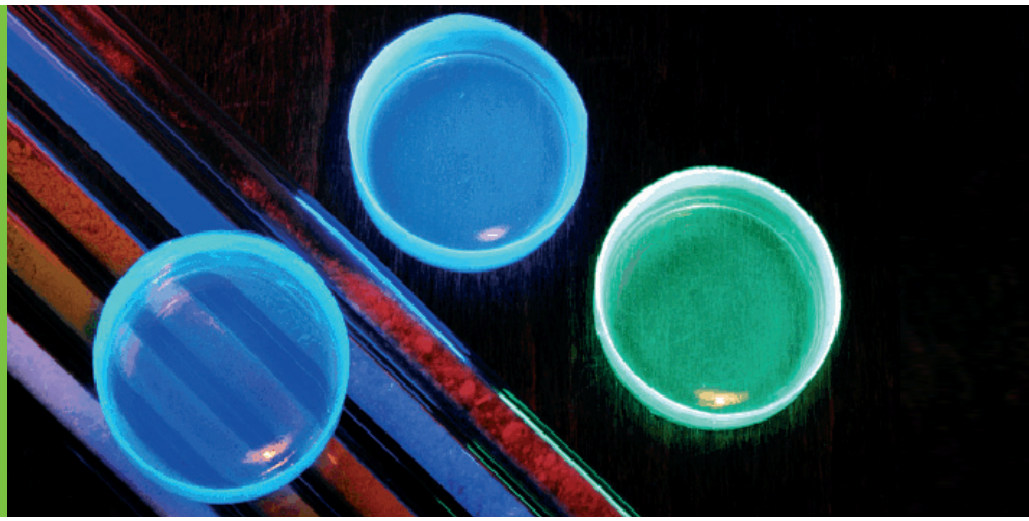
the innovation society

Safety, Risk and Regulation of Engineered Nanoparticles – Results, Trends and Perspectives



2nd International „Nano-Regulation“ Conference
13. – 14. September 2006,
St.Gallen (Switzerland)

Conference report

Christoph Meili and Florian Husmann

The Innovation Society, Ltd,
St.Gallen, Switzerland
www.innovationsociety.ch

October 2006

Patronage:

Schweizerische Eidgenossenschaft
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Swiss Federal Office for the Environment (FOEN / BAFU)
Swiss Federal Office of Public Health (FOPH / BAG)
State Secretariat for Economic Affairs (seco)

Impressum

Profile

The Innovation Society, Ltd (St.Gallen) is a Swiss-based Nanotech consulting and research firm. The company is a leading player in safety, risk and regulation issues of nanotechnology and focusing on business applications and economic impact of emerging technologies. Our customers are international industrial firms and business companies, governmental bodies and regulators and research organisations. Our interdisciplinary experts provide consulting, research and coaching services in:

- Safety- /*Risk-Management, Legal Services for Industry/Regulators*
- *Innovationmanagement Services (Product– / Processdevelopment)*
- *Communication and Stakeholder Management Services*

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Full documentation containing: Pdf-documents of all slide-presentations (Printversion), Abstracts, copy of this report (Printversion), participants and speakers list) . available on: http://www.innovationsgesellschaft.ch/shop.htm (Price: 100 Euro)

Acknowledgements:
We would like to thank our partners for the support for this conference. A special thanks goes to our three patronage organisations: the Swiss Federal Office for the Environment, the Swiss Federal Office of Public Health and the State Secretariat for Economic Affairs which have supported the conference for the second time. We would also like to thank the Swiss Society of Chemical Industries (SGCI), DSM, TA-Swiss, Burson-Marsteller and NanoEurope for their support which has made this conference possible.

Schweizerische Eidgenossenschaft
Confédération suisse
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Federal Office for the Environment (FOEN)
Federal Office of Public Health (FOPH)
State Secretariat for Economic Affairs (seco)

SGCI Chemie Pharma Schweiz
Unlimited. DSM
Burson-Marsteller
TA SWISS
nano europe fair & conference

Cover: Three layered nanoparticles in powder for in glass cuvettes and embedded in a polymer matrix fluorescing in UV-light (by courtsey of Dr. Regine Hedderich, Forschungszentrum Karlsruhe, Institut für Nanotechnologie)

Preface

This report describes the contents and results of the 2nd International "Nano-Regulation" conference which took place from 13. – 14. September in St.Gallen. The conference was organised by the Innovation Society in cooperation with NanoEurope exhibition and fair. It was focusing on scientific and societal aspects of safety, risk and regulation aspects of engineered nanomaterials.

The conference highlighted the following topics:

- Health, safety and environment protection (occupational health, product safety, environment)
- Best practises in handling and use of engineered nanomaterials (laboratory, industry)
- Trends and developments in international legislation and regulation of nanomaterials
- Communication, information, risk governance: Public knowledge / perception, stakeholder management

The annual "Nano-Regulation" conference in St.Gallen is a public part of the multi-stakeholder-platform "Nano-Regulation", which was launched in 2005 by the Innovation Society. The "Nano-Regulation"-platform serves as an international dialogue and knowledge interface providing relevant information on safety, risk and regulation issues of nanotechnology to its members and facilitating cooperation and coordination among stakeholders. The platform is supported by industrial and business companies, governmental bodies and research organisation.

Further information on: www.nanoregulation.ch

Content

The biggest risks for Nanotechnology

Dr. Christoph Meili, The Innovation Society

Dr. Christoph Meili, CEO, The Innovation Society Ltd, St.Gallen

Consumer Products

Scratch resistant car lacquers, antimicrobial mobile phones, nanocosmetics or odour inhibiting textiles. The Woodrow Wilson database currently lists 276 consumer products containing nanomaterials. The Nanomaterial Database™, another web-based nanolist contains 1,351 nanoparticles from 93 suppliers.for industrial use. The two databases may not list all engineered nanomaterials by far. The effective number of products and materials containing or consisting of engineered nanomaterials is presently unknown. But there will be a fast increasing number of new consumer and industrial products available on the markets in the near future. On the other hand there is a growing concern that some of these products could have negative impact on human health or the environment. “Magic-Nano” was a shock to the global nanocommunity and a wake-up call for media, politicians, NGOs and in some part also for the public. In Spring 2006 there were over 100 intoxications reported in Germany after the use of a bath-sealing chemical. Regarded intently “Magic-Nano” was just an “ordinary case” of chemical intoxication with a consumer chemical product because it contained no nanoparticles at all. Nevertheless it tainted nanotechnology`s image heavily. Literally spoken: “Magic-Nano” was the first “unguided Nano-missile” and therefore caused remarkable collateral damage, mainly in the field of nanotechnology`s reputation and also in public trust. (see presentation of A. Huttenlocher).

Health, Safety and Environment issues

In several countries governmental agencies and regulatory bodies have started programs and have initiated activities to investigate Health, Safety and Environment (HSE) topics. In Switzerland for instance, the Swiss Federal Office for the Environment and the Swiss Federal Office of Public Health have initiated an “Nanotechnology Actionplan 2006-2009” earlier this year (see key-note of Thomas Zeltner). It will analyse the existing regulatory framework in terms of its applicability to engineered nanomaterials and suggest measures to protect human health and the environment. On supranational level the European Commission and the OECD have both installed working groups and have intensified their activities in the field of coping with potential risk in the health,

„Magic Nano“ the first „unguided Nano-Missile“

legal and social area (s. presentations of R. Visser and N. Deliyanakis).

“Top Ten List” of safety and risk issues of Nanotechnology

The previous nano debate has already highlighted the following points as crucial in the safety and risk debate. Some of the presentations will go more into detail.

1. **Terminology and wording:** A clear and consistent definition and terminology for nanotechnology is still missing. In order to clarify the scientific and public debate and to avoid a Babylonian confusion a consistent terminology is needed.
2. **Nano-Labelling:** As the number of nano-consumer products increases the Nano-Labelling (voluntary or enforced!) will become one of the most important issues for industry and retail companies selling nanoproducts. As long as nanoparticles are in the realm of potential hazards and risks and as long as “nano” is not specified in terms of substances consumer organisations will continue to call for clear and non-ambiguous declaration and labelling regulations.
3. **Proactive risk management:** Appropriate measures (research policy, cooperation, etc.) have to be initiated systematically as soon as reasonable evidence for potential hazards is given. This ensures that the adaption of existing regulation is strongly evidence based and confirmed by research data.
4. **Review of existing legislations**: A review of existing legislations has to be done case by case in order to identify specific regulatory gaps, prioritise fields of action and suggest appropriate measures if needed. In order to save time and omit duplication of work, regulatory bodies should exchange examples of “good regulatory practice” e.g. in gap-analysis. A good example is the UK-gap-analysis study for the environment which has been published this summer (see presentation Q. Chaudhry). Industry has to support this processes providing product and materials safety informations.
5. **Nanospecific key figures for a “Nano-suitable” regulation:** We guess that more than 90% of the existing chemical regulation and legislation which is currently applied to bulk chemicals will also be applicable to engineered nanomaterials. Due to the specific properties of nanoscaled

Going for Nano: Public acceptance is key!

materials new nano– and substancespecific key figures and threshold limits have to be defined. Instead of mass limits in bulk materials the surface of a nanomaterial could be taken into account e.g. as toxicological threshold values. Specific conversion factors (mass—>surface) have to tested and could eventually be applied to threshold limits in order to develop easy-to-handle guidelines.

6. **Accompanying measures:** In order to guarantee high safety levels in manufacturing processes and laboratories the following measures could be applied: development of guidelines for a safe and sustainable use of nanomaterials; evaluation of technical measures for the protection of health and environment; voluntary labelling of potentially hazardous materials; nanotechnology inventories (potential hazards, expositions). Several countries (UK, Switzerland) are currently developing inventories for nanomaterials (see presentation of M. Riediker).
7. **Self-control mechanisms:** Delegating responsibility to the organisations which are producing or using chemical substances and materials supports the awareness of potential hazardous character of nanosized materials and adequate measures.
8. **Cooperation:** Governmental bodies, industry organisations and scientist need to establish close collaboration. The role of mutual cooperation between different players seems crucial be it on the scientific, governmental or economic level.
9. **Coordination:** Currently there are many national and supranational nanorelated projects going on. It is of great importance to coordinate activities on a global level and establish organisational structures and tools to provide and enhance information and knowledge transfer.
10. **Communication and public dialogue:** Information on technology disseminated by industry alone is seen as marketing driven and is often perceived as manipulative. Therefore interactive, bidirectional communication instead of one side information is necessary. Suitable communication

strategies involving neutral communication platforms have to be established in order to ensure optimal preconditions to meet the needs of the involved stakeholders and the public.

The biggest risk for Nanotechnology

The most important and - at the same time - the most critical success factor for sustainable development and also for commercial success of nanotechnology is public acceptance. People will have to decide one day whether the safety of nanotechnology and nanomaterials is safe enough. Public knowledge and public perception of nanotechnology will influence this judgement much stronger than sophisticated scientific risk data. The public perception whether the benefits overbalance the potential risks and whether the benefits and risks are allocated fairly will influence this judgement as well. Scientific data have to be taken into account when the regulatory framework has to be defined. On the other hand regulation is influenced influenced by societal and cultural circumstances more decisively. If nanotechnology will be perceived as a hazardous technology one day and if nanotechnology provides less benefits than risks in the public perception the regulatory framework will automatically turn to more restrictive legislation.

Unguided “Nano-Missiles” as “MAGIC-NANO” therefore influence the future regulation directly by forcing regulators to impose stricter control mechanisms and indirectly by building up negative public reputation of nanotechnology. In this context: The biggest risk for nanotechnology is not overregulation but no regulation.

