the innovation society

Regulation of Nanotechnology in Consumer Products

3rd International „Nano-Regulation“ Conference
12. – 13. September 2007,
St.Gallen (Switzerland)

Conference report

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

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Impressum

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- *Technology and Innovation Management*
- *Safety- and Risk Management* / Regulatory Issues
- *Technology Communication & Stakeholder Dialogue*

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Preface

This report summarises the contents and results of the 3rd International NanoRegulation Conference which took place from 12. – 13. September in St. Gallen (Switzerland). The conference was organised by the Innovation Society in cooperation with NanoEurope Fair & Conference. This year's focus was on consumer products containing nanotechnologies, possible risks and regulatory approaches.

The conference highlighted the following topics:

- Technical, health, environment and safety aspects of products containing nanotechnologies
- Regulatory approaches to nanotechnology
- Stakeholder perspectives on nanotechnology
- Adequacy of different voluntary measures (Code of Conduct, CENARIOS® Risk Management System, Nano Risk Framework)

The annual "Nano-Regulation" conference in St.Gallen is part of the multi-stakeholder platform "Nano-Regulation" which has been launched in 2005 by the Innovation Society and is supported by several government-, industry-, retail- and research organisations. The platform serves as an international interface providing information and communication services to their members and facilitating cooperation among stakeholders on the international level.

Next year, the NanoRegulation Conference will take place from 16 to 18 of September 2008. Please reserve these dates.

For further information, please visit www.nanoregulation.ch

Content

Introduction

Dr. Christoph Meili, The Innovation Society Ltd., Switzerland

Growing markets: It's all nano!

Nanotechnology has become ubiquitous. Nanocomponents in cosmetics, clothes, packaging, toys and even food products are already on the market and their number is growing fast. Within the last 14 months the number of listed nano-products more than doubled. The product database of the Woodrow Wilson Center currently lists 580 products supposed to contain nanocomponents (October 2007) compared to 212 in March 2007. Assuming that the figures show a representative increase of products, we are presently facing remarkably growing market-potentials in different branches.

Looking at the different categories, the “Health & Fitness” sector lists 356 products and contributes with more than 60% to the whole market. In other categories as “Home & Garden” or “Food & Beverage” the number of products is considerably smaller.

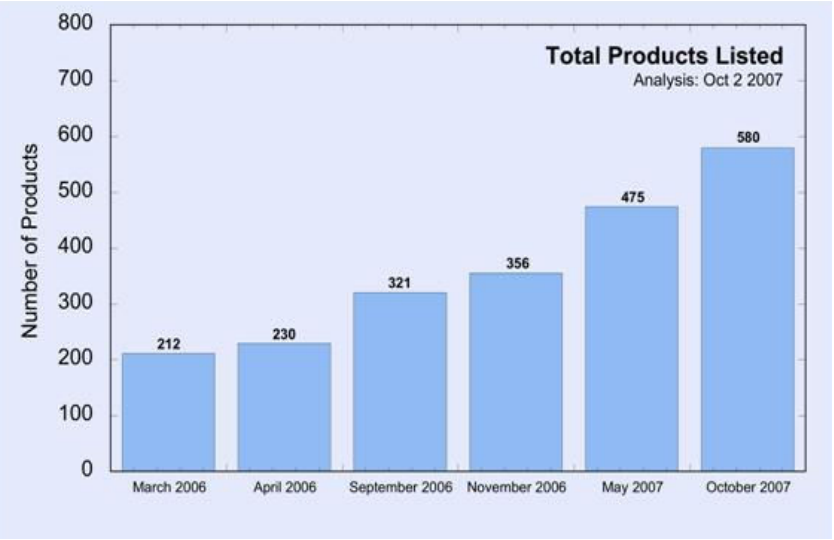
Among the major nanosized materials applied in these products, silver is currently the most widespread one and has become a real “shooting star”. Due to it's high efficiency as an antimicrobial substance and due to its good processing characteristics it has become the most prevalent nanomaterial in terms of product variety. On the other hand, nano-silver is challenged by its success.

Better Safe than Sorry: From national to communal regulations?

In 2006 SAMSUNG brought a “nano-silver-washing-machine” to the market. It provoked critical reactions from environmental- and consumer organisations. These pressure groups also triggered the first nanospecific regulation, imposed by the US Environmental Protection Agency (EPA) in Fall 2006 to protect the environment. The agency decided to regulate products with small silver particles claiming germ-killing activity. Industry will have to provide scientific evidence that the product does not pose an environmental risk.

At the same time, a regional regulatory frameworks was set up when the city-council of Berkeley (CA) decided to regulate its fast growing nano-industry in the area of the town of Berkeley by monitoring research and production sites handling potentially hazardous nanomaterials. Similar activities were discussed elsewhere in the US. Regional regulatory activities are becoming more and more popular in order to protect human health and the environment

from the potentially hazardous effects of nanomaterials. This seems reasonable. On the other hand, this tendency poses a serious problem for the industry in terms of the reliability of regulatory frameworks and also in terms of their predictability.



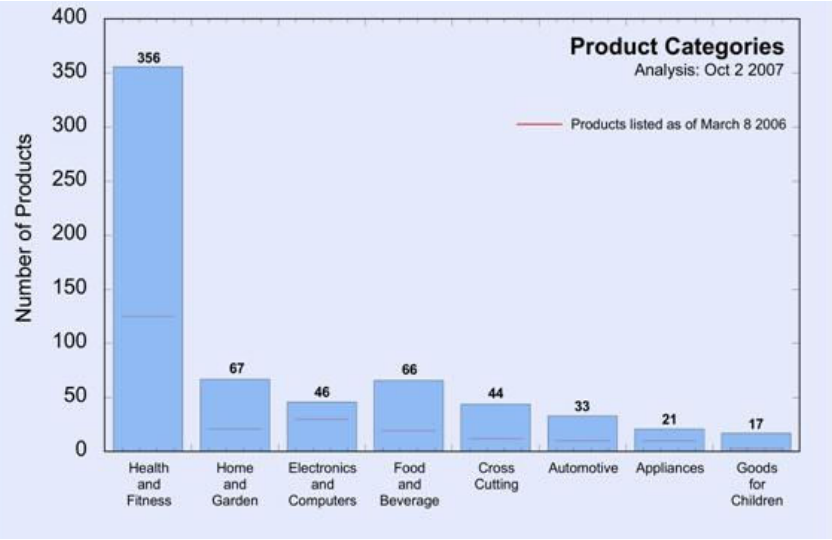
The number of nanoproducts is continuously increasing

Source: Nanotechnology Consumer Products Inventory, Woodrow Wilson International Center for Scholars. www.nanotechproject.org/consumerproducts

Nano-Labelling:
The Holy Grail of consumer acceptance and trust

"Nano-Inside" still sells, at least in mere technical applications. In consumer-near products such as food, cosmetics and textiles, "nano" is perceived more sceptically by the consumers. Several surveys have shown that consumers are not generally against nanotechnology but that they want to know what's inside the product they are buying. Mainly food and cosmetic companies are reluctant to label nano-ingredients in their products. For manufacturers, there are two main challenges: First: It doesn't make sense to address nano components solely due to their size, because most of the nano-components quickly agglomerate to microscale structures. And second: Many structures such as micelles in milk or proteins occur in natural products as well. For consumers it's nearly impossible to distinguish "true nano" (containing e.g. synthetic nanoparti-

cles) from “pseudo-nano” (e.g. chemicals which nano-effects). Nevertheless, a labelling or declaration claim cannot be neglected by regulators nor industry. These will be critical issues for the success and the acceptance of nanotechnology in consumer products. If this transparency is addressed proactively and timely, it will be an excellent instrument to gain trust and acceptance for nanotechnology.



The number of nanoproducts in the corresponding product categories

Source: Nanotechnology Consumer Products Inventory, Woodrow Wilson International Center for Scholars. www.nanotechproject.org/consumerproducts

Swiss Action Plan and Green Nanotechnology

Prof. Dr. Georg Karlaganis, Federal Office for the Environment, Switzerland

Nanomaterials – Challenges and opportunities for Switzerland
Prof. Dr. Georg Karlaganis
Federal Office for the Environment, Switzerland

It is widely acknowledged that Nanotechnology offers very promising possibilities. It will, as a horizontal or enabling form of technology, penetrate all industrial sectors in the medium term. For Switzerland as a site for research and economic activities, nanotechnology offers an enormous potential for innovation and development. In addition to this, nanotechnology also has an enormous potential to improve the environment through “green chemicals” and the sustainable use of resources. How we use the available natural resources has an impact on our health and the environment.

On the other hand, every new technology comes up with certain risks. The nanotechnology risk and regulation discussion took off in early summer 2004, when the Royal Society and Swiss Re published their reports on nanotechnologies – „Nanoscience and nanotechno -logies: opportunities and uncer-tainties“ and „Small matters, many unknowns“. These reports illustrated the fact that nanotechnologies offer many benefits both now and in the future, but that public debate was needed about their development. It was also highlighted the immediate need for research to address uncertainties about the health and environmental effects of nanoparticles.

Only one year later, the European Commission came up with the action plan "Nanosciences and nanotechnologies: An action plan for Europe 2005-2009". This programme defined a series of actions for the immediate implemen-tation of a safe, integrated and responsible strategy for nanosciences and nanotechnologies and has been an important promoter of the Swiss Action Plan on synthetic nanomaterials. In Spring 2006 work on the Swiss Action Plan was officially launched by the Federal Office for the Environment (FOEN) and the Federal Office of Public Health (FOPH). A work package was developed in collaboration with experts and stakeholders in order to identify critical applications of synthetic nanomaterials and to minimize possible detrimental effects on human health and the environment. The coordination of this work package with international organizations (OECD, ISO) and EU will be important. The promotion of safety research on synthetic nanomaterials

and the dialog with the public and stakeholders are other objectives of the Action Plan.

The first deliverable of the action plan was a **basic report**, published in July 2007 by FOEN and FOPH, containing an overview of the current knowledge about the risks of synthetic nanoparticles. Topics discussed are human toxicity and ecotoxicity of nanomaterials, occupational health and safety, regulation and standardisation, the assessment of the consequences of technology and communication. Finally, a list of risk research needs is deduced.

