

# Review of business viewpoints

## Lessons from four case studies

<b>Session 2: Examination of Four Case studies</b>		<b>Chair: Nick Pidgeon</b>	<b>University of Cardiff</b>
13:15-14:45	<i>TiO<sub>2</sub> in sunscreens/cosmetics (1h30')</i>	<i>Moderator: Takis Daskaleros</i>	<i>DG Health and Consumers</i>
13:15-13:45	Presentation (30')	Gerald Renner	COLIPA
13:45-14:00	Comments from discussant (15')	Laura Degallaix	BEUC
14:00-14:15	Comments from discussant (15')	Thomas Jung	SCENIHR
14:15-14:45	Discussion (30')	Moderator	
14:45-16:15	<i>Nanoparticles in paint (1h30')</i>	<i>Moderator: Otto Linher</i>	<i>DG Enterprise</i>
14:45-15:15	Presentation (30')	Craig Barker	Akzo Nobel
15:15-15:30	Comments from discussant (15')	David Santillo	Greenpeace
15:30-15:45	Comments from discussant (15')	Rolf Hertel	German Institute for Risk Assessment
15:45-16:15	Discussion (30')	Moderator	
16:35-18:05	<i>Carbon nanotubes in (application to be selected) (1h30')</i>	<i>Moderator: Jack de Bruijn</i>	<i>ECHA</i>
16:35-17:05	Presentation (30')	André Lecloux	Nanocyl
17:05-17:20	Comments from discussant (15')	Henning Wriedt	German Trade Union
17:20-17:35	Comments from discussant (15')	Ken Donaldson	University of Edinburgh
17:35-18:05	Discussion (30')	Moderator	

# Review of business viewpoints

## Lessons from four case studies

	Topic	Speaker	Organization
<b>Session 2: Case studies (continued)</b>			
9:00-10:30	Nanosilver in textiles (1h30')	Moderator: Bjorn Hansen	DG Environment
9:00-9:15	Presentation 1 (15')	Rainer Hanselmann	Sarastro GmbH
9:15-9:30	Presentation 2 (15')	Matthias Nüchter	Nanoinitiative Bayern GmbH
9:30-9:45	Comments from discussant (15')	Rye Senjen	Friends of the Earth
9:45-10:00	Comments from discussant (15')	Wim de Jong	RIVM
10:00-10:30	Discussion (30')	Moderator	
10:30-10:50	20' Coffee Break		
<b>Session 3: Generic lessons from the case studies (1h30')</b>		<b>Chair: Eric Gaffet</b>	CNRS
10:50-11:05	Regulatory issues (15')	Rapporteur: Diana Bowman	Monash University
11:05-11:20	Safety issues (15')	Rapporteur: Ken Dawson	SCENIHR
11:20-11:35	Consumer information issues (15')	Rapporteur: Hilary Sutcliffe	Responsible Nano Forum
11:35-11:50	Business issues (15')	Rapporteur: Thomas Epprecht	SwissRe
11:50-12:30	Discussion (40')	Moderated by the Chair	
12:30-12:35	Closing remarks (5')	Chair	

Nano-Safety4Success 2009  
 Industry viewpoints' review  
 Thomas Epprecht, Swiss Re

## Rapporteur's task

Legend for summary slides (next):

Text in black:  
Industry viewpoints

Text in blue:  
Comment by rapporteur,  
other stakeholder, or  
floor

Text: Highlighted  
issues for discussion

### Review of the industries viewpoints on:

1. Why is the product called/labelled "nano"?
2. What is the information about its availability on the market?
3. What are the regulatory requirements that govern its existence on the market?
4. What kind of safety testing is being performed?
5. What are the expected benefits and risks (manufacturer, consumer, environment)?
6. What is the involvement of stakeholders and citizens' groups?

## Review of business viewpoints

# Rapporteur's conclusions over all case studies

### Q1: named "nano", labelling

- Named "nano" / definition has not really been addressed;
  - "too broad to begin with" (or too trivial?)
  - (missed) opportunity to shape in a workable manr.
  - nano-specific properties more important, c-by-c, (see also exposure assessment algorithm of SCENIHR, CH-Precaut. Mtx)
- Threshold not addressed → registration under REACH?
- Wait-and-see on labelling –
  - definition problem; size alone not appropriate
  - choice "yes", warning "no"

### Q2: market availability

- Good, illustrative examples, presented proudly:
  - Enable progress is industries' core competence and interest
  - Need to sale, be profitable
- Are there information gaps on other products on the market (low volumes, just B2B, or not considered "nano")?
  - left open, source of (unjustified) suspicion?
- Comparison of "good" nano-product family members w/ "bad" family members omitted (apparently amicably)

### Q3: regulation & market

- Focus on existing regulatory requirements (§§ x and §§ y) and confirmation to comply
- Considerations on possible regulatory gaps and requirements to adapt were not made public / shaped actively:
  - Highly political and thus legalistic, vs. participation based on own experience?
- Quiet floor, eg on high expectations from the "no data – no market" principle: not tackled
  - Has industry given up to have a strong and supportive voice in the matter?