A Sustainable Development for Nanotechnology and Nanomaterials: An International Perspective

Dr. Rob Visser, OECD

Dr. Rob Visser, Deputy Director for Environment, OECD

The rapid progress made with nanotechnology and the rapidly increasing use of manufactured nanomaterials, as we call these products in the OECD context, are indeed very important developments in the science of chemistry. These developments present a number of opportunities and a number of challenges. Any new technology has in principle a lot of promises for improving the quality of life, for introducing efficiencies in production processes of all kinds of products and for enhancing economic growth. One of the challenges is that safety aspects would have to be dealt with in a satisfactory way in order to ensure that this new technology is accepted by the public. This means that it should be unambiguously assessed if the technology can be applied on a large scale in a way which, also in the long term, does not harm the environment and the health of workers and the general population. OECD is a very good forum to assist in setting up an international discussion and in co-ordinating follow-up of necessary international actions. OECD represents the 30 most industrialised countries in Europe, North America and the Asia-Pacific region. In the area of chemical safety, a quite advanced system is in place to help countries with implementing national, regional and international regulations. The OECD work aims to deliver good quality tools for the protection of human health and the environment, while at the same time ensuring that such protection can be delivered in the most efficient way possible. This is achieved through harmonisation activities and assisting countries in finding ways to share work.

The work of OECD therefore helps to improve efficiencies, to avoid non tariff barriers to trade, to avoid delays in marketing and to promote the creation of a level playing field. The OECD work represents a win/win/win situation for governments, industry and civil society. It is an efficient and effective way to ensure the best scientific input from across OECD to contribute to the development of common instruments. Governments are sure to get good quality, harmonised test data and a better understanding of each other's testing and assessment methods so that they can easily share work.

Industry makes savings by avoiding duplicative testing and it benefits from the minimisation of non tariff trade barriers. Civil society has a clear interest in good quality safety data and in a transparent process for development of methods and guidance. OECD is not planning to work on putting in place an international risk management system for nanomaterials. In all OECD countries chemicals management systems exist and countries are best placed to determine how these systems can deal with nanomaterials in a way which is most adapted to national needs and how they can be amended most appropriately if needed. Looking for a "one size fits all" international solution to the management issue might be very time consuming, and it might not be the most efficient and effective way forward. If the management systems are based on common testing and assessment methodologies, the various management decisions in countries will most probably not differ too much. The OECD member countries, in co-operation with all stake holders and certain non-members are now developing a program of work for 2006-2008, which aims to promote international co-operation in the health and environmental safety related aspects of manufactured nanomaterials. The main topic areas to be included in the program of work are:

- Definitions, nomenclature and characterisation (physicochemical properties, uses) where not otherwise available.
- Environmental fate and effects (hazard identification, hazard, exposure and risk assessment methods).
- Human exposure and health effects (hazard identification, hazard, exposure and risk assessment methods).
- Exchange of information on regulatory and risk management frameworks (limited mainly to the chemicals sector) as well as environmental benefits.

In addition, work will be undertaken to promote an understanding of the health, environmental and exposure implications of manufactured nanomaterials by:

- Tracking relevant scientific research efforts.
- Identifying relevant research needs.
- Developing and promoting a strategy to meet identified needs.

Manufactured Nanomaterials and Chemical Safety (1)

Challenges with respect to safety:

- How do nanomaterials fit into existing regulatory frameworks?
- Are they “new” or “existing” chemicals?
- Which safety parameters need to be tested?
- How do we test them?
- How do we assess them?

Manufactured Nanomaterials and Chemical Safety (2)

Addressing safety aspects at an early stage in OECD will promote:

- Public acceptance
- Worksharing in the development of new methods
- Convergence of methods among countries, thereby providing a basis for future work sharing
- Avoidance of future duplicative testing
- Minimisation of non-tariff trade barriers

Manufactured Nanomaterials and Chemical Safety (3)

Focussing on industrial chemicals, OECD:

- Brings specialised expertise together
- Is setting up a Working Party on Manufactured Nanomaterials to undertake priority work
- Will hold a first WP meeting in September/October 2006, London

Priorities for the Working Party on Manufactured Nanomaterials (1)

To establish a programme of work based on the needs expressed in the Chemicals Committee. The programme of work will identify proposed outputs in the following areas:

- Definitions, nomenclature and characterisation
- Environmental effects (hazard identification; hazard and exposure assessment methods);
- Human health effects (hazard identification; hazard and exposure assessment methods);
- Regulatory frameworks (information exchange)

Priorities for the Working Party on Manufactured Nanomaterials (2)

- Development of a database on research related to human health and environmental safety - in cooperation with the Woodrow Wilson Center
- Co-operation with industry on safety testing of a representative sample of nanomaterials

Priorities for the Working Party on Manufactured Nanomaterials (3)

- Promote research on Environment, Health and Safety aspects to be taken into account in R & D programmes
- Investigate possibilities for co-operation on voluntary programmes concerning risk assessments

The European Action Plan and its Research Focus

Dr. Nicholas Deliyanakis, European Commission

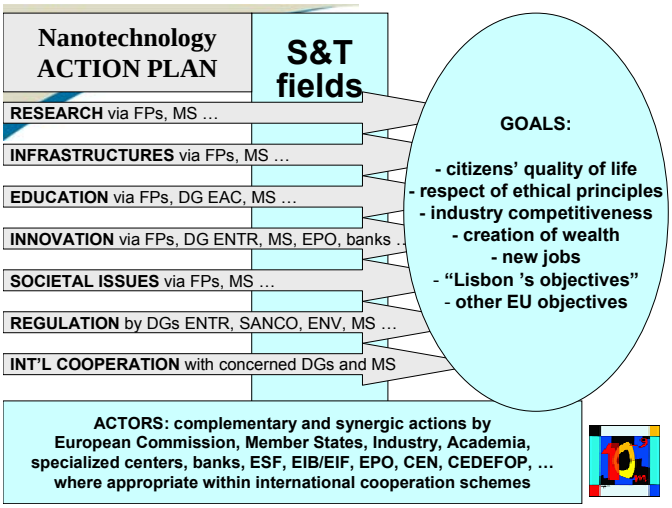
Dr. Nicholas Deliyanakis, European Commission

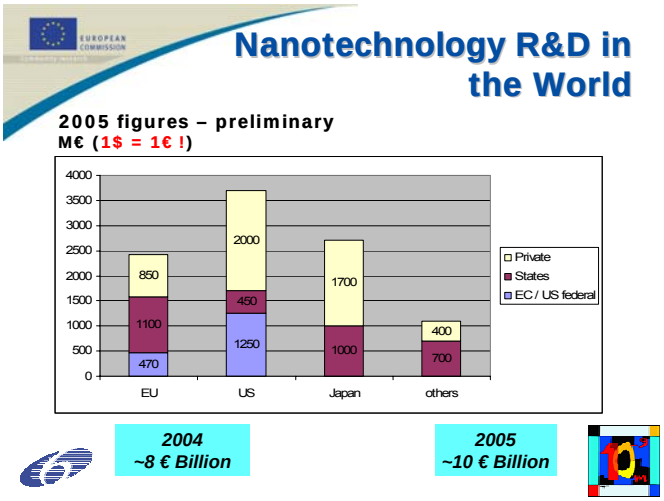
The European Union has long supported nanosciences. Action to promote this key technology were already taken in the mid- to late 1990s. As a result Europe is in a leading position in nanotechnology. Now the European industry and society in general should enter the commercialisation phase, to reap the benefits of this knowledge through innovative products and processes. To meet the challenges and to ensure Europe's competitiveness in this sector we need to join forces across disciplines, sectors and national borders. We need to increase investment, boost interdisciplinarity, create the necessary infrastructures, expand human resources and develop international co-operation to support research and foster innovation. At the same time, we need to address societal concerns brought about by the development of new applications. We also need to consider potential regulatory issues. These priorities are central to the European integrated, safe and responsible approach to nanotechnology, as proposed by the European Commission in two Communications, the European Strategy and the Action Plan 2005-09.

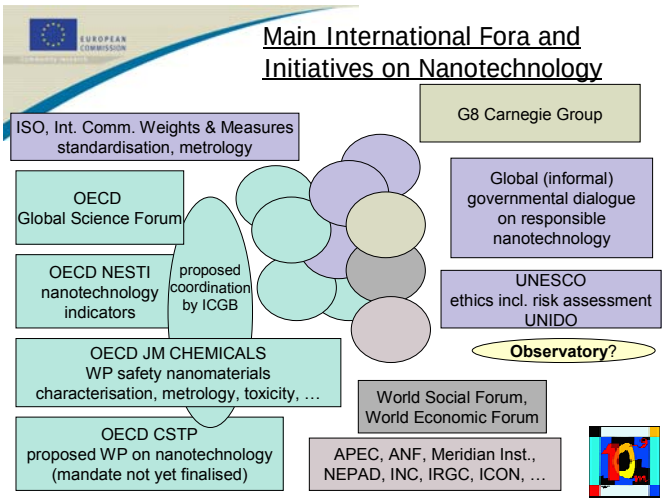
In general, Europe enjoys a strong position in terms of producing knowledge in nanotechnology (e.g. publications), but is weaker in transferring this knowledge into industrial products and services (e.g. patents and start-ups). On the other hand, the EU start-ups might prove to be more solid than in other regions. With regard to funding, the European Commission has steadily increased the level of its funding for research in nanosciences and nanotechnologies and has now become the largest single funding agency in the world; further, significant increases are expected over the duration of the 7th Framework Programme (2007-2013). On the other hand, the level of private R&D funding is lower in Europe in comparison to

some other areas e.g. the USA and Japan.

With regard to regulation, a high level of public health, safety, environmental and consumer protection is aimed at. This requires the identification of safety concerns, the collection of appropriate data for an adequate health and environmental impact assessment of the products data, and action at the earliest possible stage through adjustments, where necessary, of risk assessment procedures for issues of nanotechnology. To address these needs, some 25M€ has already been invested in relevant research projects; and an informal collection of inputs for further projects under FP7 has recently been completed. In the meantime, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has adopted an opinion on "The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies". Briefly, this has recommended addressing various uncertainties with regard to potential hazards and exposure; addressing gaps in knowledge; and further developing guidelines and methods. At the same time, current analysis shows that the current regulatory framework is, in principle, capable of handling nanomaterials. Another opinion is being drafted, on the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials. Apart from research-centred activities the European Commission is currently looking into the legislative issues of the increasing use of nanotechnologies, i.e. it is currently exploring the already existing European legislation applicable to nanotechnology and assessing its adequacy and appropriateness.







8. Implementing a coherent and visible strategy

a) Creation of a Commission **Interservice Group** to monitor and oversee the implementation of the Action Plan, see cordis.europa.eu/nanotechnology/src/contacts.htm

- *It is important to have a regular interaction with Member States*

b) **Reporting**: We plan to issue a report at the end of 2007 and one at the end of 2009

c) Activities to foster beneficial applications: addressed in proposals for FP7 calls for proposals

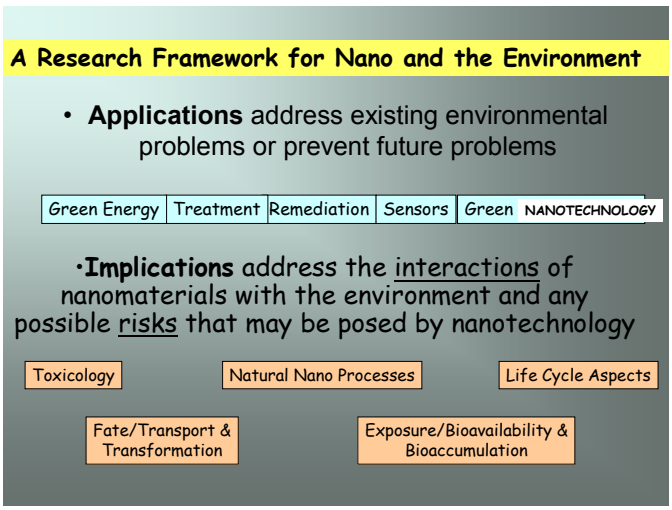
The Green Nano Initiative
A Way to Sustainable Devolpment of Nanotechnology?