Key findings of the basic report

- Our knowledge is incomplete in terms of emission sources and -quantities, toxicology, ecotoxicology and environmental behaviour. This **lack of scientific and methodo-logical knowledge** prevents us from carrying out con-clusive risk assessments for synthetic nanoparticles.
- **Definitions**, reliable **standardised methods** of measurement and **guidelines for testing** are mostly **missing**, but they are important prerequisites for legal regulations.
- Present Swiss legislation does not take account of the specific properties of synthetic nano-materials. To ensure safety, the **applicability of the legislative framework** has to be checked.
- There are considerable **legislative uncertainties**, which can lead to possible risks for health and the environment not being recognised. On the other hand this legislative uncertainty can have a negative effect on innovation, since businesses will invest less in the development of nano-technologies as long as it cannot be foreseen what legislative requirements have to be met, and what restrictions might be imposed on the manufacturer.

Based on the information and the conclusions in the basic report, a set of recommendations will be developed in order to cope with the objectives of the Action Plan.

In addition to the questions about risks and safety of nanomaterials, the aspect of **green nanotechnology** needs to be promoted. Technological innovation is a key function in terms of the promotion of an efficient use of resources; nanotechnology offers manifold possibilities in this field. It can also have positive effects on workplace safety and health protection.

1

Getting Started

Context

- It is widely acknowledged that Nanotechnology offers very **promising possibilities**
  - As a horizontal or enabling technology, it will **penetrate all industrial sectors** in the medium term
- For Switzerland as a site for research and economic activities, nanotechnology offers an enormous **potential for innovation** and development
  - Nanotechnology has the potential to **contribute to health protection, workplace safety** and the **sustainable use of resources**

2

Getting Started

Context

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3

The Swiss Action Plan

Why an Action Plan?

- The number of applications with **synthetic nanoparticles** is quickly growing.
- Insufficient **knowledge** about human health & environmental risks.
- Specific properties of synthetic nanoparti-cles are not considered in **applicable law**.
- Lack of clarity in regulations and on the manufacture, commercialisation and dis-posal and the lack of knowledge on risks tend to **restrain innovation**.
- The **EU** is taking the same approach.

- **Minimise negative effects** of synthetic nanomaterials on human health and the environment
- **Fill scientific and methodological gaps** in risk assessment
- **Promote a public dialogue** on opportunities and risks of nanotechnology
- **Promote sustainable nanotechnology**

4

The Swiss Action Plan

Basic Report: Important Findings I

- Our knowledge is incomplete in terms of emission sources and –quantities, toxicology, ecotoxicology and environmental behaviour. This **lack of scientific and methodological knowledge** prevents us from carrying out conclusive risk assessments for synthetic nanoparticles.
- **Definitions**, **standardised methods** of measurement and **guidelines for testing** are mostly missing, but they are important prerequisites for legal regulations. An international coordinated approach is necessary (OECD, ISO)
- Several large-scale research programmes are running or planned in Switzerland and on the international level. In this context, it is important to have a **coordinated, strategic approach** to deal with the most important issues.
- There are considerable **legislative uncertainties**, which can lead to possible risks for health and the environment not being recognised and to a negative effect on innovation (future legislative requirements, restrictions).

5

The Swiss Action Plan

Basic Report: Important Findings II

- Present Swiss legislation does not take account of the specific properties of synthetic nanomaterials. To ensure safety, the **action plan** could cover the following areas:
  - **Product informations** for consumers
  - guidance for **self-supervision**
  - information about synthetic nanomaterials on the **material safety data sheets**
  - **maximum tolerable concentrations** at the workplace
  - regulation on **waste disposal**
  - obligations to **report, notify or authorisation** (test requirements, special procedures for the registration of nanoparticles)
  - **limitation of emissions** into the environment
  - regulation on **major accidents** (tonnage thresholds)

6

Environmental Nanotechnology

Green Chemistry

12 Principles of Green Chemistry [1]

1. Prevent waste
2. Design safer chemicals and products
3. Design less hazardous chemical syntheses
4. Use renewable feedstocks
5. Use catalysts, not stoichiometric reagents
6. Avoid chemical derivatives
7. Maximize atom economy
8. Use safer solvents and reaction conditions
9. Increase energy efficiency
10. Design for degradation
11. Analyze in real time to prevent pollution
12. Minimize the potential for accidents

- ✓Use benign materials
- ✓Reduce material input
- ✓Recycle wastes
- ✓Use catalysts
- ✓Use energy efficiently

[1] Source: EPA, 2006

7

Environmental Nanotechnology

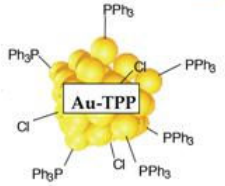
„Green Gold“

Traditional method involves:

- Diborane, toxic and highly flammable gas at room temperature
- Benzene, a highly flammable, carcinogen solvent

New method:

- Sodium borohydride (solid)
- Toluene



- ✓ much **higher yields**
- ✓ **faster reaction**
- ✓ **environmentally benign** materials
- ✓ **safer** to handle (diborane!)
- ✓ significantly **cheaper** (500 $/g instead of 300'000 $/g)

→ **ideal case: win-win-situation.**

Source: Department of Chemistry, University of Oregon

8

Environmental Nanotechnology

Water Treatment (1)

- ➢ 1.5 billion people have no acces to clean water
- ➢ population growth: 95%+ in poorer countries
- ➢ increasing irrigation, ground water depletion, untreated waste water, saltwater intrusions, …

Where nanotech applications can help:

- ✓ **physical filters** with nanoscale porous membranes: desalination of ocean water, removal of contaminants.
- ✓ **nanoscale biofilters** remove bacteria, viruses and prions.
- ✓ **precious metal recovery** with dendritic nanoscale polymers.
- ✓ **removal of contaminants** with Fe-nanoparticles: magnetic iron oxide nanoparticles strongly bind arsenic in drinking water. The arsenic can afterwards be removed using magnets.

Pictures: World Vision Australia

9

Environmental Nanotechnology

Insulation II

Silica Aerogel

Nanogel, Cabot Aerogel

- ➢ cavity insulation
- ➢ very expensive
- ➢ most effective

Vacuum Insulation

INSTILL, Dow Chem. Comp.

- ➢ complicated
- ➢ expensive
- ➢ very effective

Thin Film Coatings

Nansulate, Nanotech Ltd

- ➢ easy to apply
- ➢ cheap
- ➢ less effective

But:

- ➢ expensive and/or not yet mass producable
- ➢ not always applicable (concrete walls)
- ➢ implementation: slow rate of renovation

10

Environmental Nanotechnology

Batteries

Conventional Li-ion Battery Pack

- ➢ 250 hp, 0-100 km/h in 4 sec
- ➢ 320 km range
- ➢ **3.5 hours recharge time**
- ➢ 500 full charge-discharge cycles
- ➢ 100'000 $

Altairnano NanoSafe™ Battery Pack

- ➢ 700 hp, 0-100 km/h in 4 sec
- ➢ 400 km range
- ➢ **10 min recharge time**
- ➢ 12+ years battery life time
- ➢ still 85% capacity after 15'000 cycles
- ➢ **300'000 $**

Lightning Electric Sports Car

11

Conclusion

Barriers

nano-enhanced green technology	conventional technology
➢ high-tech is **expensive**	➢ cheaper
➢ not yet **mass produced**	➢ mass produced
➢ system **adaptations** might be necessary	➢ system conformity is given
➢ environmental benefit might **not pay out**	➢ external environmental costs

Green Nanotechnology has to …

- ➢ … compete with **well established & cheap** technology.
- ➢ … come up with **market-ready solutions** at no loss of comfort.
- ➢ … avoid big **structural changes**.

Cost competitiveness becomes the most important factor unless…

- ➢ the government promotes new technologies by promoting support programmes (NCCR, CTI, FOEN)

12

Summary

- ✓ The Swiss Action Plan is a **cooperative and consensus-based concept**, initiated by governmental agencies, and supported by industry and science organisations.
- ✓ It is a work package for the **sustainable development of nanotechnology** in Switzerland, including research, voluntary agreements, regulation, standardisation and communication.
- ✓ **Nanotechnology is a „key factor“** in the development, implementation and commercialisation of sustainable technologies and its promotion is one of the goals of the Action Plan.

Nanomaterials in EU chemicals legislation: REACH & Co.

Peter van der Zandt,
European Commission, Belgium

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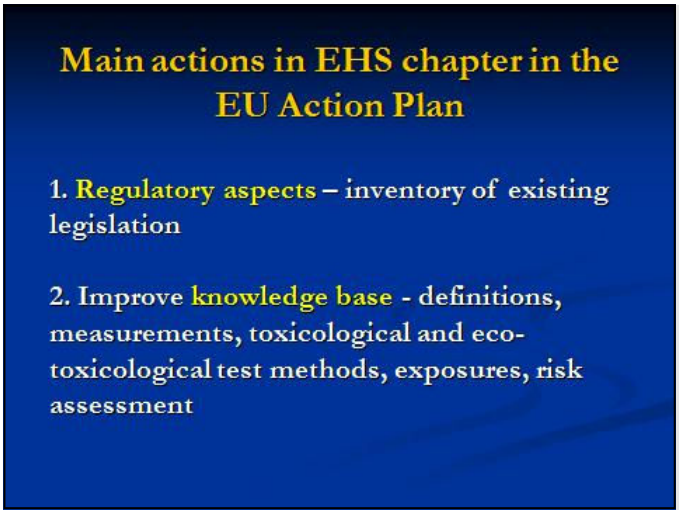