## Review of business viewpoints

# Rapporteur's conclusions over all case studies

### Q4: safety testing

- Mainly general messages and info's, thus maybe effectless:
  - Industry believes in mastering risks accordingly and to do the necessary testing (...and then...?)
  - Existing guidelines, best practice and standards considered as sufficient
  - opportunity to outline principles of problem resolving and adaptive improvement not seized
  - Time constraints may have hampered concrete answers

### Q5: benefits & risks

- Focus on benefits, beneficial examples, legitimately
- Hazards or uncertainties are rarely made explicit,
  - practitioners shortcut to risk management methods and exposure protection measures → traceable?
  - How to deal w/ uncertainties eg dispersion, protein adherence, protein corona, dose metrics, gene toxicity, similarity to subcellular structures, deserve more concrete answers (even if self-evident for industry)

### Q6: stakeholder dialogue

- Always polite and chary; when attacked reactive, defensive, legalistic (fear of "first mover disadvantage"?)
- Most active in trade-off w/ reg. institutions; purpose and added value of inventories clearly questioned
- Dialogue or monologue? Successful communication requires more than "informing, teaching, educating"
  - Persisting belief that rational, purely technical arguments must be convincing
  - "public risk perception" needs perceptive approach

# Review of business viewpoints TiO<sub>2</sub> in sunscreens / cosmetics

## Q1: named "nano", labelling

### Name (nano or not):

- ISO/OECD definition not workable for RM purposes: need to be sector specific and enforceable\* \* consensus w/ consumers
- Prerequisite for consistency and transparency:
  - terminology & definitions
  - harmonised regulation(s)


### Labelling:

- Ingredient list: for consumer information only (choice) ≠ safety information (warning)

## Q2: market availability

- 1st generation NM used in sunscreens, cleaning and colorants since 25 yrs: TiO<sub>2</sub>, ZnO, silica (size dispersion)
- How do NM "work" compared to bulk and chemical SPF: risk & benefit comparison would make added values more tangible
- Important side remark addressed perceptions on exposure: Marginal use of fullerenes, gold, platinum
- [Nanoemulsions out of scope]

## Q3: regulation & market

- EC cosmetics directive 
  - manufacturer must demonstrate safety
  - new UV filter must be submitted premarketing → positive list
  - currently no specific regul. requirements
- New (cosmetics dir. recast):
  - notification 6 mths before, adds level of scrutiny for all NM → registry
  - Concern: notification process too slow

# Review of business viewpoints TiO<sub>2</sub> in sunscreens / cosmetics

## Q4: safety testing

- Test methods always must be adapted (is not a "nano"-specific task)
  - established guidelines (OECD) work for NM, too
  - but way of looking at a problem may need a change / be a challenge
- Industry's best practice includes:
  - physical characterisation
  - quality tests
  - size and form
  - safety relevant tests not outlined in detail

Slide 7

## Q5: benefits & risks

- Benefits:
  - UV attenuation, light scattering (high SPF)
  - nanoform easy to apply
  - claim for better performance, comparison w/ alternatives (and risks) not optimally communicated
- Risk (exposure) testing:
  - pharmacokinetics (dermal penetration ...) identical; aggregates, agglomerates
  - tox. effects identical / non existing by normal use
- NM vs. non-NM → no additional risk

## Q6: stakeholder dialogue

- Not specifically addressed:
  - (justified?) trust in shaping consumers' confidence by way of consistent regulation(s)
- Consumers claim for answers mainly on:
  - effects of regular (life-long) use
  - synergistic effects because of other routes / sources of exposure
  - transparency (public inventory) vs. undisclosed proprietary information

# Review of business viewpoints

## Nanoparticles in paint

### Q1: named "nano", labelling

- Definition and labelling not elaborated
  - is a risky strategy, warns NGO representative
  - is actually a helpful hint: unnecessarily under fire?
- "Complete declaration of ingredients useless since not considered by consumer"
  - [but the right to vote is also independent from how one makes use of it]

- Key is: What kind of declaration adds really to information content, size only ;-(

Slide 8

### Q2: market availability

- Paints contain only a few types of NP:
  - Ag, C, clays, amorphous silica, metal oxides (Fe, Ti, Zn, Sn, Al, others)
- Few examples, including comprehensive risk / benefit information (eg anti-fouling)
- Function of nano-component could be addressed more comprehensively

### Q3: regulation & market

- Not addressed beyond "current regulation sufficient" (legalistic approach)
- Public authority standpoint: Product safety regulation requires manufacturer to deliver safe products, full stop.