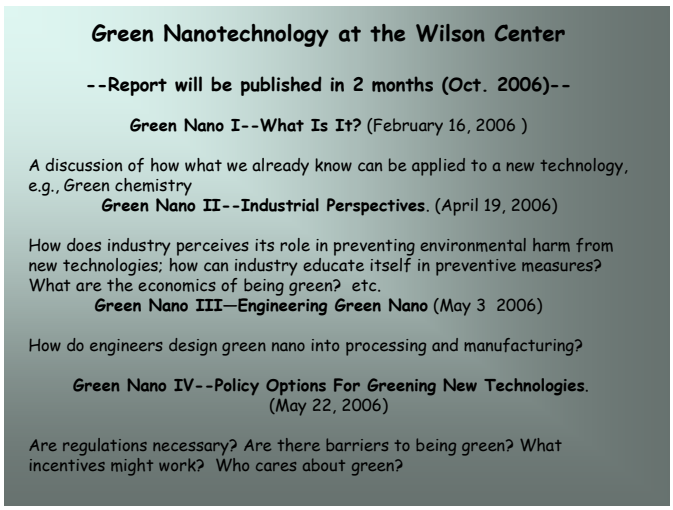
Dr. Barbara Karn, Woodwrow Wilson International Center for Scholars

Dr. Barbare Karn, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars

New technologies have the opportunity at their beginning to develop sustainably. Since the Brundtland Commission defined it in 1989, governments and industries have tried to incorporate sustainable development into their practices and policies. The opportunity for designing sustainability into products and processes exists in their earliest stages. As an emerging technology, nanotechnology offers the opportunity to design products and processes sustainably. However, this opportunity will not last long. Learning from the past and using the principles of green chemistry and green engineering, nanotechnology can develop in a sustainable and environmentally benign manner.

In her presentation Barbara Karn focused on how the parts of sustainability fit into nanotechnology. She emphasized the goals and framework for research in Green Nanotechnology and gave examples of some work and programs that define and enable Green Nano.





Green Nanotechnology has two goals:

Producing nanomaterials and products without harming the environment or human health

Producing nanoproducts that provide solutions to environmental challenges.

www.nanotechproject.org

A Framework for Green Nanotechnology

1. Production of nanomaterials and products does not harm the environment

Making NanoX "greenly"

e.g., Green chemistry, Green engineering, DfE, Smart business practices

Using NanoX to "green" production

e.g., Nanomembranes, nanoscaled catalysts

Pollution Prevention Emphasis

2. Products of nano help the environment

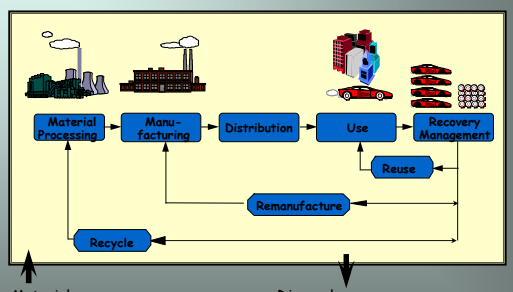
Direct Environmental Applications e.g., environmental remediation, sensors

Indirect Environmental Applications e.g., saved energy, reduced waste,

Addressing a full systems approach to nanomaterials and nanoproducts

NEXT STEPS: Policies that offer incentives for developing green nanoproducts and manufacturing techniques

A Full System View is Necessary



Raw Materials
(Energy, Renewable Resources, Nonrenewable Resources)

Disposal
(Air Emissions, Liquid and Solid Wastes)

J. Golden

Parting Thoughts

Nanotechnology can help achieve sustainability in many ways

However…

No technology will lead to sustainabilty

Technologies merely buy us time by slowing down the rate of non-sustainable practices

Only a change in Human values and behavior can lead to true sustainability

Humantoxicology of Nanoparticles

Dr. Lang Tran, Institute for Occupational Medicine, Edinburgh

Dr. Lang Tran, Institute of Occupational Medicine, Edinburgh

Within the last 10 years there has been an increasing realisation that the adverse health effects of environmental particles (PM_{10}/ $PM_{2.5}$) are very likely driven by the combustion-derived nanoparticle (NP, particles <100nm diameter) component e.g. diesel soot. For combustion-derived nanoparticles, three properties appear important – surface area, organics and metals. All of these can generate free radicals and so induce oxidative stress and inflammation. Inflammation is a process involved in the diseases exhibited by the individuals susceptible to the effects of PM – development and exacerbations of airways disease and cardiovascular disease. It is therefore possible to implicate combustion–derived NP in the common adverse effects of increased PM. The adverse effects of increases in PM on the cardiovascular system are well-documented in the epidemiological literature and, as argued above, these effects are likely to be driven by the combustion-derived NP. The epidemiological findings can be explained in a number of hypotheses regarding the action of NP:

1) Inflammation in the lungs caused by NP causes atheromatous plaque development and destabilisation

2) The inflammation in the lungs causes alteration in the clotting status or fibrinolytic balance favouring thrombogenesis

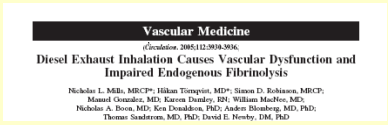
3) The inflammation causes stimulation of the autonomic nervous system culminating in alterations in the heart rhythm, leading to fatal dysrhythmia.

4) The NP themselves or metals/organics released by the particles enter the circulation and have direct effects on the endothelium, plaques, the clotting system or the autonomic nervous system/heart rhythm.

Environmental NP are accidentally produced but they provide a toxicological model for a new class of purposely ‘engineered’ NP arising from the nanotechnology industry, whose effects are much less understood. Bridging our toxicological knowledge between the environmental NP and the new engineered NP is a considerable challenge.

Results of the diesel inhalation study

1. Normal endothelial is dysfunctional after diesel exposure
2. The ability of the endothelium to dissolve clots is decreased by a third after diesel exposure
3. These effects are probably caused by oxidative stress removing Nitric oxide, which is necessary for normal endothelial function
4. Therefore after diesel exposure one is more likely to have heart atatck and if a clot does form it is less easily dissolved


Vascular Medicine

(Circulation. 2005;112:3930-3936.)

Diesel Exhaust Inhalation Causes Vascular Dysfunction and Impaired Endogenous Fibrinolysis

Nicholas L. Mills, MRCP*; Håkan Törnqvist, MD*; Simon D. Robinson, MRCP; Manuel Gonzalez, MD; Kareen Darnley, RN; William MacNee, MD; Nicholas A. Boon, MD; Ken Donaldson, PhD; Anders Blomberg, MD, PhD; Thomas Sandstrom, MD, PhD; David E. Newby, DM, PhD

Hot off the press!!

In a recent study where the particles were filtered out and the subjects received the gases only, there was no effect on the cv endpoints

(i.e. it's the particles that cause the effect)

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Nanotubes and asbestos

•To behave like pathogenic fibres nanotubes would, according to the current paradigm, need to be long, thin and biopersistent

•Are they thin? – yes SWNT ~5nm; MWNT ~200nm

•are they biopersistent? – yes- they are graphitic

•Are they long ?– they would need to be longer than about 20μm – none this length looked at toxicologically so far

•If they were long AND THERE WAS SUFFICIENT EXPOSURE they could cause lung cancer, mesothelioma, fibrosis

•They will be difficult (impossible) to regulate by PCOM in the way fibres are currently regulated

Even when not long enough to act like long fibres they will act like nanoparticles- they seem to have unusual ability to stimulate fibrosis


Carbon Nanotubes: A Review of Their Properties in Relation to Pulmonary Toxicology and Workplace Safety

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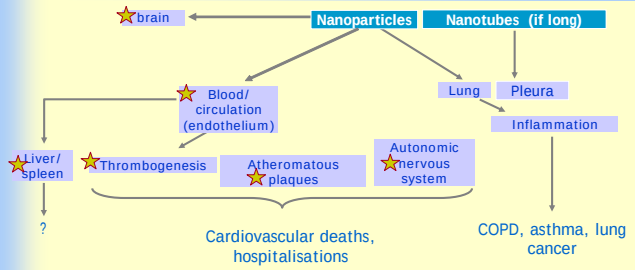
Summarising the potential human health effects of Nanoparticles



NP may be able to affect a number of new targets not previously considered for particle effects

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Conclusions

- Research in Nanotoxicology is continuing
- Importance of Nanoparticle distribution in the body – Bio-kinetics.
- Importance of multi sources of exposure: Inhalation, Ingestion, Injection, Dermal.
- Need for international collaborative, multi-disciplinary research programme.

Ecotoxicological Impact of Engineered Nanoparticles

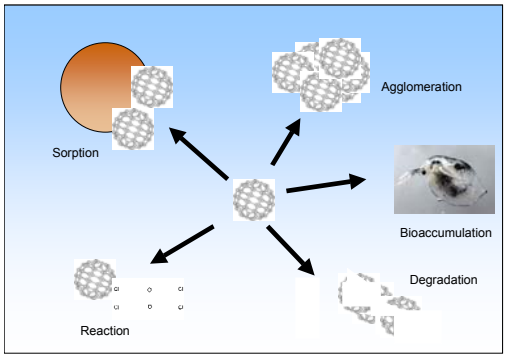
Dr. Alistair Boxall, Central Science Laboratory, University of York

Dr. Alistair Boxall, Central Science Laboratory, University of York

It is inevitable that during their manufacture and use, nanoparticles will be released to the environment. The proliferation of nanotechnology has therefore prompted concerns over their risks to organisms in the environment and on the potential indirect exposure of humans to nanoparticles residues in water and soil systems. Available data indicates that nanoparticles are likely to exhibit very different properties and effects in the environment than the chemical compounds or elements from which they are constructed. Because of this, it is likely that current approaches for assessing and monitoring the impacts of synthetic chemicals on environmental systems are likely to be inappropriate for the assessment of nanoparticles.

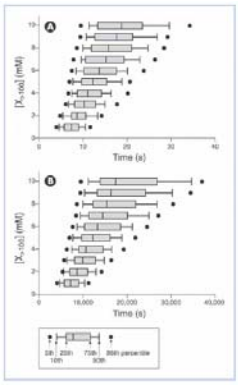
In his presentation Dr. Boxall provided an overview of recent research into the uptake and ecotoxicity of nanoparticles to a range of species (algae, fish and daphnids). He described methods for detecting nanoparticles in environmental matrices and discussed the application of these methods to understanding the fate (sorption, persistence and agglomeration) of nanoparticles. The presentation highlighted gaps in our current knowledge and listed priorities for

Fate of Nanoparticles



Aggregation in aquatic systems

- Aggregation likely to affect transport and effects
- Potential to aggregate can be determined theoretically (Mackay et al., 2006)
  - Buoyancy properties
  - Molecular collisions
  - Adhesion
- Experimental data almost non-existent and new approaches for detection are required

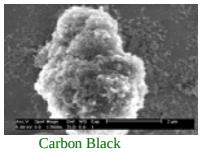


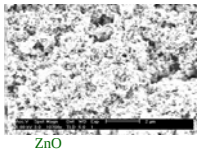
Overview over Current Risk Data

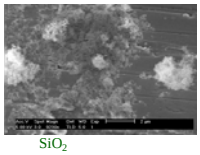
Our Approach to Analysis

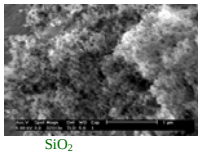
- Imaging of NPs:
  - Scanning electron microscopy SEM
  - Atomic force microscopy AFM
- Quantitative and qualitative analytical methods:
  - Inductive coupled plasma mass spectrometer ICP-MS
  - Size exclusion chromatography SEC
  - Energy dispersive x-ray spectrometry EDS

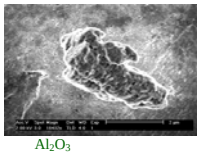
SEM

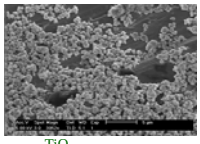

Carbon Black


ZnO


SiO_2


SiO_2


Al_2O_3


TiO_2

First results

- NPs already present in the lake waters
- Spiking experiments with single NPs and mixtures in lake waters
  - Single NP studies - Titanium dioxide (5 –10 nm), Zinc oxide (50 – 70 nm), fullerene C_{60} agglomerate in lake water – particle size around 2 μm
  - Mixture studies – agglomeration of titanium, fullerene C_{60} significantly reduced

Summary and future priorities

- Increasing concern over the potential environmental impacts of NPs
- NPs taken up by organisms and distributed around body
- Range of acute and chronic effects observed
- Experiments generally highly artificial and at high exposure concentrations
- Initial fate experiments and modelling suggests NPs will agglomerate in natural systems
- First results indicate behaviour could be complex – different sizes, mixture effects
- Priority should be to combine exposure and effects experiments to determine whether NPs really do pose a risk
- Results need to be fed in to develop guidance for risk assessment

Nanoparticles in Cosmetic Products

Prof. Jürgen Lademann, Charité Berlin

Prof. Jürgen Lademann, Center of Experimental and Applied Cutaneous Physiology, Charité Berlin

Nanoparticles are frequently used in cosmetic products. In particular sunscreens with a high sun protection factor represent a mixture of organic or inorganic UV-filter substances. Very often, TiO_2 nanoparticles are used.