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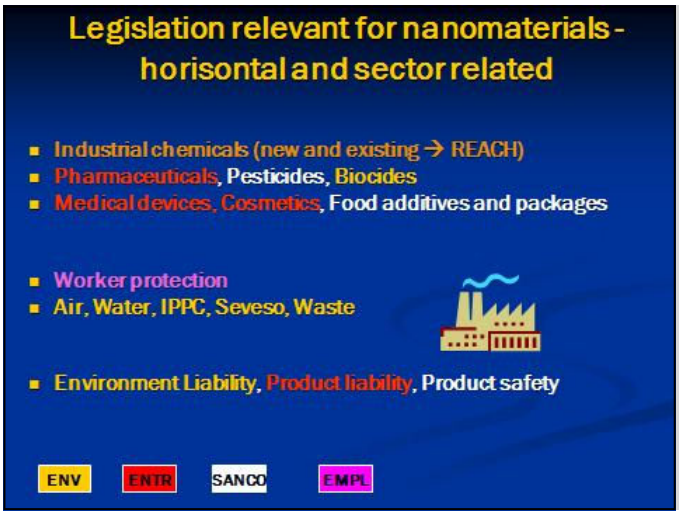

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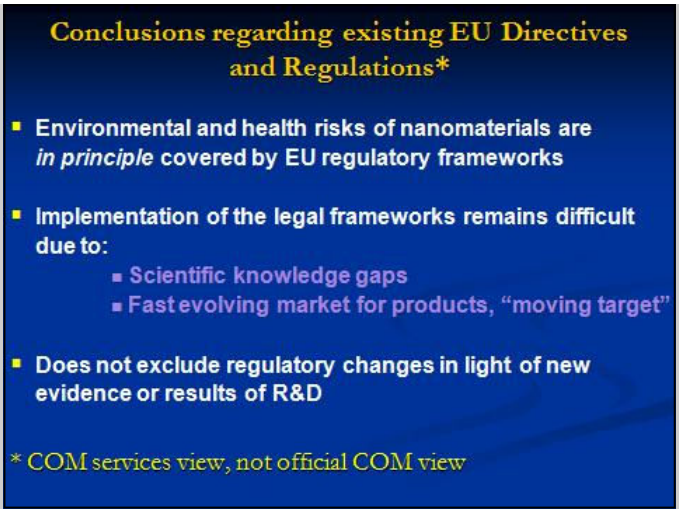

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Identifying knowledge gaps from an E&H perspective

- Nomenclature, definitions, standards
- Data on human health and environmental effects and test methods to generate data
- Data on exposures throughout the lifecycle, exposure assessment methods
- Measurement, characterisation and analytical tools

6

EU Chemicals Legislation

7

EU wg recommendations on existing chemicals legislation

- The decisive criterion whether a nanomaterial is a new or existing substance is the same as for all other substances, i.e. whether or not the substance is on EINECS.
- Nanomaterials having specific properties may require a different classification and labelling compared to the bulk material.
- Invite industry to provide a number of dossiers on different representative nanomaterials, to show what kind of data is available, how risk assessment is being performed and how the risks are controlled.
- For the longer term, review the applicability of testing methods and risk assessment methods at international level (e.g. within the OECD chemicals programme) with active input from industry and contributions from the EU.

8

REACH - key elements

- Registration of substances ≥ 1 tonne/yr
- Increased information and communication throughout the supply chain
- Evaluation of some substances
- Authorisation only for substances of very high concern
- Restrictions - the safety net (Community wide action)
- Agency to efficiently manage system

9

REACH and Nanomaterials

- REACH requirements apply to nanomaterials. REACH does not contain specific provisions for nanomaterials
- On the basis of knowledge development:
  - Guidance for implementation, eg. on safety assessment, may need to incorporate specific elements related to nanomaterials
  - Review REACH at a later stage as appropriate with regard to adequacy to address and manage the safety of nanomaterials (incl. information requirements, assessments and management by industries)

10

OECD Working Party on Safety of Nanomaterials

Established under the Chemicals Committee in September 2006. A work programme 2006-2008 has been endorsed as well as 6 projects:

- Database on environment and health effects
- Research strategy on EHS and international co-ordination
- Safety testing of a set of nanomaterials
- Test guidelines
- Voluntary schemes
- Risk assessment

Overview over international developments and framework USA: Existing regulatory frameworks for consumer products

Dr. Treye A. Thomas, U.S. Consumer Product Safety Commission, USA

Overview - Strategies for Assessing Nanomaterial Health Risks in Consumer Products

Dr. Treye A. Thomas
U.S. Consumer Product Safety Commission, USA

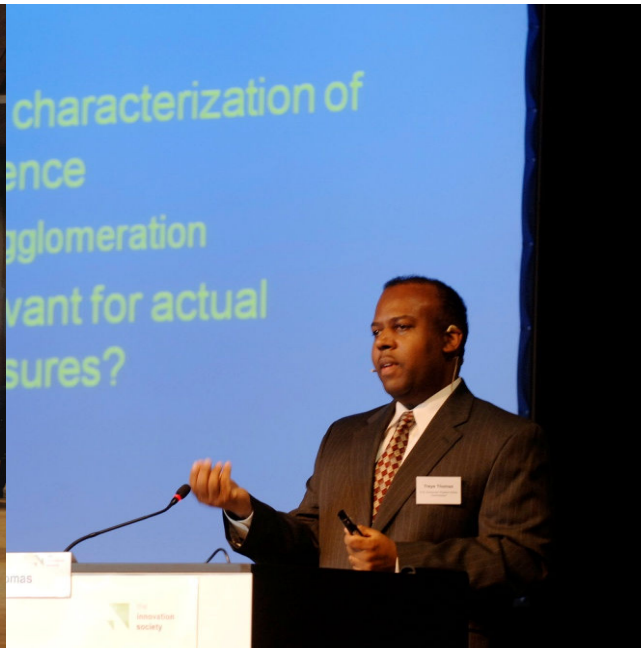
The U.S. Consumer Product Safety Commission (CPSC) is an independent regulatory agency created in 1973. CPSC's jurisdiction includes over 15,000 types of consumer products used in or around the home, except certain items excluded by statute, for example, motor vehicles, tobacco, food, drugs, cosmetics, most medical devices, and pesticides. 15 U.S.C. § 1261 (f)(2). Examples of products that are regulated by CPSC include clothing, hazardous household cleaners and substances, electronic devices, appliances, furnishings, building materials, toys and other juvenile products.

The potential safety and health risks of nanomaterials, as with other compounds that are incorporated into consumer products, can be assessed under existing CPSC statutes, regulations and guidelines. Neither the Consumer Product Safety Act (CPSA) nor the Federal Hazardous Substances Act (FHSA) requires the premarket registration or approval of products. Thus, it is usually not until a product has been distributed in commerce that the CPSC would evaluate a product's potential risk to the public.

Under the CPSA, the staff evaluates a consumer product to determine whether such product contains a defect which creates a "substantial product hazard" or warrants proposing that the Commission set a consumer product safety standard by regulation to prevent or reduce an unreasonable risk. In the absence of an express regulation, as it does with other consumer products, the staff will look to see whether a defective product composed of or containing nanomaterials creates a substantial risk of injury to the public because of, among other factors, the pattern of the defect, the number of defective products distributed in commerce, and the severity of the risk. Manufacturers, retailers and distributors of products composed of nanomaterials have the same reporting obligation as those of other products, namely to report to the Commission immediately if they obtain information that reasonably supports the conclusion that such product fails to comply with an ap-

plicable consumer product safety rule; contains a defect which could create a substantial product hazard; or creates an unreasonable risk of serious injury or death.

The introduction of consumer products containing nanomaterials into the marketplace may require unique exposure and risk assessment strategies. One of the primary data needs will be the identification of the specific nanomaterial in the consumer product. The current definition of a nanomaterial used by federal agencies specifies that the base constituent be between 1 and 100 nm in length. Identifying any potential health hazards from a specific product will require characterization of the materials to which a consumer is exposed during product use, including assessment of the size distribution of the materials released. Once the exposure has been characterized, toxicological data that is appropriate for the particle sizes represented in the exposure assessment will be used in any assessment of health risks.



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Regulation of Products

- Jurisdiction over 15,000 types of products used in or around the home
- Regulatory authority extends to [such products as]: toys, electronic equipment, appliances, clothing/textiles, household cleaners/chemicals, and building materials.
- Exceptions include foods, drugs, cosmetics, medical devices, pesticides, certain radioactive materials, and automobiles.

2

Definitions of Toxicity

- CPSC regulates many chemical hazards under the Federal Hazardous Substances Act (FHSA).
- Under the FHSA, the term "hazardous substance" is defined as:

"Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children."

3

Exposure and Toxicity

- To be considered a "hazardous substance," a substance or product must satisfy a two-part definition.

  It must be "toxic", or present one of the other hazards enumerated in the statute.

  It must have the potential to cause "substantial" illness or injury during or as a result of "reasonably foreseeable handling or use."
- Thus, a potential hazard depends on risk (toxicity and exposure).

4

Assessing Health Risks

- **Population estimates**
  - Variation in use patterns, frequency of use, diversity of products, variation in types of housing
- **Human factors evaluation of consumer interaction**
  - Published studies
  - Other agency guidelines (e.g., EPA Exposure Factors Handbook)
  - Professional judgment
- **Best estimate (50th percentile)**
  - Upper (95th percentile) and lower bound (5th percentile) screening
- **Uncertainty – often assume reasonable worst-case scenario**
- **Reasonably foreseeable misuse**
  - Mouthing by young children
    - In the case of lead jewelry, ingestion by children

5

Estimating Exposure

- Three routes of exposure considered: inhalation, ingestion, dermal
- **Inhalation**: direct monitoring, modeling, surrogate data
- **Ingestion:** extraction with simulated saliva or gastric juices - assume mouthing by children
- **Dermal:** Estimating amount of substance in contact with skin
  - Experiments to quantify material leaching from product
  - Surface area of skin contacted, duration, frequency of contact, thickness of liquid interfacial layer
- **Nanomaterial considerations**
  - Increased bioavailability, disposition in the body (i.e., blood/brain barrier), excretion and body burden

6

Options

- Labeling
- Product Recalls
- Product Bans
- Voluntary Standards
- Mandatory Standards
- Other

7

Products Containing Nanomaterials

Products claiming to contain nanomaterials

- Reported product categories under CPSC jurisdiction that may contain nanomaterials
  - Sports equipment, clothing and textiles, air deodorizers/cleaners, household chemicals, paints, appliances and building materials
- Wilson Center products database identifies over 300 commercial products claiming to contain nanomaterials
  - CPSC, FDA, EPA identified as primary regulatory agencies
  - Woodrow Wilson staff determined that nearly 70% of the selected products were under CPSC jurisdiction
    - Not verified by CPSC staff
- Lux Research reports 148 global corporations with nanotechnology initiatives today, and projects 290 by 2008
  - $32 billion dollars in products sold last year
  - $1 Trillion in 5 – 20 years (Lux Research, NSF)

8

Possible Exposure and Risk Assessment Approaches

- Toxicity data for nanomaterials in product
  - Calculation of ADI
- Determination and characterization of nanomaterial presence
  - Size distribution, agglomeration
- Is toxicity data relevant for actual nanomaterial exposures?