# Review of business viewpoints Nanoparticles in paint

## Q4: safety [testing\*]

Safety taken as a given because of precautionary approach:

- NP dispersed in liquid medium whenever possible
- Workplace exposure to solid NP: Personal protective equipment is minimum standard, but "exposure needs to be engineered out"
- \*Safety testing not addressed
- Exposure scenarios / life cycle assessment → beneficial for uncertainty / concerns management

Slide 9

## Q5: benefits & risks

- Benefits "sustainable":
  - weight, ie CO<sub>2</sub> reduction
  - increased strength
  - single layer coatings
  - For acceptance, make benefits even more tangible
- (No) risks:
  - no release of respirable NP during application
  - during use NP embedded in resinous matrix
  - negligible release / abrasion of NP during physical manipulation

## Q6: stakeholder dialogue

- Rather reactive & awkward:
  - "Ongoing debate is real and requires closure, try to handle situation"
  - "Do not close eyes to debate, prepared to answer concerns"
- Prepared to collaborate w/ regulators, trade unions, NGOs, but not said how
  - "to generate the required sound science"
- To start w/ providing credibility is fundamental for success: Generate trust or gain trust?

# Review of business viewpoints

## Carbon Nanotubes in coatings

### Q1: named "nano", labelling

- Definition and labelling not elaborated
  - self-evident: diameters in nm dimension
- Case study considered only flexible, non asbestos-fibre-like CNT-types in coatings (different production method)
  - Properties of different types of CNT barely addressed;
  - distinction between "good" and "bad" CNT assumed

### Q2: market availability

- MWCNTs as fillers (market):
  - composites w/ plastics → weight reduction / better mechanical properties
  - high mech. strength, very good electrical and thermal conductivity
- MWCNTs in coatings (R&D):
  - anti fouling resin (marine)
  - as flame retardant in polyethylene
- Similar benefits of NP in paints and CNT in coatings: overlap?

### Q3: regulation & market

- B2B only
  - How to ensure safe handling of intermediate manufacturers: Info on safety data sheet and its contents was missing
- Registration under REACH and TCSA (pending)

# Review of business viewpoints

## Carbon Nanotubes in coatings

### Q4: safety testing

- Dermal, ingestion, inhalation: no acute toxicity determined, because NP agglomerated
- Methods and devices to sample, detect, measure exposure are not trivial:
  - Problems: standards, specific detection, size distribution, volume (mass) vs. number, background
  - < 1.5  $\mu\text{g}/\text{m}^3$  measured vs. no effect level 2.5  $\mu\text{g}/\text{m}^3$
- MWCNT not soluble in water: hurdle for ecotox. studies
- LCA and risk/benefit analysis

### Q5: benefits & risks

- Benefits of flexible types of CNT considered in this application (see also Q2)
- Distinction from MWCNT-fibres and asbestos not made here. Fibre paradigm addressed elsewhere
- Risk management measures:
  - minimize exposure,
  - closed processes
  - ventilation
  - protective equipment
  - measuring air concentration

### Q6: stakeholder dialogue

- “Willingness to be transparent” (how?),
  - but main addressees are regulators and OECD
- Controversy / literature on CNT addressed only partly:
  - Donaldson: CNT could cause a particle and/or a fibre hazard
- “China” case report (Song et al.) would have provided an opportunity to demonstrate what means good practice as an alternative concretely.

# Review of business viewpoints Nanosilver in textiles

## Q1: named "nano", labelling

- Metallic nano-Ag ~ 15 nm
- Hypothesis: dissolves to Ag<sup>+</sup>
  - needs clarification
- no further characterisation

## Q2: market availability

- Highest diversity of Ag-containing products (WW db)
  - several products & applications mentioned
  - Antimicrobial surfaces: Ag-NP fixed in a Si-O-Si matrix
- Med / food / textile: Antimicrobial agent and reduction of biofilm
- Textile: impregnation, washing machine

## Q3: regulation & market

- Applicable directives and norms cited.
  - Europ. Med. Device Directive and norms
  - German legal framework
- REACH not addressed
  - a lot of information available for bulk Ag is not available for nanoform
    - ecotoxicity
    - transplacental passage
    - kinetics of dissolution
- Comparative studies lacking

# Review of business viewpoints Nanosilver in textiles

## Q4: safety testing

- Not fully clear responses, problems to detect / distinguish
- Dermatological tests
  - according to established test procedures based on approved standards...
- Specific material tests like migration test, abrasion and scratch resistance
  - comparability?
- Effects on non-target micro-organisms not addressed

## Q5: benefits & risks

- Benefits: Biocidic effects
  - against eg “germs in cars” & microorg. monocultures
  - Low risk to generate multiresistant germs
  - safe for humans (>100 yrs experience w/ bulk)
  - “nano”: smaller amounts required compared to bulk
- Risks: not made very explicit
  - Cytotoxicity: “Paracelsus” paradigm; find the dose
  - Ag generally seen as beneficial (in medicine)

## Q6: stakeholder dialogue

- “Permanent fight against smattering and technophobia”
  - ambivalent attitude to dialogue, frustration?
- School programs: provide practical experience w/ NM (educational path)
- For a more comprehensive review of this case study see presentation of Wim de Jong, RIVM

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