Analysing the penetration of these nanoparticles into the skin, it was found that the nanoparticles were located only in the upper corneocyte layers of the corneocytes in the stratum corneum and were penetrated deep into the hair follicles. However, during the investigations, it was found that the nanoparticles did not penetrate into every hair follicle.

For the first time, the effect of "open" and "closed" hair follicles was observed. It was found that the follicles are open for penetration, if they show sebum production and/or hair growth. These observations support the hypothesis that hair follicles are closed by a covering, which has to be removed from inside by sebum production or hair growth, in order to give the topically applied substances the opportunity to penetrate into the hair follicles.

A penetration of the $Ti0_2$ nanoparticles into the viable dermis could not be detected.

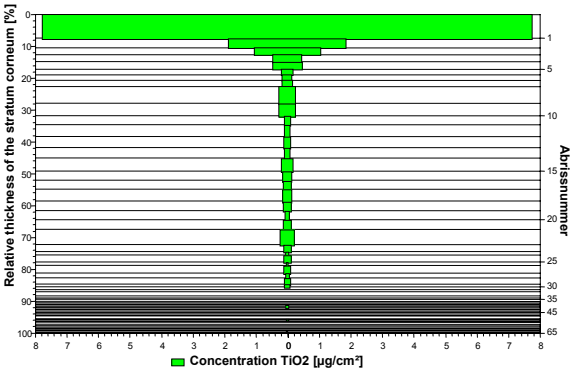
If substances penetrate into the hair follicles, the hair follicles represent a long-term reservoir for these substances. Analysing the penetration of particle and non-particle containing formulations, it was found that particles with a size between 300 and 700 nm penetrate much more efficiently into the hair follicles than smaller or larger particles. Using the method of differential stripping, it is possible to determine the amount of nanoparticles

that are stored in the hair follicles.

From the structural analysis of the hair surface and hair follicles, it is known that the cuticle produced by keratinocyte desquamation forms a structured surface, which can be approximated by a zigzag relief. This relief is determined by the thickness of the keratin cells, which is between 500 and 800 nm. If the hairs are set into motion by massage, the cuticle cells may act as a geared pump. Particles, comparable in size to the surface structure of the hairs and hair follicles, are probably pushed into the follicles by means of the pump movement of the hairs.

Up to now, there has been no evidence that nanoparticles at a size bigger than 100nm penetrate to the barrier into the living skin. To what extent nanoparticles at a diameter less than 100 nm can penetrate through the skin into the living tissue is still an object of intensive investigations.

Penetration profile of TiO_2 in the stratum corneum



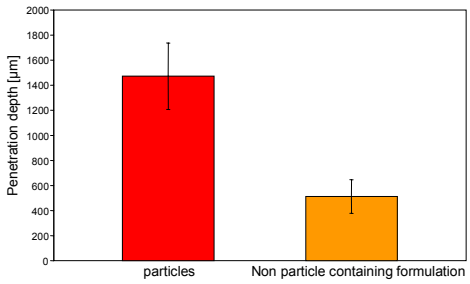
Transfollicular absorption

Unexpected results:

- The follicles are "open", when hair growth and/or sebum production are detected. The follicles are "closed", when **no** hair growth and **no** sebum production can be measured.

Determination of the penetration depth

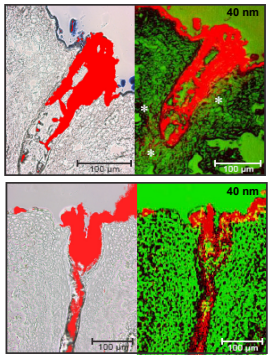
a) With massage

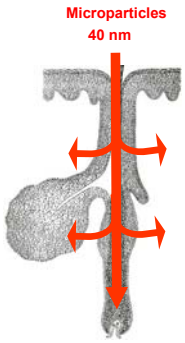


A. Vogt et al. JID will be published

- 40 nm, but not 750 or 1,500nm, nanoparticles enter epidermal CD1a + cells after transcutaneous application on human skin

Targeting of human hair follicles





Vogt et al. *J Invest Dermatol*, Epub 2006

CHARITÉ

Summary

In contrast to the stratum corneum hair follicles represent a efficient long-term reservoir for topically applied NP.

optimal size: 300 – 700 nm

Removal out of the hair follicles by sebum flow and hair growth.

No real evidence that NP > 100 nm penetration though the barrier into the living tissue.

The penetration of NP < 100 nm is still an object of investigation

Nanotechnology and Occupational Health in Switzerland

Dr. Martin Gschwind, Suva

Dr. Martin Gschwind, Dep. Occupational Safety, Suva

Adressing the unknown healthrisk of Nanoparticles at workplaces the Suva (Swiss National Accidents Insurance Fund) published a set of recommendations to protect workers at nanoparticles production sites.

Dr. Martin Gschwind presented an overview over Suva's set of recommendations. He underlined following important topics and guidelines in the use and handling of nanomaterials:

- Minimization of Exposure
- Technical Safety Measures as:
  - Substitution of healththreating substances
  - Technical measures to detect and limit exposure
  - Individual protection (e.g. protection suits)
- Material Safety Data Sheets (Information about possible health risks, safety recommendations, emergency procedures)
- Risk Assessments (Evaluation of safe handling by an interdisciplinary team: Occupational Medicine, Toxicology, Occupational Hygiene)

Even in the absence of fundamental data concerning the health effect of nanoparticles precautionary measures at workplaces handling nanoparticles are of an outmost importance. Therefore Suva has recently published a website on Nanotechnology and

Work with substances without known exposure limits

- **List with occupational exposure limits:**

➔no official occupational exposure limit **means not no hazard**

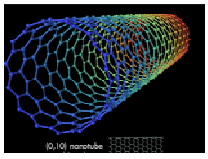
➔Work with such substances **differs not** from work with substances with published exposure limits

suvaPro

Evaluation of Conditions with Nanoparticles at work places

- **New Nanoparticles**
  - Epidemilogical experience is lacking or is still very faint
  - Some information from experimental studies
  - In general no known exposure limits are published for these substances which could be used for the evaluation of the workplace conditions

-**> what to do?**



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Which Safety Measures are necessary ?

- For work with substances with or without published occupational exposure limits

-> All Safety measures have to be taken which

- are **necessary** by experience
- correspond to the **state of the art** and
- are applicable **according to the circumstances**

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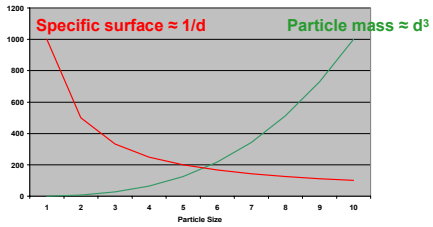
Additional Parameters for Risk Assessment of Nanomaterials

- **Surface Properties**
  - High Ratio of Total Surface to Particulate Mass
- **Particulate Count**
  - in Addition to the Concentration in mg/m^3



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Further Activities of Suva

- Support of some research projects
  - EMPA (Sampling und development of analytic tools)
  - IST (Nano Inventory)
- Improvement of analytical tools
  - International collaboration
  - Optimizing our own analytical Infrastructure
- Measurements at workplaces
- Observation of further development
- Information
  - Advisory support of companies
  - Update of the published information (e.g. Internet)

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Conclusions

- Substances without known exposure limits don't automaticly imply no hazards
- Products are produced now and the necessary safety measures have to be assessed now
- There are many tasks to be performed by those companies producing and applying nanomaterials together with specialists
- The authorities will give assistance. However companies cannot wait until authorities solve all their problems

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The Swiss Nano-Inventory: Challenges, Results and Outlook

Dr. Michael Riediker, IST Lausanne

Dr. Michael Riediker, Institute for Occupational Health Sciences (IST) Lausanne

Nanoparticles (particles smaller than 100 nm in at least two dimensions) are interesting for industrial and medical applications since they have properties, which are different from those of the same substance at larger size. Many new types of nanoparticles and applications are currently being developed and introduced into industrial processes and consumer products. Currently, the safety and health risks of these novel manufactured nanoparticles are insufficiently evaluated. There is an urgent need to evaluate the risks of these particles to ensure their safe production, handling, use, and disposal. The here presented study aims at providing more knowledge about industrial exposures in Switzerland.

The study consists of three steps: 1) A pilot-study about the data available to the safety experts in Swiss companies, 2) a representative questionnaire-survey about nanoparticle applications in Swiss industries and 3) workplace exposure measurements for typical applications to estimate the likely exposure range of the Swiss working population.

The pilot study consisted of a qualitative telephone survey among two hundred Swiss companies, which were believed to be likely users or producers of nanoparticles. This selection was based on published technology reports, self-declarations, member lists of industrial associations, and the yellow pages. Questions were asked about applications and particle types, the potential exposure of workers to nanoparticles, and the current safety policy and practice in the company.

Applications were identified in the fields of coating, cosmetics, food (animal feed, sport food and food packing), metal, optics, paintings, powder production, surface treatment, and research laboratories.

Several of these applications already used dozens of tons of nanoparticles per year, mostly nanoparticles of Ag, AlO3, Fe-Ox, SiO2, TiO2 and ZnO2. Most of the companies used safety measures that included both, technical as well as personal protection measures.

The pilot survey shows that nanoparticles are not fiction but already reality in Swiss companies. Nanoparticles are already used in up-scaled productions, even though many appear to be still in a research and development state. The companies contacted are probably not representative for the Swiss industry. However this pilot study allowed the identification of industrial sectors with established nanoparticle-use and gave valuable information about the knowledge of production and safety managers. It allows developing a questionnaire that will be used to obtain a representative and comprehensive picture of industrial processes, sectors and companies using or producing nanoparticles.

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Goal of the study “Nanoinventory”

To estimate

the extent of nanoparticle use in Swiss industries

the nanoparticle exposure of the Swiss working population

the release of nanoparticles into the environment in Switzerland

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The 3 steps

1) **Pilot-study**.
Evaluate data available to the safety experts in Swiss companies.

2) **Representative questionnaire-survey**. Identify and describe Swiss industries with nanoparticle applications.

3) **Workplace exposure assessment**.
Measure exposure for typical applications and combine with survey-data.

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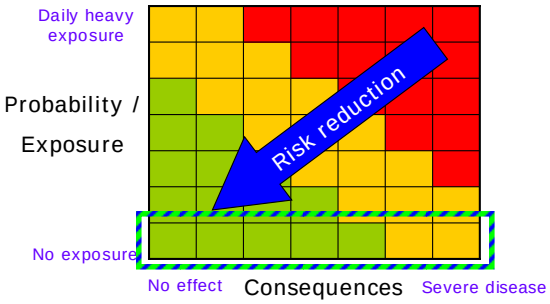
SHE-Approach for new substances



Treat unknown substances equal to very dangerous ones

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What can safety experts do?