9

Data Needs for Exposure and Risk Assessment of Nanomaterials

- Identify consumer products that contain nanomaterials
- Characterize nanomaterials in a consumer product
- Determine size distribution of particles released from products
  - Toxicity data for those sizes - does toxicity change ?
  - Coatings – does toxicity change?
- Instrumentation
  - Development of analytical protocols
  - Feasibility

10

Summary

- Toxicity and exposure assessment are critical components in assessing potential risks from consumer products
- Approach to regulating products with nanomaterials will likely be similar to approach used to regulate products containing other chemicals
- Need for new toxicity data and exposure assessment (analytical) techniques appropriate for nanomaterials

Nanotechnology, cosmetic and sunscreen safety

Dr. Gerhard Nohynek, L'Oréal Research and Development, France

GREY GOO ON THE SKIN?

Dr. Gerhard J. Nohynek, Ph.D., D.A.B.T.
L'Oréal Research and Development, Worldwide Safety Department, France

Many modern cosmetic or sunscreen products contain nano-sized components. Nanoemulsions are transparent and have unique tactile and texture properties. Nanocapsules, nanosomes, niosomes or liposomes are small vesicles (range: 50 to 5000 nm) consisting of traditional cosmetic materials, and are mainly used to protect light- or oxygen-sensitive cosmetic ingredients. Vesicle materials do not penetrate human skin beyond the superficial layers of the *stratum corneum*. When compared with the skin penetration of ingredients in traditional formulations (solution, gels or creams), nano-sized formulations may enhance or reduce penetration, albeit at a limited order of magnitude.

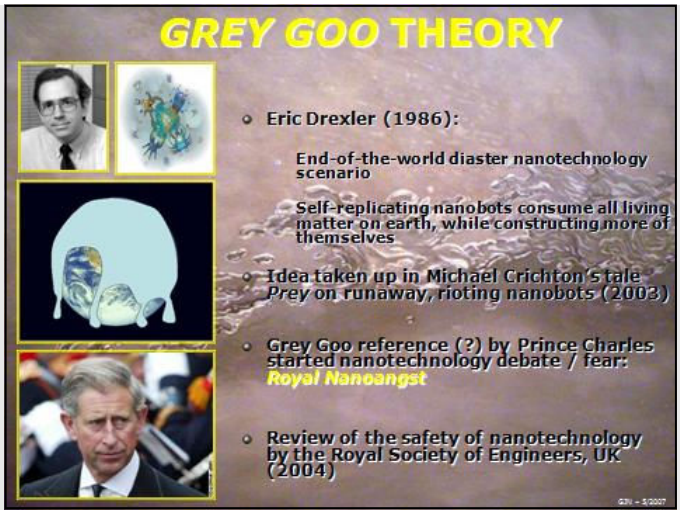
Modern sunscreens contain insoluble titanium dioxide (TiO_2) or zinc oxide (ZnO) nanoparticles (NP), which are colorless and filter UV more efficiently than larger particles. The available evidence suggests that TiO_2 or ZnO nanoparticles do not penetrate into or through normal as well as compromised human skin. The experience of transdermal drug delivery research has shown that significant passive skin penetration may only be achieved for substances combining a low molecular weight, melting point and a favorable $logP_{O/W}$, which excludes insoluble nanoparticles. Oral and topical *in vivo* toxicity tests revealed that TiO_2 and ZnO nanoparticles have low toxicity and are well tolerated on the skin. Cytotoxicity, genotoxicity and photo-genotoxicity studies on TiO_2 nanoparticles found no difference in the safety profile of micro- or nano-sized materials, all of which were non-toxic. Although ZnO particles were suspected to be photo-genotoxic *in vitro*, recent results showed the absence of photo-genotoxic effects.

Published *in vitro* investigations on TiO_2 and other insoluble particles reporting uptake by cells, oxidative cell damage or genotoxicity should be interpreted with caution, since such findings may also be attributed to adverse effects secondary to phagocytosis of mammalian cells exposed to high concentrations of insoluble particles. Results of studies on wear debris particles from surgical implants and

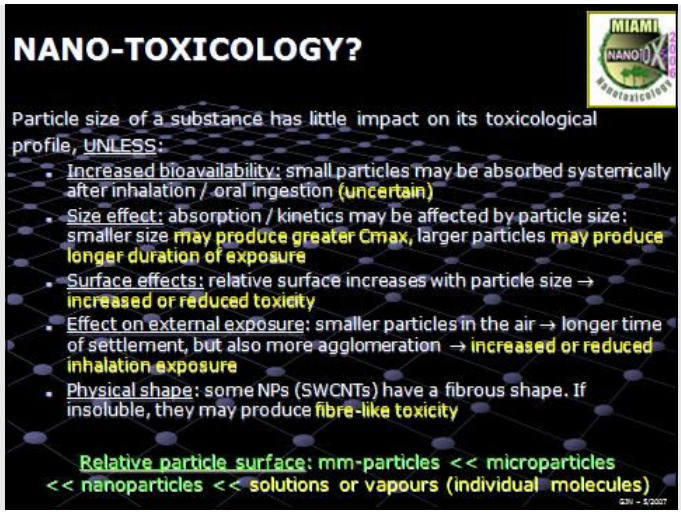
other toxicity studies on insoluble particles rather support the experience of traditional toxicology that the toxicity of small particles is mainly related to their chemistry, rather than their particle size.

There is little evidence supporting a general rule that effects of particles to the skin or other tissues increase with smaller particle size, or produce novel toxicities when compared with those of micro-sized materials. Overall, the weight of current scientific evidence suggests that the use of nano-sized cosmetic or sunscreen ingredients poses no or negligible potential risk to human health.

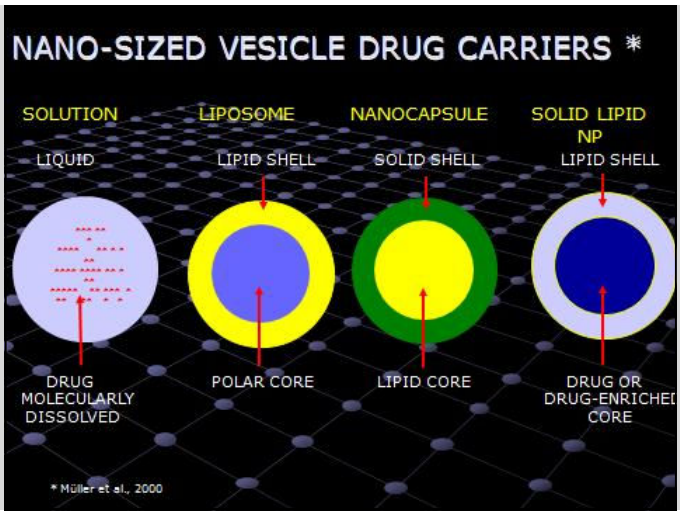
1


GREY GOO THEORY
Eric Drexler (1986):
End-of-the-world diaster nanotechnology scenario
Self-replicating nanobots consume all living matter on earth, while constructing more of themselves
Idea taken up in Michael Crichton's tale Prey on runaway, rioting nanobots (2003)
Grey Goo reference (?) by Prince Charles started nanotechnology debate / fear:
Royal Nanoangst
Review of the safety of nanotechnology by the Royal Society of Engineers, UK (2004)

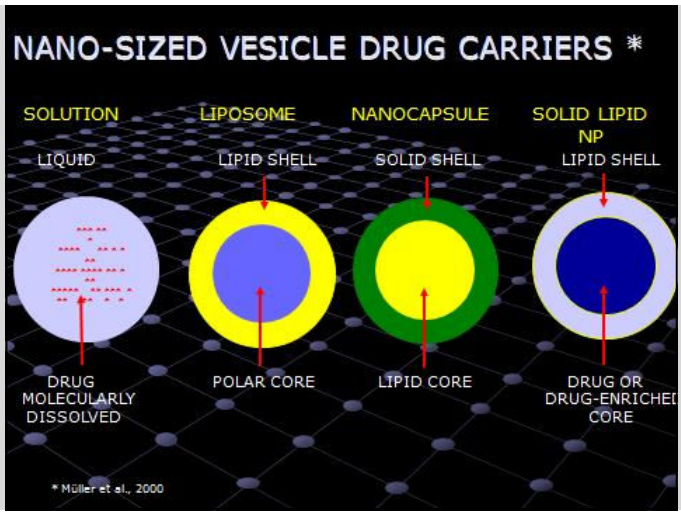
2


NANO-TOXICOLOGY?
MIAMI NANO
Particle size of a substance has little impact on its toxicological profile, UNLESS:
Increased bioavailability: small particles may be absorbed systemically after inhalation / oral ingestion (uncertain)
Size effect: absorption / kinetics may be affected by particle size: smaller size may produce greater Cmax, larger particles may produce longer duration of exposure
Surface effects: relative surface increases with particle size → increased or reduced toxicity
Effect on external exposure: smaller particles in the air → longer time of settlement, but also more agglomeration → increased or reduced inhalation exposure
Physical shape: some NPs (SWCNTs) have a fibrous shape. If insoluble, they may produce fibre-like toxicity
Relative particle surface: mm-particles << microparticles << nanoparticles << solutions or vapours (individual molecules)

3


NANO-SIZED VESICLE DRUG CARRIERS *
SOLUTION
LIQUID
LIPOSOME
LIPID SHELL
NANOCAPSULE
SOLID SHELL
SOLID LIPID NP
LIPID SHELL
DRUG MOLECULARLY DISSOLVED
POLAR CORE
LIPID CORE
DRUG OR DRUG-ENRICHED CORE
* Müller et al., 2000

