definition must be wider than 100 nm
- Ideally, the definition should be based on properties, not size
- However, a size trigger for the testing for novel properties is needed
- The definition must include soluble nanomaterials

## **BUND/FoE Proposal:**

- All manufactured materials  $\leq 300$  nm in one dimension are regarded primarily as nanoparticles
- Materials with novel properties should be subject to nano-specific regulation

# Nanotechnology and REACH

REACH: The EU legislation covering most substances (but excluding those covered in other legislation)

REACH could be used to start with the regulation of nanomaterials

BUT: Many open questions:

- How to adequately define nanomaterials?
- Registration as phase-in or non phase-in substances?
- Are the tonnage triggers adequate for nanomaterials?
- How to test and assess nanomaterials?
- How to deal with nanoforms of substances in Annex IV and V?
- ...

+ REACH can only apply to first generation nanomaterials!

# Phase-in or Non Phase-in ?

## Regulation as Phase-in Substances

- The total production volume of all bulk- and nanoforms of a substance could be counted together
- Tonnage triggers are more easily met, data requirements according to total amount of bulk- + nanomaterial

## BUT

- Ignores that nanomaterials often exhibit novel properties in comparison to the bulkmaterial, and thus are substantially different from the bulkmaterial
- Might lead to confusing dossiers and as a result to an inadequate assessment of nanomaterials

## Possible Way Forward

- Registration as phase-in substance, but separate registration dossier from bulk material (interim solution ?)

# Phase-in or Non Phase-in ?

## Regulation as Non Phase-in Substances

- Registration independent from bulk material
- Takes into account novel properties of nanomaterials
- Avoids confusing registration dossiers
- Registration independent from tonnage based deadlines

## BUT

- Tonnage of bulk- and nanomaterials cannot be counted together
- Tonnage triggers are less easily met
- Lower data requirements could result

## Possible Way Forward

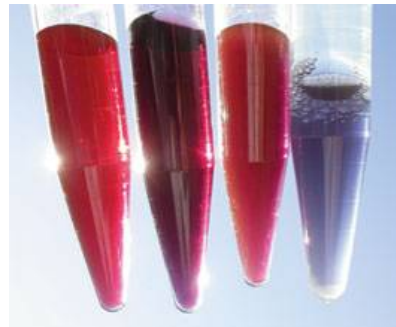
- No (or at least lower) tonnage triggers for nanomaterials
- Requirement to produce a Chemical Safety Report for all nanomaterials
- Possible intervention point: revision of REACH 2012

# Different nanoforms of one substance

- Nanomaterials of the same chemical composition can have different properties
- A typical example: gold changes its properties (e.g. colour) several times within the nano size range
- Silver: different toxicity depending on particle shape

## Possible Way Forward

- Separate assessment of nanomaterials of the same substance, if they show different properties related to size and shape
- Separate Registration or Registration Dossiers?



# Tonnage Thresholds for Registration

- Nanomaterials can be more potent than bulk material
- Lower amounts might be needed for a product, still the toxicity can be relatively high
- Nanomaterials can have a high toxic potential, even if the produced amounts are low
- German survey shows that most “nano-companies” are SME’s producing volumes of below 100 kg/year
- Nanomaterials might be registered only very late, if at all, as long as there are no nano-specific tonnage thresholds

## Conclusion

- The existing thresholds might be inadequate for the registration of nanomaterials, thus nanomaterials should be registered independent of the tonnage
- Nanomaterials should be always subject to a Chemicals Safety Report

# Data requirements

- The registration of phase-in substances between 1-10 tons per year requires only existing safety data
- When nanomaterials (together with the bulk material of the same substance) are produced in volumes of less than 10 tons/year no additional EHS data must be submitted so far

## Conclusion

- Nanomaterials should be principally tested at least according to Annex VII and VIII
- Thus, a Chemical Safety Report should be obligatory for nanomaterials
- For nanomaterials additional physicochemical properties should be taken into account: type of nanomaterial, size and shape (distribution), surface structure and area, polarity, absorption, metabolism etc.
- Assessments of exposition should cover not only the total mass, but also the number, surface area and concentration of particles

# Test Specifications

- There are still no standardised test methods for the safety assessment of nanomaterials
- The Technical Guidance Document (TGD) on data requirements does not yet include specifications for the assessment of nanomaterials
- It is still unclear if the common toxicological and ecotoxicological end-points are valid and/ or sufficient for nanomaterials (e.g. environmental behaviour, degradability, effect on soil organisms, etc.)
- The test requirements within REACH need to be adapted for nanomaterials, adaptation of TGD and annexes VII-X needed
- No „Waiving“ should be allowed for nanomaterials, as they cannot be regarded as „same“ to bulkmaterial



# Substances in articles

- Substances in nanoform can be very potent even at very low concentrations
- Therefore, it seems likely that they will in many cases be used in concentrations below 0,1 % of the total volume of an article, but still be toxically relevant

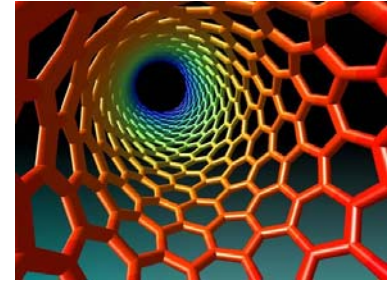
## Conclusion

- The current threshold of 0,1 % should be revised for nanomaterials
- Else, the regulation of substances in articles under REACH might turn out to be effectless for nanomaterials
- This would also affect the new information right for consumers about Substances of Very High Concern (SVHC) in articles