→ For all substances: ***Use safety data sheets!***

→ If particles size and distribution not known: ***Ask questions!***

→ If particles < 100 nm: ***Be careful!*** *Particle toxicology might differ from known substance toxicology.*

→ If nanoparticles exist in your company: ***Keep records!***
- Substance (composition, size, trade name)
- Quantity and frequency
- Process type and protective measures
- Identify potentially exposed personnel

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Outlook for Nanoinventory

Representative survey is about to start:

- 2000 Swiss companies
- Type of particles (substance, size, matrix)
- Amounts used and stored
- Types of applications
- Type of safety measures
- Waste treatment / recycling
- Release into the environment

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Conclusions

Pilot study:

Nanotechnologies are **today a reality** in the Swiss industry.

Representative survey:

Will answer, how widespread nanoparticles are today.

- Interesting for investors and government!
- Allows to **set priorities** for research
  Safety: Test efficiency of protective measures
  Health: Prospective health surveys, acute effect studies
  Environment: Estimate release potential and dispersion

-> Less uncertainty about the risks (health, safety, financial)

--> Healthy workers with good, efficient low cost protection

Aerosol Measurements: State of the Art at Workplaces

Dr. Markus Berges, BGIA, Sankt Augustin

Dr. Markus Berges, Berufsgenossenschaftliches Institut für Arbeitsschutz - BGIA, Sankt Augustin

There appears to be a particular health risk from ultrafine dust particles and nanoparticles respectively in respiratory air. Ultrafine aerosol particles are for the most part byproducts in thermal and chemical reactions whereas nanoparticles are specifically engineered. BGIA (BG-institute for occupational safety and health), in conjunction with the German institutions for statutory accident insurance and prevention (Berufsgenossenschaften - BG), carries out a measurement programme at selected workplaces. The aim is to gather and catalogue information on ultrafine - and nanoparticles occurring at different work processes. Workplaces in metal processing like melting, casting, welding, soldering, cutting, laser beam processes, workplaces in glass production, vulcanization of rubber, processes in food industry like bakery or meat smokery, or workplaces on an airport field were scrutinized. The particle size distribution between approximately 10nm and 700nm and the number concentration of these particles were determined. BGIA was equipped with a suitable measurement device (scanning mobility particle sizer – SMPS) for these particular measurements, added with instruments like a cascade impactor or aerosol samplers for the inhalable and respirable dust fraction. The number concentrations in the measurement range varied between approximately 10 000 particles per cm^3 in clean areas up to 40 000 000 particles per cm^3 in welding plumes. Peaks in particle size varied between a few ten nanometers up to a few hundred nanometers, depending on the degree of aggregation and agglomeration.

Additionally tests on the penetration of ultrafine particles through breathing masks were performed. The institutions for statutory accident insurance and prevention hope to provide thus a basis for a discussion on this topic, and improve the possible methods of prevention.

Measurement of Dust

Number concentration

- Total number conc.:
  - CPC
- Size distribution:
  - Mobility particle sizers: SMPS, SMPS+C, WPS
  - electron microscopy
  - Thermal precipitator (qualitatively)
  - ELPI (indirect)

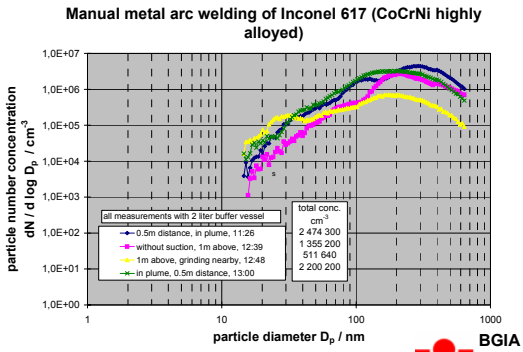
BGIA
BG-Institute for Occup. Safety & Health

Measurement campaign

- German statutory occupational accident insurances (Berufsgenossenschaften) started survey on workplaces
- Execution by BGIA and IGF **since 1998**
- Results of appr. 50 different industrial sites and 160 single workplaces
- Mostly occasionally produced ultrafine particles
- Since 2006 focus on nanoparticles

BGIA
BG-Institute for Occup. Safety & Health

Arc welding of highly alloyed steel



BGIA
BG-Institute for Occup. Safety & Health

Summary of results – No shift data!

Process	Total concentration in measurement range 14-673 nm particles/cm³	Maximum of number concentration nm
Outdoor, office	up to 10 000	
Silicon melt	100 000	280-520
Metal grinding	up to 130 000	17-170
Soldering	up to 400 000	36-64
Plasma cutting	up to 500 000	120-180
Bakery	up to 640 000	32-109
Airport field	up to 700 000	<45
Hard soldering	54 000 up to 3 500 000	33-126
Welding	100 000 up to 40 000 000	40-600

BGIA
BG-Institute for Occup. Safety & Health

BGIA - Nano Mission

- Measurement campaign on ultrafine & Nanoparticles
- Standardisation activities
- ISO TC 146 SC2 WG1: Compilation of a "Technical report"
- ISO TC 229 Nanotechnologies:
  - WG 1 Terminology and Nomenclature (Led by Canada, SCC)
  - WG 2 Measurement and Characterisation (Led by Japan, JISC)
  - WG 3 Health and Safety (Led by USA, ANSI)
- German mirror group DIN NA 062-8-17 for TC 229

BGIA
BG-Institute for Occup. Safety & Health

Conclusion

- A wide variety of measurement methods exist
- Convention by European Institutes for Occ. Safety to measure
  - **Particle number concentration**
    Up to now: stationary, but in the breathing zone
  - In addition mass concentration
  - mikroscopic analysis when appropiate
- Measurement and control strategy are a unit
  - NIOSH Draft: REL for TiO_2 (<100 nm) of 0.1 mg/m³
- Measurement campaign by BGIA on UFP **since 1998**
  - Results of appr. 50 different industrial sites and 160 single workplaces
- In the near future we will present measurements on Nanoparticles

BGIA
BG-Institute for Occup. Safety & Health

Nanotechnologies: A challenge for Public Health

Prof. Dr. Thomas Zeltner, BAG

Prof. Dr. Thomas Zeltner, Director Swiss Federal Office of Public Health (FOPH / BAG)

Scientific potential of Nanotechnologies

Nanotechnologies are widely seen as having huge potential to bring benefits to many areas of research and application. Nanoscience is a rapidly developing scien-ti-fic discipline that enables researchers to manipulate and characterize mat-ter at the level of single atoms and small groups of atoms. It integrates cellular and molecular components with engineered materials to produce nanoscale ob-jects that have wide-ranging potential for applications in science and enginee-ring, from molecular biology to the physical sciences. In the health sector, na-no-tech-no-logies allow new approaches in drug delivery, as well as providing non-invasive imaging and the development of new diagnostic tests or therapeutic methods.

Health risks of Nanotechnologies

Potential new health risks of nanotechnologies are a matter for ongoing dis-cus-sions. Concerns have been raised that the very proper-ties of deliberately engineered nanoparticles and nanotubes (such as high surface reactivity and the ability to cross cell membranes) being taken advantage of in certain applications might also have negative impacts on health and the environment. Results from studies on pollutant nanopartic-les known to be present in large numbers in urban air and mineral dusts in some workplaces, indicate that ex-posure to engineered nanoparticles could cause respi-rato-ry (e.g. inflam-ma-tions, fibroses or cancer) or cardiovascular disea-ses. There are still substantial uncertainties concerning the toxicity of engi-neered nanopartic-les (e.g. influ-ence of chemical composition, particle size, surface coa-ting, etc.). Even less is known about the amount of human exposure to engineered nano-par-tic-les espe-cially compared with pollutant nano-particles from other sour-ces (e.g. combustion processes). The evidence suggests that at least some engineered nanoparticles will be more toxic per unit of mass than larger particles of the same chemical. It also seems likely that nanoparticles will penetrate cells more readily

than larger particles. In order to perform reliable risk assess-ments on en-gineered nanopar-tic-les further scientific work has to be undertaken. It will take several years until the relevant know-ledge gaps are clo-sed. Authorities are faced with the challenge to handle these uncertainties when considering adequate measures to protect both man and the environment.

It must be pointed out that there are many nanotech-no-logical applications that pose no new risks to health. Almost all the concerns relate to the potential im-pact of deliberately engineered nanoparticles that are free rather than fixed or within a material.

Activities of the Swiss Office of Public Health

How much precaution is necessary? The Swiss Office of Public Health and the Swiss Office for the Environment set up a national expert board in order to analyze the current scientific knowledge and work out a 'Swiss action plan for the risk evaluation and risk manage -ment of engineered nanomaterials until 2009'. The final project report is expected in January 2007. Taking into account international initia-tives (e.g. of EU, OECD and CEN/ISO) the action plan should propose and initiate necessary national activities with respect to risk and safety of nano-materials (including nanoparticles, but also other nanostructured ma-te-rials such as nano-emulsions, liposomes or 2D structures):

- Promotion of risk and safety research projects (university, industry)
- Promotion of harmonized Definitions, Characterization Methods and vali-dated Test guidelines for the Risk evaluation and assessment (in Cooperation with OECD, ISO, EU und UNEP)
- Promotion of an Inventory on the use of nanoparticles in Switzerland
- Support and strengthen stakeholder awareness for self-control principles (Code of conduct)
- Support precautionary measures with respect to occupational health in R&D and Industry

- Adaptation of the existing legislation in Switzerland, if necessary
- Dialogue with Stakeholders (Science, Industry, Politics, NGO, Public, etc.)

Learning from the biotechnology debate, public attitudes can play a crucial role in realizing the potential of technological advances. Public concerns have to be taken into account in the risk management process and the action plan will put special focus on public dialogue and information.

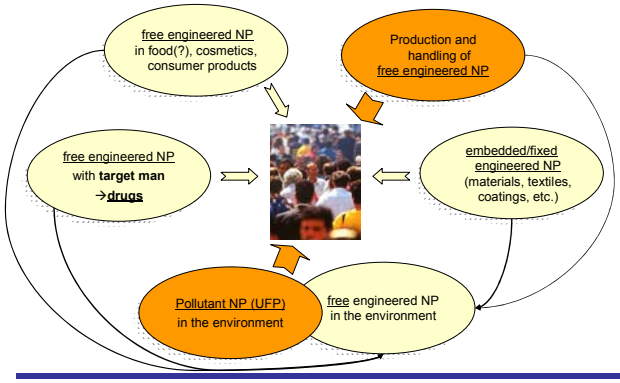
The Swiss Office of Public Health is taking a leading role in this process. Further-more, the Swiss Office of Public Health promotes initiatives and projects that aim at the integration of all interest groups and stakeholders. For example, in the following weeks, the Swiss Centre for Technology Assessment (TA-Swiss), supported by the Swiss Office of Public Health among others, is organizing five workshops involving small groups of the general public (PubliFocus) on the subject of nanotechnologies and their meaning for public health and the environment. The PubliFocus will help us to define the objectives of a public dialogue in Switzerland.

Possible Health Risks of Nanoparticles (NP)

	But:
▪ possible adverse health effects in the lungs due to NP reaching deep lung areas: : ▪ (chronic) inflammation ▪ fibrosis (e.g. silicosis, asbestosis due to mineral dust) ▪ cancer	▪ animal studies are available only for a few type of engineered nanoparticles (e.g. Carbon, TiO_2) ▪ adverse effects only with very high dosages in installation studies (overloading the lung defense, real exposure situation?)
▪ translocation of NP via lung, derma(?), gut in the blood circle ▪ effects on secondary target organs: ▪ correlation of combustion dust load and cardiovascular diseases (indirect?)	▪ amount of translocation? ▪ no adverse effects found on other secondary target organs
▪ translocation of NP via olfactory nerves to brain	▪ high dosage ▪ adverse effects?