4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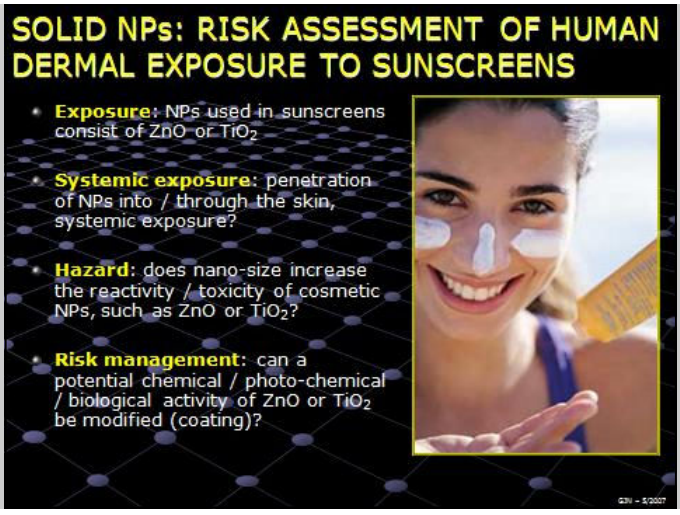
* Müller et al., 2000

5


SOLID NPs: RISK ASSESSMENT OF HUMAN DERMAL EXPOSURE TO SUNSCREENS
Exposure: NPs used in sunscreens consist of ZnO or TiO2
Systemic exposure: penetration of NPs into / through the skin, systemic exposure?
Hazard: does nano-size increase the reactivity / toxicity of cosmetic NPs, such as ZnO or TiO2?
Risk management: can a potential chemical / photo-chemical / biological activity of ZnO or TiO2 be modified (coating)?

6


Transparency of TiO2 Nanoparticle Dispersions
195 60 35 15 10 nm
10nm TiO2 produces transparent dispersions for all skin types.
(Slide made available by KOBO, www.koboproducts.com)

7

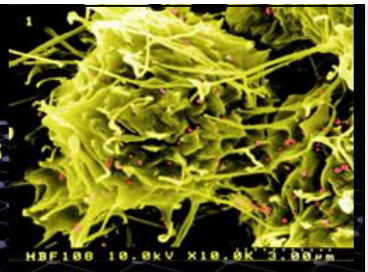
(SOME) PUBLISHED STUDIES ON DERMAL ABSORPTION OF INSOLUBLE NANOPARTICLES: NO PENETRATION

STUDY	MATERIAL	RESULTS
Tan *et al.*, 1996	Microfine TiO_2	No penetration into epidermis / dermis *in vivo*, man
Lademann, 1999	Microfine TiO_2	
Pflücker *et al.*, 2001	TiO_2, 10 and 100 nm	
Schulz *et al.*, 2002	TiO_2, 10 -100 nm, different coatings and shapes	
Alvarez Roman *et al.*, 2004	Polystyrene NPs, 20 and 200 nm	No penetration into epidermis / dermis, accumulation in the follicle orifice, but no penetration into living skin (pig)
EU Nanoderm project (T. Butz, 2005)	Fluorescent particles	No evidence for penetration into living skin (preliminary data, ECETOC, 11/2005)
Gamer *et al.*, 2006	ZnO and TiO_2 (10-200 nm)	No penetration of Zn, ZnO, Ti or TiO_2 porcine skin *in vitro*
Cross et al., 2007	ZnO, 15 and 30 nm, human skin	No penetration into epidermis or dermis
Mavon et al., 2007	TiO_2, 20 bm human skin in vitro and in vivo	No penetration into epidermis or dermis; epidermal artefacts in vitro

CONCLUSION: NO EVIDENCE THAT TOPICALLY APPLIED NPs PENETRATE INTO NORMAL SKIN (NPs will always penetrate less than substance in solution)

8

Phagocytosis of bacteria, viruses, insoluble particles by mammalian cells *

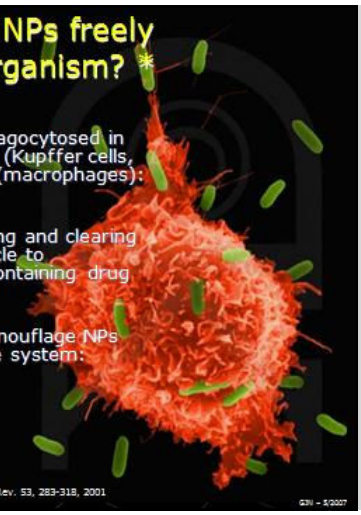


- Mammalian cells in culture tend to phacocytose small insoluble particles
- Release of peroxide and lysomal enzymes → reactive oxygen species → lipid peroxidation → cell damage → cytoxicity → genotoxic effects
- Normal physiological reaction of cells exposed to an excess of insoluble particles, well-known from hip and knee joint implants (wear debris)
- Micro-particles generally more toxic than NP (critical size 0.2 to 0.8 µ)
- Relevance of *in vitro* studies on describing such effects?

* Görög et al. *Artherosclerosis*, 1988

9

Once absorbed, do NPs freely roam around the organism? *



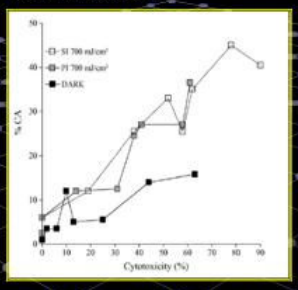
- Intravenous particles are phagocytosed in the blood (monocytes), liver (Kupffer cells, macrophage-like) or spleen (macrophages): « phagocytic barrier »
- Highly efficient barrier filtering and clearing small particles: major obstacle to intravenous NP- or vesicle-containing drug formulations
- Major research efforts to camouflage NPs against detection by immune system: « stealth particles »

* Moghimi et al., Pharmacol. Rev. 53, 283-318, 2001

10

PSEUDO-PHOTO-CLASTOGENICITY of ZnO

Incidence of chromosome aberrations (% cells with CA) at equitoxic ZnO concentrations in the dark (non-irradiated), pre-irradiated (PI) or simultaneously-irradiated (SI) CHO cells (UV dose: 700 mJ/cm²) *



Clastogenicity, photo-clastogenicity or pseudo-photo-clastogenicity: Genotoxic effects of zinc oxide in the dark, in pre-irradiated or simultaneously irradiated Chinese hamster ovary cells

Eric K. Dufour[a,*], Tenkalikandram Kumaravel[b], Gerhard J. Nohynek[a], David Kirkland[b], Hervé Toutain[a]

CONCLUSION: effect of ZnO + UV due to an increased sensitivity of the cells subsequent to UV irradiation

N.B.: >50% OF ALL TESTED SUBSTANCES ARE CLASTOGENIC *IN VITRO*...

11

HAZARDS OF NP IN PERSPECTIVE

- Major potential human health hazard from NP: inhalation exposure
- Indoor emissions represent 50-80% of human exposure to NP (10.000 to 240.000 NP/mL air)
- Polluted city air: 10.000 to 50.000 NP/mL air
- EMISSION SOURCES
  - Burning natural gas
  - Candles, toasters
  - Oven roasts, pan frying
- Man has lived with NP since the invention of fire
- Many initial inhalation findings (systemic exposure to NP, toxicity of NP > µP) were not confirmed by recent studies

12

NANO-HYPE and NANO-FACTS

HYPE	FACT
Exposure to nanomaterials is a new human health risk	Human exposure to nanomaterials is as old as the invention of fire, maybe older
NPs are carcinogenic after inhalation	High concs. of inert µPs or NPs (TiO_2, CB) carcinogenic in rats (chronic lung overload): irrelevant for man under normal exposure conditions
Inhalation of NPs produces new toxicities. NPs more toxic than MPs	Some inert NP (TiO_2, CB) somewhat more toxic than µPs, others (SiO_2, ZnO) equally or less toxic. No novel toxic effects. New study showed same effect of TiO_2 NP and µP (Warheit et al., 2006)
Inhalation of NPs produces asbestos-like carcinogenicity	SWCNT or MWCNT are µ-sized, insoluble fibres and produce toxicities typical for fibres
NPs penetrate through the skin, enter the circulation and produce systemic toxicity	No evidence for penetration into or through the living skin. No known mechanism producing active penetration. NP in blood are cleared by macrophages.
NPs penetrate into living cells, e.g. brain cells (*in vitro*)	Many mammalian cells have phago-/endocytic capacity (active uptake).
NP produce oxidative damage and genotoxic effects in skin, somatic or brain cells	Normal physiological sequel of mammalian cells phagocytosing excess of insoluble particles
NPs (fullerenes) produce brain damage in fish	Fullerenes reported to produce ↑ lipid peroxidation in the brain, but ↓ in the liver. No µP-controls included in the study. Study of uncertain value. New studies show no toxicity.
NANO-TOXICOLOGY?	***LITTLE EVIDENCE FOR TYPICAL NP TOXICITY OR NOVEL HAZARDS***

OFTEN, PUBLISHED STUDIES ON NPs LACK µ-SIZED CONTROL GROUPS: ADVERSE EFFECTS NANO- OR TEST SUBSTANCE-RELATED?

Micelle inside ingredients by miVital

Dr. Paul Schneider, miVital Switzerland

Micelle inside: Ingredients by miVital
Dr. Paul Schneider
miVital, Switzerland

By nutrition we supply all vital substances to our body. Absorption takes place via intestine cells, which are covered with water. Only water-soluble substances, which can permeate a water film, are directly absorbed. The bioavailability of highly water-soluble substances, such as vitamin C is therefore optimal. Fat-soluble substances, such as Coenzyme Q10, are resorbed with the aid of gall salts via micelle formation in the small intestine. This process is associated with low bioavailability of the relevant substances. For example, anyone ingesting Coenzyme Q10 loses 75% of this valuable substance. Three quarters are excreted unused.