# Evaluation

- Due to the high level of uncertainty regarding the proper registration of nanomaterials, all registration dossiers affected nanomaterials should be evaluated
- Nanomaterials should also be prioritised for substance evaluation, when it is not clear if the provided data is sufficient

# Annexes IV and V



**Substances listed in Annexes IV and V are exempted from regulation under REACH because they are generally assumed to be safe**

- However, nanomaterials of substances which are non-toxic in bulkform can turn out to be toxic in nanoform
- As a result, toxic nanoforms of a substance could be excepted from regulation under REACH if the substance is listed in annex IV or V
- Examples: Fullerenes und CNTs

## **Latest Development:**

Carbon and Graphite exempted of annex IV

## **Disadvantages:**

- Nanoforms of other substances in annexes IV and V could also turn out to be toxic, but will be excepted from regulation under REACH, until excluded from Annex IV/V
- A safety assessment for all applications of carbon and graphite will be mandatory, even though many applications can already be regarded as safe

## **Possible Way Forward**

- General preliminary exclusion of nanomaterials from annexes IV and V, until a specific nanoform can be proven to be safe

# An adaptation of REACH on several levels will be needed

## Adaptations in the law:

- Regulation as non phase-in substances
- Deletion of tonnage thresholds for the registration of nanomaterials
- Deletion of the 0,1 % threshold for (nano-) substances in articles
- Stricter data requirements, eg. mandatory CSR for all nanomaterials

## Adaptations within the Annexes:

- General exclusion of nanomaterials from annexes IV and V, revision of test requirements according to annexes VII-X

## Adaptation of TGDs:

- TGD regarding data requirements

# More than just REACH

- REACH does not cover all applications
- Fields of application covered in other legislation are not included in REACH, the relevant legislation will need to be adapted as well
- The risks of future more complex nanomaterials and nano systems cannot be covered by REACH
- The debate on a regulation of nanomaterials needs to take into account the potential medium- and long-term implications of future generations of nanotechnology

# Conclusions / Summary

## Standardisation:

- The definition of “nano” must be extended

## REACH is a good starting point, but adaptations are needed:

- Regulation of nanomaterials as new chemical substances
- No tonnage limits for nanomaterials for registration
- Obligatory Chemical Safety Report for all nanomaterials
- Removal of the current threshold of 0,1 % for products
- Differentiated evaluation of nanomaterials of one substance
- Prioritisation of nanomaterials for substance and dossier evaluation
- No „waiving“ of tests should be allowed for nanomaterials
- Immediate revision of the technical guidelines and of the annexes for the data requirements

# Conclusions / Summary

## **Interim solution until REACH is revised:**

- Introduction of a compulsory notification to a national authority

## **Furthermore/And:**

- Adaptation of other legislation will be needed to cover applications not covered by REACH (eg. food and cosmetics)
- Early initialisation of a public debate about the regulation of future generations of nanomaterials and -systems

**We call onto Member State Governments  
and the EU Commission to develop proposals  
for adequate regulatory steps forward !**

# BUND/FoE publications regarding nanotechnology

## **BUND Publications:**

### **Aus dem Labor auf den Teller**

([http://www.bund.net/fileadmin/bundnet/publikationen/nanotechnologie/20080311\\_nanotechnologie\\_lebensmittel\\_studie.pdf](http://www.bund.net/fileadmin/bundnet/publikationen/nanotechnologie/20080311_nanotechnologie_lebensmittel_studie.pdf))

### **BUND-Positionspapier: Für einen verantwortungsvollen Umgang mit der Nanotechnologie**

([http://www.bund.net/fileadmin/bundnet/pdfs/chemie/20070500\\_chemie\\_position\\_nano.pdf](http://www.bund.net/fileadmin/bundnet/pdfs/chemie/20070500_chemie_position_nano.pdf); English version available upon request)

### **Kriterien zur Kontrolle von Nanotechnologien und Nanomaterialien**

([http://www.bund.net/fileadmin/bundnet/publikationen/nanotechnologie/20080220\\_nanotechnologie\\_kontrolle\\_kriterien.pdf](http://www.bund.net/fileadmin/bundnet/publikationen/nanotechnologie/20080220_nanotechnologie_kontrolle_kriterien.pdf))

## **Friends of the Earth Publications:**

### **FoE Europe/US/Australia: Out of the laboratory and on to our plates**

([http://www.foeeurope.org/activities/nanotechnology/Documents/Nano\\_food\\_report.pdf](http://www.foeeurope.org/activities/nanotechnology/Documents/Nano_food_report.pdf))

### **FoE Europe: Nanotechnology and the current legislation – Briefing Paper**

([http://www.foeeurope.org/activities/nanotechnology/Documents/Legislation%20briefing\\_Nov07.pdf](http://www.foeeurope.org/activities/nanotechnology/Documents/Legislation%20briefing_Nov07.pdf))

### **FoE US: Nanotechnology and Sunscreens**

([http://www.foeeurope.org/activities/nanotechnology/Documents/FoEUS\\_Nano\\_Sunscreen.pdf](http://www.foeeurope.org/activities/nanotechnology/Documents/FoEUS_Nano_Sunscreen.pdf))

### **FoE Australia: Nanotechnology in Sunscreens and Cosmetics**

(<http://www.foeeurope.org/activities/nanotechnology/nanocosmetics.pdf>)



***Thanks for your attention!***

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