Swiss Federal Office of Public Health — Nanoregulation 2006 14.09.06 — Page 4

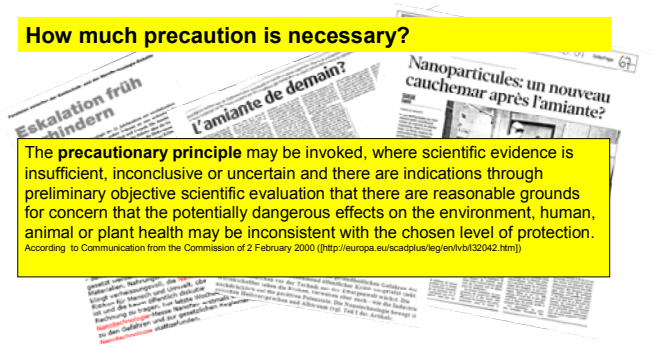
Assumed Exposition of man to nanoparticles (NP)



Swiss Federal Office of Public Health — Nanoregulation 2006 14.09.06 — Page 5

Nanoparticles – A Challenge for Public Health

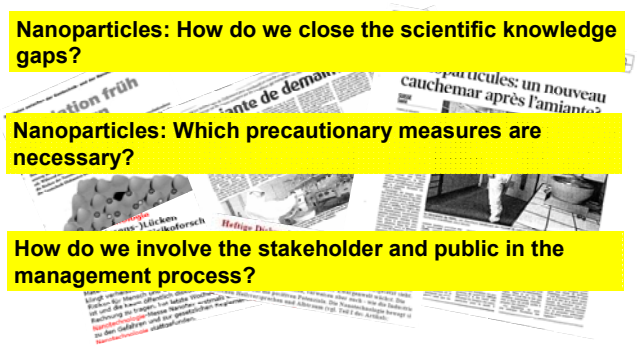
How much precaution is necessary?



The **precautionary principle** may be invoked, where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.
According to Communication from the Commission of 2 February 2000 ([http://europa.eu/scadplus/leg/en/lvb/l32042.htm])

Nanotechnologies – A Challenge for Public Health

Nanoparticles: How do we close the scientific knowledge gaps?



Nanoparticles: Which precautionary measures are necessary?

How do we involve the stakeholder and public in the management process?

Swiss Action Plan (1)

Project: Swiss Action Plan "Risk evaluation and management of engineered Nanoparticles until 2009" :

- Initiation in February 2006 by the Swiss Federal Office of Public Health and Swiss Federal Office for the Environment
- Installation of a National Expert Board to cover the work
- Focus of the Swiss Action Plan:
  - Coordination of Swiss national und international activities
  - Proposition of measures and activities to protect workers, consumers and the environment (with respect to food, packaging, chemicals, materials, cosmetics, etc.)

Swiss Action Plan (2)

Topics to be covered:

- Support and strengthen stakeholder awareness for self-control principles (Code of conduct)
- Promotion of risk and safety research projects (university, industry)
- Promotion of harmonized Definitions, Characterization Methods and validated Test guidelines for the Risk evaluation and assessment (in Cooperation with OECD, ISO, EU und UNEP)
- Promotion of an Inventory on the use of Nanoparticles in Switzerland
- Support precautionary measures with respect to occupational health in R&D and Industry
- Adaptation of the existing legislation in Switzerland, if necessary
- Stakeholder and Public Dialogue

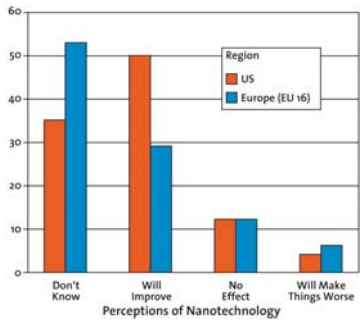
Public Knowledge and Public Perception of Nanotechnology

PD Dr. Michael Siegrist, NSSI ETH Zürich

PD Dr. Michael Siegrist, NSSI ETH, Zürich

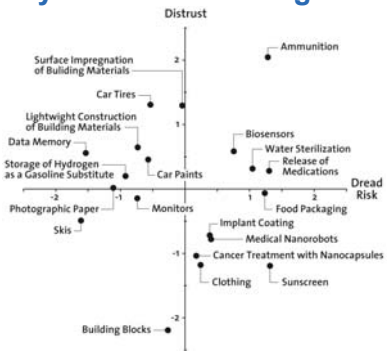
It is expected that nanotechnology will become increasingly important in the near future. Public perception will be crucial to the realization of these technological advances. Surveys suggest that public knowledge about nanotechnology is very limited. Surveys suggest that public attitudes differ across countries. US people are more optimistic about nanotechnology than Europeans. Mass media are important for shaping public attitudes to nanotechnology. The articles of NZZ, FAZ and NYT were content analyzed to identify the prevalence of concepts of benefits and risks. There is an upward trend in the media coverage of nanotechnology. Interestingly, all three newspapers reported more often about benefits than about risks. To test whether lay people and experts differ with respect to risks associated with nanotechnology, we asked lay people and experts working in the domain of nanotechnology to assess the risks of various nanotechnology applications, which were described in short scenarios. Results show that lay people's perceptions of the risks associated with nanotechnology were significantly higher than the experts' perceptions of risks. Results of our survey suggest that experts and lay people differ in their perception of the risks associated with nanotechnology. Based on their perceived risks, experts may not be inclined to initiate the risk assessments that are expected by the public. To investigate which procedures are employed by industry to assess risks, we sent a questionnaire to companies producing or applying nanotechnology materials and located in Switzerland or Germany. Our data suggest that a substantial segment of the companies that produce or apply nano-particulate materials perform no risk assessments. This contrasts with public concerns and may undermine public trust in the nano-industry. Lack of trust may be a key factor in explaining why the public is hesitant to accept some new technologies. The importance of trust for the positive perception of new technologies suggests that a preventable event with significant negative consequences must be avoided. Such an event, indicating lack of concern for public welfare, could have a disastrous impact on trust and result in decreased acceptance of nanotechnology. Thus, the industry should promote voluntary initiatives and regulations designed to prevent

Survey Results: US & Europe

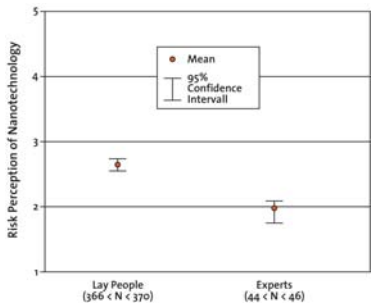


Gaskell et al., 2005

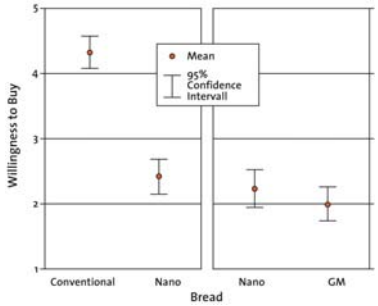
Psychometric Paradigm



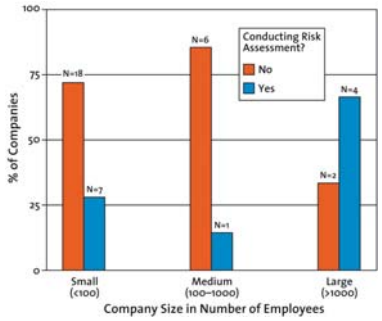
Risk Perception: Experts and lay people



Study 2



Risk Assessments



Conclusion

- The public is not well informed about nanotechnology
- Newspapers emphasize benefits and not risks
- Lay people perceive more risks than experts
- Trust and affect influence acceptance of nanotechnology
- Few companies conduct risk assessments

A Framework for proactive Nanotechnology Risk Governance

Dr. Qasim Chaudhry, Defra, United Kingdom

Dr. Qasim Chaudhry, Defra, United Kingdom

The rapid proliferation of nanotechnology in recent years has led to an ever-increasing application of nano-scale materials in a vast array of industrial and consumer products. These now range from cosmetics to paints and coatings, catalysts and foods and drinks. Such widespread use of nanomaterials, that are largely untested in terms of effects on human health and the environment, has also led to a number of uncertainties and concerns. Apart from some current technological barriers, a number of societal factors may play a major role in enabling the achievement of full economical and social benefits from the new technology. On the other hand, a negative public perception may pose a major barrier to future prospects of nanotechnology.

This overview presents an outline of a framework for proactive nanotechnology risk governance, based on known and projected products and applications, the main societal, regulatory and policy issues arising from the new technology, and the potential implications in terms of safety to human health and the environment. The overview will highlight those sectors of nanotechnology that need particular priority, and will discuss the use of precautionary principle versus an evidence based approach in the absence of data on potential hazards, exposure and risks posed by the products and applications of nanotechnology.

Recommendations: Technical

- Priority research on dispersive and active NMs to assess hazard, exposure and fate, and the revise current methods of risk assessment
- A clear nomenclature for nanotechnology that allows for distinct risk factors to be integrated into risk assessment methods
- Risks and benefit analysis on the basis of entire lifecycle of a nanoproduct or application
- Guidelines and best practices for risk analysis strategies that can be shared internationally

Source: IRGC workshop 'A Conceptual Risk Governance Framework for Nanotechnology', Zurich, 30-31 January 2006

Recommendations: Risk Communication

- Better communication of science, innovation and risk
- Communication of potential risks and benefits of nanotechnology to the public
- Sharing of risk data and governance practices internationally without jeopardising competitive advantage

Source: IRGC workshop 'A Conceptual Risk Governance Framework for Nanotechnology', Zurich, 30-31 January 2006

Recommendations: Social

- A system for accruing intellectual property rights
- Reduction of barriers to trade through internationally accepted standards
- Governments promote innovation that is socially and environmentally beneficial
- Risks, benefits and potential societal change to be identified prior to development
- More research on the long-term implications of nanotechnology with respect to the human dimension
- International coordination of risk governance
- Transparent decision making processes

Source: IRGC workshop 'A Conceptual Risk Governance Framework for Nanotechnology', Zurich, 30-31 January 2006

Regulatory Gaps

- Definition of nanotechnologies and NMs
- The scope and objectives of a legislation
- Thresholds or exemptions under relevant legislation
- Uncertainties over:
  - the effects (or impacts) of nanotechnologies and NMs
  - agreed dose units that can be used in hazard and exposure assessments;
  - reliable and validated methods for measurement and characterisation that can be used in monitoring exposure

Materials / Applications	Fullerenes (C60, C70, C80, derivatized)	Metallofullerenes (with endohedral metals)	Multi-wall nanotubes	Single-wall nanotubes	Rods	Fibers	Whiskers	Metals and metal oxides	Ceramics	Colloids	Quantum dots	Non-Quantum-dot semi-conducting materials	Silica	Polymers	Composites	Dendrimers	Intermetallics	Ion-beam processed materials	Thin films (nm thickness)	Biomolecules	Molecular motors
Hydrogen storage	X		X	X											X						
Environmental remediation								X							X		X				
Catalysis		X						X			X				X		X				
Drug delivery	X	X	X	X				X							X	X				X	X
Medical imaging	X	X	X	X				X		X	X	X			X	X				X	X
Photovoltaics	X	X	X	X	X		X	X			X		X	X	X		X				
Textiles			X	X		X									X						
Therapeutics	X	X									X					X				X	X
Reinforced composites			X	X		X								X	X						
Electronics and electronic devices	X	X	X	X	X		X	X	X		X	X	X	X	X		X	X	X		
Optics and optical devices	X	X						X		X	X	X	X	X	X		X		X		
Coatings and pigments	X	X	X	X				X		X				X	X		X		X		
Cosmetics								X							X						
Ceramics applications									X												
Anti-oxidants									X												
Lubrication	X							X						X	X						
Sensors and sensing devices	X	X	X	X	X		X	X		X	X	X	X	X	X	X	X	X	X	X	
Absorbents								X		X				X	X		X				
Energetics and energetic materials			X	X				X							X		X				
Magnetics and magnetic devices								X							X		X				
Water purification and filtration media			X	X		X		X						X	X						
Air emissions reduction							X	X						X	X						
Natural and green products															X						
Quantum computing		X						X			X	X			X						
Masonry and building materials			X	X		X			X						X						
Photonics and photonic devices	X	X						X		X	X	X	X		X						
Surfactants										X				X	X						