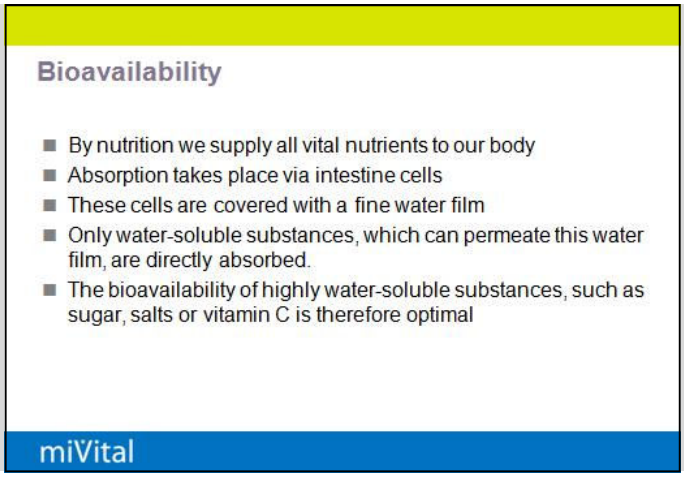
Based on its unique, patent pending technology miVital converts fat -soluble substances into a water-soluble micelled form. The micelles have a diameter between twenty and forty nanometers. However, the body's own intestinal micelle formation process is not necessary. **The benefit is a much higher bioavailability of the relevant substances.**
The substances transported in the product micelles remain chemically completely unchanged. miVital does not employ nanoparticles, rather it is concerned with the transport of vital substances by defined quality encapsulation in the nanometre range according to Nature's example, consequently to this, creating a nanoscaled structure.
Micelles are completely water-soluble and can be integrated directly and irrespective of recipe characteristics into final products. They are stable with respect to pH and temperature and even shear forces. In conclusion the product micelle is an optimum carrier system of hydrophobic substances for a higher and faster intestinal resorption of vital ingredients.

Vitality is an enormous trend creating a fast growing market. Based on the unique bioavailability of micelle inside ingredients products with genuine USP's (USP = unique selling proposition) can be launched by miVital partners. The most important retailer in Switzerland assumes leadership in the "vitality" market and conse-

quently has a partnership with miVital for the Swiss food market. For poorly water-soluble substances, the quoted advantages of the micellation open up completely new application possibilities in the foodstuffs, cosmetics and pharmaceuticals sectors.

Micelle inside ingredients: an advantage for future miVital partners and a perceptible increase in value for the consumer, achieving a noticeably better effect with the same quantity of active ingredients.

1



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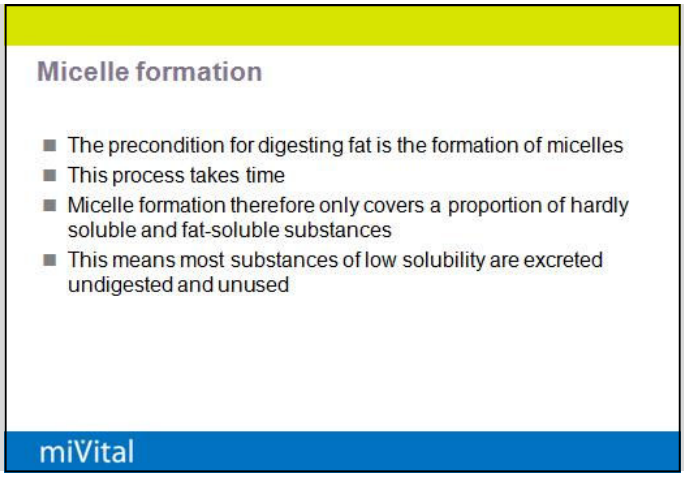

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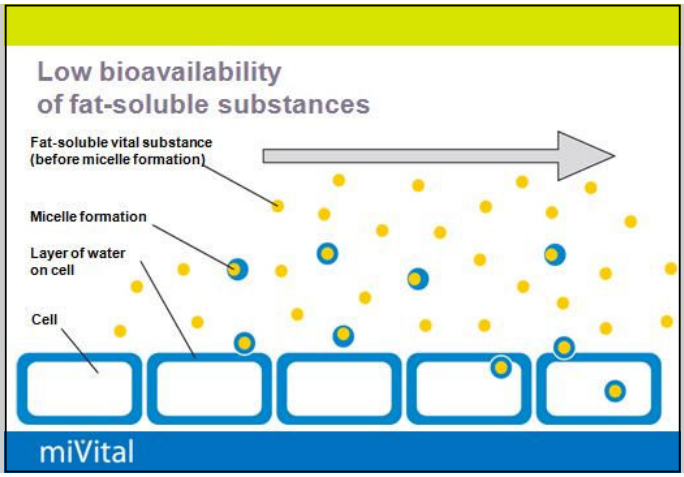

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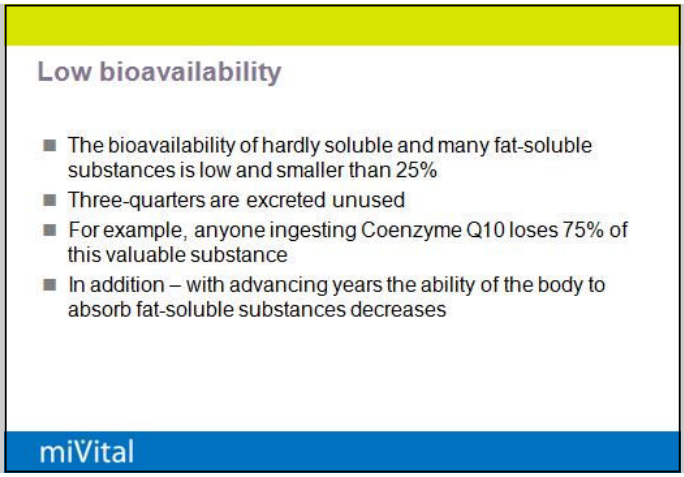


5

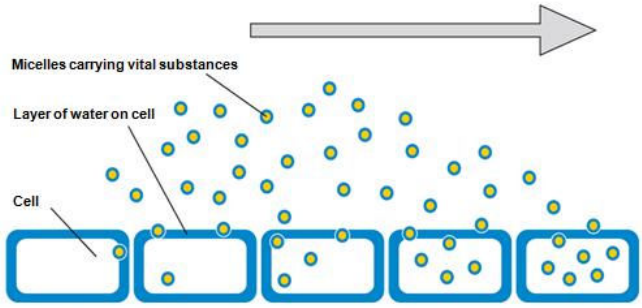
Augmentation of bioavailability up to 100%

- Fat-soluble substances are converted into a water-soluble form
- The body's own micelle formation process is no longer necessary
- This micelle formation process can be applied to the most diverse fat-soluble substances
- The benefit – a much higher bioavailability compared to a non treated form

miVital

6

High Bioavailability



miVital

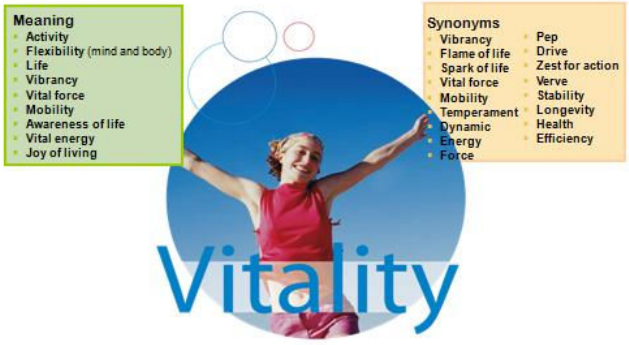
7

Unique process

- The multiple benefits of the water-soluble pharmaceutical form are scientifically documented
- Slightly soluble and fat-soluble substances can be added to the final product simply and in tasteless form
- High thermal, mechanical and sensory stability
- A patent is pending for this innovative micelle formation procedure

miVital

8



miVital

9

Products on the Swiss market

MIGROS
Partner of miVital

miVital

10

Products with coenzyme Q10

miVital

Nanoparticles in drug delivery: Potential avenues and issues

Dr. Martin Kuster, Novartis International AG

Nanoparticles in drug delivery: potential avenues and issues
Dr. Martin Kuster, MD MOH
Novartis International AG, Switzerland

Since ancient times people used medications to treat illnesses. A drug is a substance that has the chemical possibility to pass through membranes and reach a target organ in order to relieve symptoms and cure the person. With time, the application methods got refined, but the general basic principle of pharmacology remained the same: The substance must be soluble to a certain extent in order to be taken up orally, transdermally, parenterally or by inhalation.

However, nano-particles as transport vehicles of drugs have the potential to change the existing paradigms of treating people. Their physico-chemical properties will allow an easier passing of membranes. As small corpuscules, they can be engineered in a way, that they target certain parts of the body. This will lead to better patient compliance, reduced need of drugs over all and hence better safety profiles and better therapeutic successes. These nanoparticles, most come in a size around 100 nm diameter, can be split into biodegradable particles (lipids, proteins, sugar-polymers) and non-biodegradable ones (e.g. carbon nanotubes, fullerenes). Of the foreseeable particulates of the near future, lipid vesicles and sugar/protein polymers are most advanced in research for therapeutics. For diagnostics (especially contrast enhancers) carbon nanotubes are under evaluation.

The issue with the nanoparticles is the unknown toxicology especially of the non-biodegradable ones. On nano-scale, innocuous substances can develop e.g. caustic properties and many lead to oxidative stress in tissues and therefore to acute and chronic inflammation most often combined with scar formation in the target organ. Several well known occupational diseases can serve as clinical models of these effects, e.g. silicosis.

Regulators and NGO's pick up on nanoparticles and -technology. The different properties of nanoparticles mandate new sets of tests, as the classical toxicological test are bound not to deliver meaningful results.