Summary

- Uncertainties requiring R&D to:
  - assess the effects of nanotechnologies on human health and impacts on the environment to assessment of risks
  - prioritise products and applications with potential high risk
  - develop validated methods for monitoring NMs in the environment
- Regulatory inadequacies and gaps requiring adjustments to:
  - set clear definitions for nanotechnologies and NMs, which encompass their distinct properties
  - make scope and objectives of the legislation directly relevant for properties, uses and effects of NMs
  - allow for hazard identification, exposure assessment, risk characterisation and risk calculation
  - set clear thresholds and exemptions considering the (potential) effects and levels environmental impacts
  - apply precautionary principle in situations that might pose a high risk to human health or the environment

Communication Prinicples for Industry and other Stakeholders

Armin Huttenlocher, Burson-Marsteller, Berlin

Armin Huttenlocher, Managing Director Burson-Marsteller, Berlin

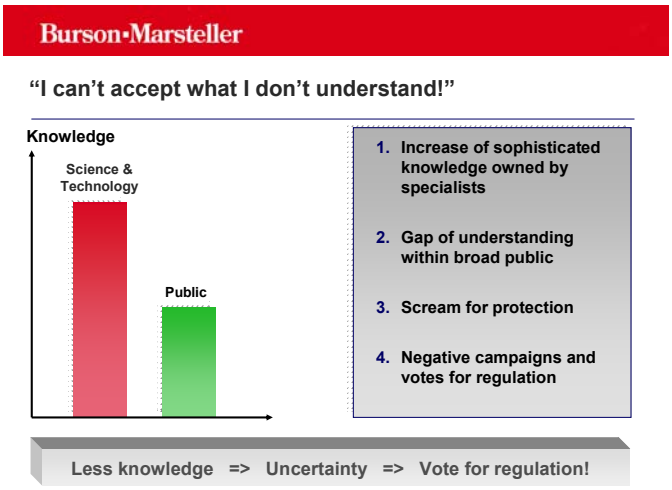
The public acceptance of Nanotechnology is of outmost importance for the success of this emerging technology. In our ambivalent world Nanotechnology is rather enthusiastically regarded in the media but there are also articles claming the fear of the unknown. A few „unguided missiles“ - as the withdrawal of the product „Magic Nano“ - are jeopardizing the whole nano industry and cause growing uncertainty in the public.

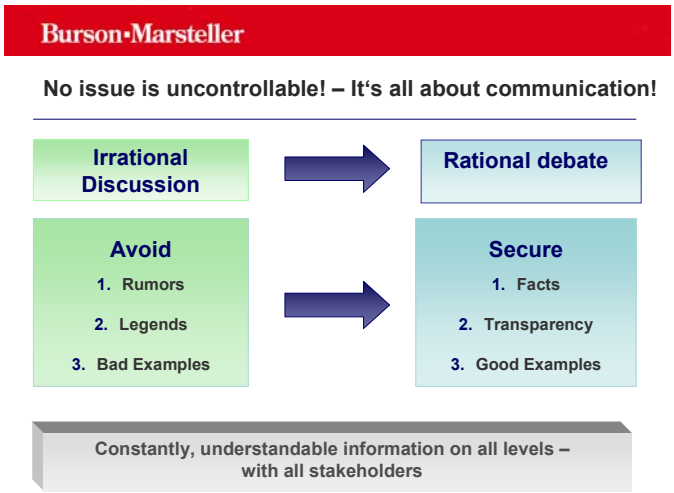
The complexity of the topic nanotechnology creates gaps of understanding within the broad public. Negative campaigns could easily provoke votes for (over-)regulations.

To achieve a broad acceptance for this new technology the nano-industry must state a clear commitment to take responsibility. In his presentation Armin Huttenlocher underlined that there is a historic chance to achieve acceptance of a new technology by:

- Taking the initiative
- Raising the questions before they‘re being raised
- Pro-actively building bridges
- Strictly follow the rules of transparent information plus coherent argumentation

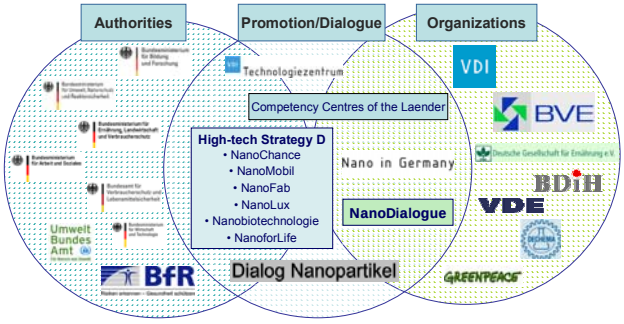
Nano-stakeholders must transparently inform about their activities in order to avoid future bans of nanotechnology as it happened to GMO in the past.





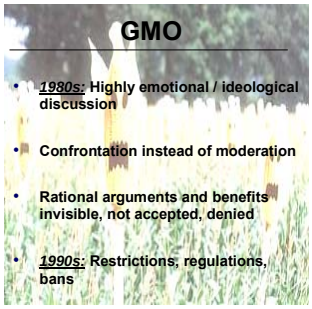
Burson-Marsteller

Make the ***thought leader*** become a ***trusted partner!***



Burson-Marsteller

Just learn from history and experience!



- ***1980s:*** **Highly emotional / ideological discussion**
- **Confrontation instead of moderation**
- **Rational arguments and benefits invisible, not accepted, denied**
- ***1990s:*** **Restrictions, regulations, bans**
- ***2000s:*** **No significant break through on negative public opinion**

Brominated Flame Retardents

- ***1980s:*** **Most discussed group of chemical products,**
- **Significant uncertainties, scream for ban**
- ***1990s:*** **Industry starts coherent research plus information strategy (risk assessment, issue management, information)**
- ***2000s:*** **Break through on public opinion**
- **Level of knowledge raised; specific BFRs allowed, balanced view on risks vs benefits**

Burson-Marsteller

Thesis 3

There is a historic chance to achieve acceptance of a new technology by…

… taking the initiative

…raising the questions before they're being raised

… pro-actively building bridges

… strictly follow the rules of transparent information plus coherent argumentation

Burson-Marsteller

Conclusion

1. ***Be a thought leader***
   Share knowledge. Feed the debate.
2. ***Be active, stay credible***
   Build networks, keep networks. Particularly to the sceptic.
3. ***Become a trusted adviser***
   Offer insights. Outline visions. But take any uncertainty serious.

Nanotechnology in the media

Niels Boeing, bitfaction, Hamburg

Niels Boeing, bitfaction, Hamburg

Nanotechnology (NT) has doubtless become a hot topic in the media. The coverage has followed what Lux Research calls a typical „hype curve“: from approximately 200 mentions in English-language media articles in 1995 to more than 18,000 in 2005. A similar trend holds for German-language media.

One can roughly distinguish three phases:

1. the „futurist phase“ in which articles were dominated almost exclusively by awe for stunning discoveries, giving room for the visions of NT pioneers. This phase went into 2002.
2. the „possibility-centered phase“ in which reporting shifted to a more realistic and timely approach featuring real applications, first products and interesting research projects. A visionary undertone though was still noticeable. This was accompanied by an economical perspective that emphasized new investment opportunities.
3. the „skeptical phase“ in which environmental and health concerns as well as reality checks of NT’s promises start to gain importance. We have been entering this phase in 2006 with reports about fake nano-products like the one of Neosino AG or health problems of consumers that had used Magic Nano. Also the number of risk studies and public panels has contributed to this shift in the media’s awareness of the darker sides of NT.

Despite increasing media coverage public understanding of NT is still limited. Polls in the USA, the UK and Germany found that approximately three quarters of the public have no or only poor or distorted knowledge of NT. There are three main reasons for this.

First of all the futurist phase firmly built up what I would call the „nanobot meme“ referring to Richard Dawkins’s concept. Memes are cultural icons, storylines or concepts that spread much like genes in the biological gene pool. As some genes are more dominant than others so are memes. The nanobot was introduced by Eric Drexler in 1986 then popularized by Michael Crichton’s novel „Prey“. Even if

media articles deal with real NT in a balanced way nanobots are nevertheless used for illustration of the topic, thereby repeating the theme again and again. This is especially widespread in coverage about nanomedicine where the „nano submarine“ cruising through a man’s blood system has become the lowest common denominator in the understanding of what nanomedicine is about.

Secondly, the term „nanotechnology“ is still blurred in popular media coverage. Time and again it is described as the science of the small. This prevents a proper understanding of NT as a field of engineering seeking practical solutions to real problems. NT is rarely explained as a new phase of technology in which all different branches of technologies exploit nanoscale effects of small matter like atoms, molecules and clusters. On the other hand industry publications or those close to it tend to overemphasize the engineering details in stressing the continuity from chemistry or device physics to NT, thereby losing the big picture.

A third point are stereotypes the usefulness of which is not questioned anymore. One is the typical size comparison of nanoscale objects to the width of the human hair. As the human hair is quite an extended object though very thin it is no good reference for point-like objects like buckyballs or quantum dots nor for nanostructured materials that extend macroscopically in two dimensions.

Taken together these three points contribute to a very reduced picture of NT that it is „somehow“ dealing with the very small, that it is a bit magical in the sense of Arthur C. Clarke’s Predition Law No. 3 and that it is potentially not controllable. Thus NT media coverage should refocus on the real NT with keeping the big picture of its meaning for economy, society and the environment in mind. That is no easy task but it has to be solved.

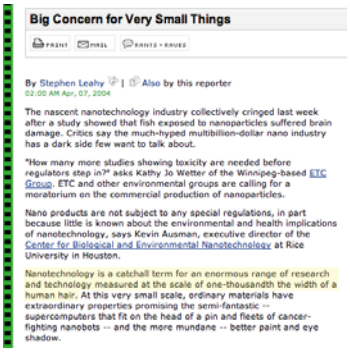
Three phases of NT in the media

- Futurist phase
  fading out by 2001
- Possibility-centered phase
  around 2000 – now
- Skeptical Phase
  2006 – ?

Three deficits in NT reporting

- The „Nanobot Meme“
- Blurred concept of nanotechnology
- Not so helpful stereotypes

Not so helpful stereotypes



Big Concern for Very Small Things

By Stephen Leahy | Also by this reporter
02:00 AM Apr, 07, 2004

The nascent nanotechnology industry collectively cringed last week after a study showed that fish exposed to nanoparticles suffered brain damage. Critics say the much-hyped multibillion-dollar nano industry has a dark side few want to talk about.

"How many more studies showing toxicity are needed before regulators step in?" asks Kathy Jo Wetter of the Winnipeg-based ETC Group. ETC and other environmental groups are calling for a moratorium on the commercial production of nanoparticles.

Nano products are not subject to any special regulations, in part because little is known about the environmental and health implications of nanotechnology, says Kevin Ausman, executive director of the Center for Biological and Environmental Nanotechnology at Rice University in Houston.

Nanotechnology is a catchall term for an enormous range of research and technology measured at the scale of one-thousandth the width of a human hair. At this very small scale, ordinary materials have extraordinary properties promising the semi-fantastic -- supercomputers that fit on the head of a pin and fleets of cancer-fighting nanobots -- and the more mundane -- better paint and eye shadow.