In summary,

- nanoparticles and even –technology are the future of drug delivery for many drugs and indications for treatments
- behavior of nanoparticles is different from the same material in micrometer scale
- biodegradable substances should not elicit any effects, but the desired transport of a substance
- non-biodegradable substances need to be characterized towards their chemical, physical, toxicological and biological effects, before being introduced into people
- nanoparticles are expected to reduce the side-effects due to targeted drug delivery and/or reduced amount of drug needed

1

Fate of medications
Absorption/Distribution/Metabolism/Excretion

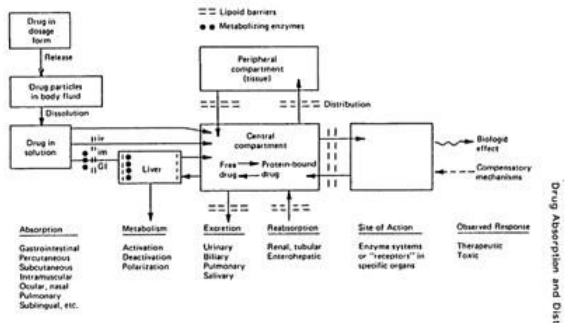


Figure 1 Diagram illustrating the factors that influence the onset, duration, and intensity of drug effects. Adapted from Barr [46], courtesy of the American Journal of Pharmaceutical Education.

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Drug Delivery Systems
Current status

- Oral/rectal:
  - Composition of the tablet/capsule/suppository can enhance or retard the uptake of a water soluble drug
- Injections:
  - Ensures direct access to body systems; certain substances can delay release
- Trans dermal:
  - Use solvents to carry medication through skin.
- Inhalation:
  - Delivery system is the inhaler. Uptake in lungs possible, but not easy to steer systemic effects

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Drug Delivery Systems
What can be improved with novel systems

- Improve efficacy by increased Bio-availability
- Improve safety by more constant plasma levels and less peaks
- Decrease side effects due to targeted delivery
- Improve patient convenience and compliance by
  - reduced administration frequency
  - combination products
  - smaller tablets or injection volumes
- Product differentiation & patent extension

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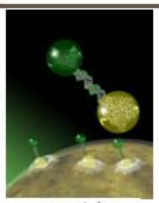
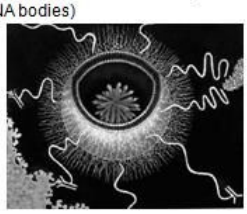
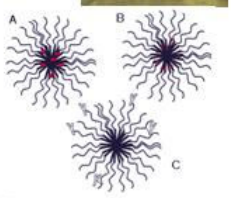
Nanoparticle Drug delivery Systems
What is available: biodegradable

- Biodegradable:
  - Proteins: Virosomes
  - Polymers: Polylacto-gluconates, others
  - Liposomes ("lipid-bubbles"), Emulsions
  - Others (combination of the above; RNA/DNA bodies)

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Nanoparticle Drug delivery Systems
Lipid based, commercially available medication

- **Sandimmun/Neoral**
- Drink solution
- Soft gelatin capsules

- Product is a "Microemulsion" preconcentrate
- Self assembles in situ to an emulsion in the 30 nm size range upon dilution with water or gastric fluid
- Effect: increased bioavailability, decreased variability

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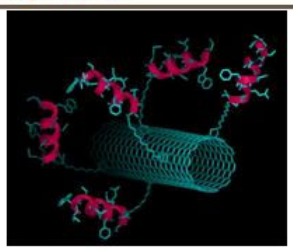
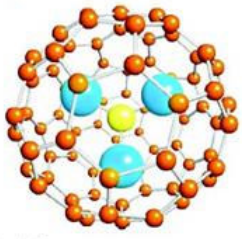
Nanoparticle Drug delivery Systems
What is available: not biodegradable

- Tubes/balls:
  - Single walled carbon nanotubes
  - Multiwalled CNT
  - C-60/C-80 Fullerenes
  - Others

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Issues of Nanoparticles
Academic discussion

Awareness of knowledge	Content of knowledge (hazards and controls)
1. What we know we know	Health effects of ultrafines, air pollution, and fibers How to control ultrafine particles in the workplace Importance of size, surface area, and surface characteristics Serious health effects of some nanoparticles in animals Translocation of some nanomaterials along the olfactory nerve in animals
2. What we know we don't know	Measurement and characterization techniques Hazards of newly engineered particles Extent of translocation in the body Interaction with contaminants in the workplace Importance of dermal exposure Health effects in workers Risks to workers Effectiveness of controls Advisability of medical screening and biological monitoring Risk to workers' families
3. What we don't know we know	Extensive experience available in controlling hazardous substances and agents (radiation, biological agents, pharmaceuticals) that can be applicable to nanoparticles Proprietary nanoparticle information Lessons from previous "new" technologies
4. What we don't know we don't know	Unanticipated new hazards Unanticipated new controls Wrong assumptions about hazards and controls

Adapted from Drew (1999) and Schulte et al. (2004).

Source: Schulte, Environmental Health Perspectives 1/2007

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Nanoparticles
Future politically

- A wide-spread discussion on the advantages and dangers of nanoparticles and – technology started in US and EU
- Industry has high hopes; NGO's caution very much
- As a revolutionary technology, the commonly used risk-assessments fail at present, we need as revolutionary test methods
- Regulators start to learn and keep a pragmatic approach
- There are proven generic protection measures for workers and environment alike

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Nanoparticles
Future technologically

- Nanoparticles will play an important role soon in commercially available medications
- The preferred start of development of such particles should be bio-degradable materials
- With increasing knowledge and engineering, non-degradable particles can be introduced (e.g. for targeted drug delivery)

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Nanoparticle Drug delivery Systems
What is different

Classical DDS

- Tablet: have a constant uptake of the medication
- Injection: get material across intestinal barrier
- Inhalation: bring enough material into the bronchial tree or lungs

Nanoparticle

- Can be used in all three application forms!
- Is used to ease the transport of a chemical across all barriers, incl BBB, due to small size
- Can be used for targetted application: find a special spot in the body

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Examples of nanotechnology based products in healthcare

- Gadolinium chelate for MRI imaging
- Iron oxide particles for MRI Imaging (Feridex)
- Nanoparticles based on NanoCrystal Technology (Rapamune, Emend)
- Liposomes (Doxil, Daunoxome)
- Microemulsion (Sandimmun/Neoral)
- Albumin bound nanoparticles (Abraxane)

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Summary

- Nanoparticles and even –technology are the future of drug delivery for many drugs and indications for treatments
- Behavior of nanoparticles is different from the same material in mikro-meter scale
- Biodegradable substances should not elicit any effects, but the desired transport of a substance
- Non-biodegradable substances need to be characterized towards their chemical, physical, toxicological and biological effects, before being introduced into people
- Overall, it is expected to reduce the side-effects due to targeted drug delivery and/or reduced amount of drug needed

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Insuring nano: Perspective of MunichRe

Dr. Gerhard Schmid, MunichRe, Germany

Insuring nano – Perspective of MunichRe
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Need to gauge the risk

The application of nanotechnology products and processes could bring about a whole new dimension in personal injury, property damage and pure financial losses as well as third-party liability risks, for instance in product, environmental and third-party liability.

From the underwriting point of view, this "risk of change" arises because, as scientific knowledge increases, defects are discovered which are hidden in new products or processes.

This leads to

- fundamentally new types of loss scenarios (resulting from new material properties),
- exponentiation of existing loss potentials (incidence and major claims risk, including the question of regulation),
- more stringent bases of liability, as a result of changing legislation and jurisprudence

This applies particularly because under liability law in many countries, third-party liability does not depend only on whether the apparently responsible party is at fault (fault-based liability). On the contrary, such liability also exists in cases where neither user nor manufacturer of nanotechnology products and processes had reason to foresee a risk of loss and where they were acting in accordance with the state of the art and science applicable at the time (no-fault liability).

In particular, **product liability** is the key question today and could take on new dimensions in view of the complexity of the potential applications of nanotechnology products and processes. Basically, we are dealing with two distinct groups (passive and active nano products).

Passive nanotechnology products such as surface coatings, powders or similar products have already been manufactured in the

past using non-nanotechnology methods such as the so-called colloid chemistry. These products often feature the following much-debated causes of loss:

- Development errors
- Design errors
- Faulty manufacture
- Information errors
- Product monitoring

Active nanotechnology products are able to act autonomously. Defects in active nanotechnology products may be caused by the factors referred to above. However, the active products differ significantly from their passive counterparts inasmuch as they are able to move around in the environment independently.

The following factors are a basic guide:

Monitoring and retrievability

On the one hand, progress in nanotechnology increases the area of risk: in the case of the passive products through possible combinations of various material properties; with active products, mainly through their self-organization ability and the consequent incalculability regarding bodily injury, property damage and financial loss.

On the other hand, it is that very progress in the realm of passive and active products which affirms society's claim to an even higher and better-protected standard of living. This mentality is flanked by product liability laws which are constantly being adapted. It is true that consumers are better protected in this way but, at the same time, it tends to encourage claims consciousness.

Product recall

In view of the innovative nature of the manufacturing methods and consequently increased risk of teething problems, there are likely to be more frequent product recalls. As recalls are not covered under product liability as a general principle, insurance companies can expect an increasing demand for product recall policies. Moreover, a major technological effort is required to tag nanotechnology products and processes. This means that the manufacturer can only fulfill his duty to monitor the product to a limited extent; tracing the products is virtually impossible.

Public liability

In some countries product liability is incorporated into public liability. This increases the significance of public liability as far as nanotechnology products and processes are concerned.

From the point of view of the insurance industry at least three aspects then increase the risk:

- As legislation strengthens the hand of the aggrieved party, the risk that companies which produce active nanotechnology products will be presented with a claim in the event of loss is statistically increased (cf. no-fault liability in the case of Environmental Liability Act facilities).
- More stringent liability standards will apply to the manufacturers of active nanotechnology products.
- Where the manufacture of active products is concerned, the consumer-friendly interpretation of those standards will further increase the third-party liability risk.

Environmental impairment liability

The manufacture of nanotechnology products will aggravate the conventional risks of third-party losses and damage to natural resources. Not only people, property and capital but also the environmental constituents of earth, air and water are threatened. It is though advisable to assess each risk on its own merits, particularly since we lack experience with losses of this type.

Workers' compensation

The special features of nanotechnology with its infinitely small-scale products make it essential that sterile, clean room technology working conditions be provided to protect employees. Active nanotechnology products or nano particles might then be released during manufacture, endangering the lives of workers and environment.

Medical malpractice

Medical malpractice insurance for hospitals and community-based physicians will doubtless be subjected to increased risk of loss due to the use of nanotechnology.