- The hair as reference point;
- the talk of the „second industrial revolution“;
- the 1-billion-dollar world market forecast

The task of NT reporting

- Nanotechnology is not „magic“
- It‘s a new phase of technology exploiting quantum effects and nano building blocks
- It‘s not only about innovation for new markets but also about consequences for environment and health
- It‘s not devellopping autonomously but driven by conscious decisions

Communication, Education and Participation. Public Participation in Nanotechnology in Switzerland: The publifocus

Michael Emmenegger, TA-Swiss

Michael Emmenegger, TA-Swiss

The development of nanotechnology is on a fast track. There are huge expectations for new solutions in almost every industrial sector. Nanotechnological products and future treatments will have a big effect on our daily life as well as on the environment. The economic potential of nanotechnology is presented as being enormous, and nanotechnology stocks are rising high.

This nano-boom also involves questions. Toxicological researches on synthetic nanoparticles show that there are possible health risks. But it is not clear yet what the dangers are and how they could be regulated. On the other side, nanotechnology is associated with visions of a "better world". But such visions also make questions about social and economic issues. And, last but not least, there is quite a wide interpretation what "Nano" means. Today, a lot of "Nano" is just marketing, and that confuses the whole discussion about nanotechnology.

Stakeholders from R&D, industries and administration are already discussing such questions as well as opportunities and risks of nanotechnologies. In Switzerland, however, no public discussion about nanotechnologies has started yet. Although one third of all articles about nanotechnology in Swiss newspapers are about chances and risks of this new technology, the general public is more or less indifferent. Nanotechnology is not in the minds yet.

In 2003 already TA-SWISS focussed on the issue in the study "Nanotechnology in Medicine". This study clearly showed that the public has to be involved in the discussion about the development of nanotechnologies, like many studies from other countries did over the past few years. Possible new laws have to integrate citizen opinion. TA-SWISS is – among others – responsible for this dialogue with the public and therefore started a participatory project on nanotechnologies. To stimulate the public debate at this early stage, five *publifocus* are to be held in the different language regions of Switzerland in September 2006. The aim of the *publifocus* on nanotechnologies is to form a picture of what people think about them, where they see possibilities, and where they see risks. We

don't elaborate recommendations or plans of action in a *publifocus*. Rather, we provide a picture of the various arguments, opinions and positions that exist among the public.

The *publifocus* is one of three different participative methods used by TA-SWISS (PubliForum, PubliTalk, *publifocus*). These methods are based on well known examples like Scenario Workshops, Future Conference, Citizen Panels and Concensus Conference. In a *publifocus*, 15 randomly selected "average" citizens, so-called laymen, discuss various questions about a given issue. In this case, about possible effects of nanotechnologies on health and environment. A final report will be published in order to inform the members of the Swiss Parliament and the interested public. This will be at the end of this year. For this project TA-SWISS collaborates with the Zurich University of Applied Sciences Winterthur (ZHW) and the Federal Offices of Public Health (FOPH) and for the Environment (FOEN). With this *publifocus* we would like to make a valuable contribution to the political debate surrounding this new key technology.

TA-SWISS – Centre for Technology Assessment

Since 1992 TA-SWISS assesses the impact of new technologies and gives advice to the Swiss Parliament and the Swiss Federal Council. Scientific studies record trends in biomedicine and in information- and nanotechnology, and participatory methods involve citizens in the debates. TA-SWISS is financed by the Federal Government and is affiliated to the Swiss Science and Technology Council.

The Aims of the *publifocus*

- To describe the range of the different opinions and to get a picture of what people think → Nanotechnology
- To stimulate the public debate at an early stage
- To inform the members of the Swiss Parliament and the interested public
- To give a contribution to the elaboration of a regulatory framework and to possible legal foundations

Current State

- The development of nanotechnology is on a fast track and the expectations are huge
- Studies show possible health risks of synthetic nanoparticles
- There is a lack of regulation and declaration
- „Nano-Products“ are part of our daily life
- There is no clear structure and definition of nanotechnology yet
- There is an increasing confusion due to the intensive use of the term „nano“

Public Debate in Switzerland

- The public awareness and the state of knowledge is low
- The public discussion about the effects of nanotechnology has not started in Switzerland yet
- Various studies recommend to initiate a public discussion (e.g. TA-SWISS 2003, Nanotechnology in Medicine)
- Legislation must take the public‘s view into consideration
- Different roles of media, politics, authorities, economy and industry, environmental- and consumer protection-organizations, research and science

Findings from other studies

- Balance chances and risks and show advantages
- Avoid health and environmental hazard through nanoparticles
- Clarify possible social and ethical effects at an early stage
- Control the developments carefully and adjust regulation
- Extend information, dialogue and participation with the public
- Use the possibilities of nanotechnology for favorable intentions

Strategy Workshops

Dr. Qasim Chaudhry moderating a Strategy Workshop

In three different workshops the participants of the conference focused on relevant issues that will support a prosperous development of Nanotechnology in the future. The workshops regarded following topics:

- Nano Communication for Stakeholders
- Nano Participation and -Education
- Risk-Governance

In order to guarantee a successful and sustainable development of Nanotechnology in the future following topics must be considered:

- A fact oriented basis of knowledge and scientific data to various risk aspects of Nanotechnology is urgently needed.
- A transparent and problem guided dialogue process should be initialized between the different stakeholders of the nano branch to guarantee availability of information and to avert a disacceptance of the “new technology” in the public.
- Transparency in communication and information enables nano-stakeholders to take an unequivocal stand on controversial issues and create public trust.

Governments in cooperation with the industry should establish a clear guidance framework to assess the risk of Nanoparticles and to protect reputable producers from possible image losses or liability claims. By self regulation approaches and a basic control of standards Nanotechnology could be assessed safely without the urgent need of rash regulations implying the risk of over-regulation and though retarding the technologies’ expansion. Possible regulations of nanotechnology in the future must be fact based and well assessed. The running action plans of different national and international organisations are already dealing with this important issue.

The "Triple S"- NanoRoadmap 2011

Participants of the NanoRegulation conference developing the „Triple-S"-NanoRoadmap 2011

The participants of the conference had to develop a Triple-S" (safe, sustainable, successful) Roadmap to the Nano World in the year 2011. The following questions / topics were discussed:

Phase 1: Decribe the "ideal" Nano-world of 2011. What should the Nano-Word look like in 2011?

- Broad scientific database on various risk aspects enables a profound risk assessment of Nanotechnologies
- Accepted International Standards for Nanotechnologies
- Wide range of safe Nano-applications and –products on the market
- Transparent Dialogue between different Nano-stakeholders and the public
- Broad public acceptance of Nanotechnology

Phase 2: Identify the key obstacles to getting to the ideal Nano-World 2011.

- The risk assessment of Nanotechnology is very expensive in terms of time and money consumption.
- Possible sporadic Nano-incidences ("unguided-missiles") could insecure the public and influence the public acceptance of Nanotechnology in a negative way.
- Inadequate "Over-Regulation" of Nanotechnology could handicap its development.

Phase 3: Suggest potential actions or measures which can be taken to overcome the obstacles your group has identified to Nano-World 2011

- "Nano-Regulation" is assessed on a multi level approach:
  - Government carefully assesses possible Regulation-gaps
  - Industry is running self regulation process (Codes of Conduct, good practice guidance)
- Broad funding of Risk-assessment research projects
- Promotion of public information by industry, various platforms and the media could foster the dialogue and the public acceptance of Nanotechnology
- Creation of "Nano-Labels" to transparently inform consumers about the content of Nanoproducts

Outtakes from Lunch-over-IP Blog

Susan Kish, Moderator, FirstTuesday, Zürich

What we don‘t know about nanotech

- by guest blogger Susan Kish

Last week I moderated a conference on Nanotech Regulation in St Gallen, organized by Christoph Meili and The Innovation Society. St. Gallen is in north-eastern Switzerland, and is known for its university and its fabulous library in the Abbey. We have been following the nano industry with forums and discussions since 2002. This forum focused on nanotech regulations - and therefore on nanotech risks. Here are a few things I learned:

- We don’t know/1: the legislation – The UK has just completed its first gap analysis of nano-related regulation. While there have been several gap analysis completed in the US, this was the first done in Europe (one is being performed currently at the EU level). Qasim Chaudhry of the Central Science Lab in York, UK, presented the key results, which will go to the UK government this week. Personally, I found it terrifying. In addition to a wonderful chart which listed all the areas where we have NO definitive research, Dr. Chaudry made a compelling case for all the gaps in the existing UK and EU legislation – whether they arise because legislation is designed for (a) materials of normal weight (i.e. a minimum of 1 ton for a regulation doesn’t help much with nano-sized particles), or (b) weight vs. surface area (which can often be the determinate of impact at that size), or (c) nano comes up in a wide variety of governmental departments (from Public Health to Worker Safety to Food and Drug, to the Environment to Chemicals etc) with very little coordination. That complexity clearly increases the cost and uncertainty of regulatory enforcement and compliance.

- We don’t know/2: the data – The speakers also confirmed that nano-particles do cross the blood brain barrier, and that they can be found all over the body. Dr. Lang Tran, a senior scientist at the Institute for Occupational Medicine in Edinburgh, added that the question is open as to whether these nano-

particles can cross into the placenta. Apparently research is just starting on that area. Why do we care? Well, until the toxicologists get the research done, they can’t set acceptable levels for the regulators or for the industry to set standards, which means that occupational safety and public health officials will have to wait, too. A call for action (translate that as "funding") voiced by several speakers.

- We don’t know/3: the skin barrier - It seems that the debate about our skin vs titanium dioxide particles in sunscreen just keeps on going. We’ve heard the disclaimers that nano particles won’t penetrate our skin, which has the pragmatic impact of letting us buy sunscreen cream without concerns. That disclaimer was repeated during Q&A. After all, our skin has evolved over millennia to protect us from the traditional nanoparticles of environment, those from fire or volcanic ash or whatever. However, what at least I learned from Prof. Jürgen Lademann of Berlin's Charité-Universitätsmedizin Berlin was that nanoparticles of 40-60 nm may enter our skin through hair follicles. And go in just a bit farther with skin massage (think about rubbing in that sunscreen cream). I asked him about whether it would be safe buying the sunscreens currently on the market for my kids. Answer? Sunscreen is safe. Except of course for babies of less than a year, because their skin isn’t sufficiently developed to protect them. Except, of course, for things like cuts and scratches. Except that disquieting statement on hair follicles. Contradiction? His point seemed to be that we should not worry because balancing that against the risk of melanoma it clearly comes out in favor of using the sunscreen cream.

But there are more specific and pressing take-aways:

- We need to have answers: 10% of the billions of research money worldwide should go into toxicology studies, now - and not in five years when we may start to see the first incidents and the first reactions arising in “nano-workers”.

- We need to know what we’re buying: Industry needs to take the lead in clear labeling for the consumer. Educate the public, so we know what we’re buying, and so new mother’s know that they should not use sunscreen on babies less than a year.

- We need to improve regulations: National governments need to work with industry and key stakeholders (“co-regulation”) to have good data and to understand the risks. Governments need to start doing gap analysis studies of regulation. And the lead needs to come from the national level: although everyone agrees that a global regulatory framework is what is needed, it’s also clear that this will take forever. (Check out the IRGC white paper - *PDF* - for thoughts on a framework for nano risk governance).

Ah, I almost forgot: at the Energy Venture Fair, Swiss explorer Bertrand Piccard spoke passionately about his plans to build an airplane powered solely by solar power, and fly around the world.

I'm wondering what sunscreen he will use.

Comments:

That's down to the point, Susan. I'd only like to add, that we should consider already now developments in bionanotech that are not yet at the point where chemical nanotech is with the use of nanoparticles. Unfortunately some very remarkable thoughts on that by ETC were blurred in their diffuse "atom technology" rhetoric. But if you look at Synthetic Biology which I'd put into the field of bionanotech we should start talking about that, too. At least the SynthBio people are aware of the problems as their draft for safety guidelines as discussed at Synthetic Biology 2.0 in Berkeley in May 2006 shows.

Niels Boeing

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