- Nanotechnology changes atoms and molecules and so encroaches on a sensitive area which is prone to errors and oversights, the type of therapy being brand new.
- There may also be unforeseeable interactions with other, possibly gene technology-type, therapies.
- Nanotechnologically created products, which can sometimes have unpredictable effects, are administered to patients.

The real risk lies in our ability to control nanotechnology. This control cannot be achieved by devising new insurance concepts nor is it logically possible to calculate suitable premiums, risk loadings or rebates as long as we are unable to estimate the potential claims cost. Consequently, we should concentrate on developing risk management tools designed to prevent and reduce losses.

This is an area where the insurance industry is reliant on cooperation between scientists and safety engineers: with the aid of technical and scientific data, the essential issues and problems of nanotechnology can be analyzed and evaluated and condensed into a product safety and crisis management system. The aim of risk

management is, thus, to reduce the risk to such an extent that the third-party liability insurer covers only the residual risk. Both in-house and external expertise are required to determine the scope of this risk. However, what is even more important is to establish an ongoing dialogue between insurers and the manufacturers and consumers of nano products and procedures, so as to reduce the risk for all concerned.

Specifically, risk management should cover the following:

- Technological assessment and an appraisal of the effects of each nanotechnologically produced article.
- Risk management system including loss prevention strategy, quality assurance system and crisis management plan
- Use of active nanotechnology products with guaranteed, continuous monitoring.
- Lifecycle-monitoring obligation on the manufacturer and devising of recall strategies and technical options.
- Setting up of discussion and decision-making organs on social, corporate, ethical and political levels, to give all interested parties a chance to voice an opinion.

1

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Risks of nanotechnology products for consumers

Risks from nanotechnology may occur

- in the production process
- through product consumption
- during waste disposal

The German Federal Institute for Risk Assessment has grouped the current major consumer risks into application categories:

- Surfaces - Food - Cosmetics - Textiles

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2

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Possible threat scenario 1

"Blood-brain barrier"

- Nanoparticles are absorbed through the skin
- Free particles become mobile
- Particles cross the blood-brain barrier
- They accumulate in the brain, causing neurological diseases

➡ **Conceivable impact on**

- Bodily injury/consequential & pure financial losses
- Product liability, recall, health & life insurance

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3

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Risk identification

- Keeping a record of companies and other institutions involved in nanotechnology
- Segmentation by field of business
- Analysing the individual sectors to identify the main risks
- Compiling special-purpose risk questionnaires

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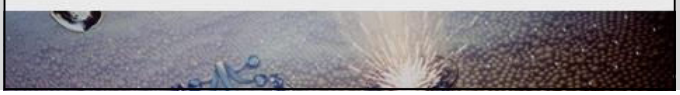
Risk evaluation

- Assessing the occurrence probability and extent of potential losses using purpose-designed risk matrixes
- Systemic risk identification
- Fault tree analysis



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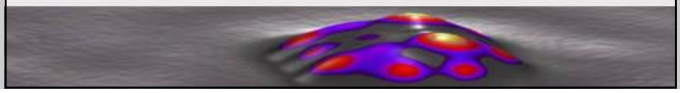
Loss potentials: Sol-gel vs. new nanotechnology Same story as always with new products?

Thesis

- Fundamentally new types of loss scenario (for example resulting from new material properties, such as magnetic fluids) which did not exist in the past
- Exponentiation of existing loss potentials (incidence and major claims risk, including the issue of regulation)
- More stringent bases of liability as a result of changing legislation and jurisprudence



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Affected insurance lines

- **Liability insurance**
  - Public liability insurance
  - Environmental liability insurance
  - Workers' compensation insurance
  - Product liability insurance and recall insurance
  - Liability insurance for water damage
  - Professional indemnity insurance and D&O insurance

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7

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Affected insurance lines

- **Liability insurance**
  - Motor liability and motor own damage insurance
  - Medical malpractice insurance
  - Homeowners' and householders' liability insurance
  - Owner's and contractor's protective liability insurance
  - Personal liability insurance
  - Liability insurance for pure financial losses

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8

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Affected insurance lines

- **Agriculture**
- **Life, health**
- **Private health insurance**
- **Property insurance** (buildings, operations, fire, FBI, MBI, multi-risk)
  - Householders' insurance
  - Homeowners insurance
  - Fidelity guarantee insurance

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9

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Affected insurance lines

- **Engineering insurances**
  - Machinering insurance
  - Electronic equipment insurance
  - Erection all risks insurance
  - Machinery/electronic equipment loss of profits/business interruption insurance
  - Machinery/electronic equipment increased cost of working insurance
- **Marine insurance, aviation insurance**

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10

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Hot topics in the insurance industry

- Product liability and recall of faulty products
  - Development errors
  - Design errors
  - Faulty manufacture
  - Information errors
  - Product monitoring and the retrievability
- Environmental liability
- Worker´s compensation
- Medical malpractice
- Passive and active nanoproducts

Dr. Gerhard Schmid 22

11

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Measures

- Technological assessment and appraisal of the effects of each nanotechnologically produced article
- Risk-management system including loss-prevention strategy, quality-assurance system and crisis-management plan
- Use of active nanotechnology products with guaranteed, continuous monitoring
- Lifecycle-monitoring obligation on the part of the manufacturer and devising of recall strategies and technical options

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12

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>> Measures

- Formulation of retrievability strategies and technological options
- Setting up of discussion and decision-making organs on social, corporate, ethical and political levels, to give all interested parties a chance to voice an opinion
- Data collection and early-warning system via the internet

Dr. Gerhard Schmid 25

Buying nano: What consumers want to know

Monika Büning, Federation of German Consumer Organisations

Buying Nano – What Consumers Want To Know
Monika Büning
Federation of German Consumer Organisations (vzbv), Germany

Consumers want to know what they are buying - they want to buy safe and secure products.

Speaking about nanoproducts and what consumers want to know, we should start with the point of sale: Consumers are buying products labelled “nano”, but in fact it does not mean that there is nano inside. Sometimes the companies use the term “nano” just to promote their products but they do not use nanoparticles, and sometimes it is the other way round.

In different consumer dialogues in Germany, the United Kingdom and in Switzerland, the consumers emphasized that they want to know whether there are nanomaterials in the product they buy. The consumers emphasized in all the different countries that they want a clear labelling on the products.

What does this mean for consumer protection?

First of all we need a clear definition of nanomaterials and an obligation for the producers to declare when a product contains nanoparticles – and we need a prohibition to use the word “nano” on the package, if there is no nano inside.

It is important that the products getting on the market are safe – that is a fundamental requirement. But the next step is to declare on a product that nanoparticles are inside, because the consumer should always have freedom of choice. If he does not want to buy a product with nanoparticles inside, he should have the possibility to do so.

We have to discuss how to declare it. On cosmetics, a short notice would be enough. On food, it could be like it is on food containing GMO. On textiles it is not so easy to find a good solution, because we do not even have a regulation to declare which chemicals are used while producing the textile.

Last but not least we need good working market surveillance. If there is no adequate control there will always be a misuse of the regulations and laws. For this we need measuring methods etc.

1

verbraucherzentrale Bundesverband

The Federation of German Consumer Organisations - vzbv

- vzbv is a **non-governmental organisation** acting as an umbrella for 40 German consumer associations.
- We **represent the interests of consumers** in public and vis-à-vis legislators, the private sector and civil society.
- Our goal is to **protect and empower the consumer**.
- Consumer advice is provided at a regional level by the 16 consumer centres of the German states (Verbraucherzentralen), while product testing is undertaken by our supporting member Stiftung Warentest.

2

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Does the consumer know…

…that he buys Nano?

Yes and No…

3

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…because

- there are producers using the word „nano" on the label – but there is no nano inside
- there are products containing nanomaterials, but the producers do not mention that

4

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What consumers want to know - different attributes of products

- Distinction between three different attributes related to most products
- Search attributes
- Experience attributes
- Trust attributes

5

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What consumers want to know? Results of Consumer Dialogues and Conferences

- Discussion about ethical, social and environmental impacts of nanotechnologies
- „Call for nanoparticle testing before being allowed into the environment" (NanoJury UK)
- Obligation to declare „Nano" in products (Transparancy)

6

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Demands of the Federation of German Consumer Organisations

- A clear definition on the international level
- Transparency and a clear labelling on products
- A prohibition to declare that there is Nano inside if it is not
- An efficient market surveillance

Selling nano: How the retailers are dealing with nanoproducts

Del Stark, European Nanotechnology Trade Association, Great Britain

Selling Nano
Del Stark
European Nanotechnology Trade Association, Great Britain

The European Nanotechnology Trade Alliance (ENTA) acts as the voice for industry regarding nanotechnology. ENTA offers an integrated programme aimed at promoting the benefits of nanotechnology and mitigating regulatory and reputational risk for the whole industry and supporting all actions that ensure new nanotechnologies are developed in a safe and responsible manner.

In addition to the above, ENTA represents the interests of nanotechnology businesses across Europe and acts to bridge the gap between industry, governments, science, and importantly, the public in promoting the benefits of nanotechnology.

Some examples of ENTA members and their exciting new products include: Thomas Swan and Co who are manufacturing single walled carbon nanotubes, a revolutionary new material, for energy storage and other applications; QinetiQ Nanomaterials who are examining the possibility of combating bird flu using specially designed nanoparticles; and NanoCover Scandinavia A/S who are developing revolutionary nanotechnology based surface applications. These and many other companies are involved in making new products and devices, based on nanotechnology, that have the potential to greatly benefit society.

In today's talk I will elaborate some on the EC's nanotechnology strategy, and share views on safety and the regulator's interests, but primarily focus on NanoCover Scandinavia A/S, a company that is acting to protect people's health and safety by ensuring risks regarding their products are known. The talk will cover topics such as getting products to market, correspondence with customers, regulation and liability.

1

ENTA

- Established in 2005
- Industry funded – no government funding
- Allow industry the opportunity to invest in an integrated programme aimed at promoting the benefits of nanotechnology and mitigating regulatory and reputational risk for the whole industry
- Interface with the public, the media, government and bodies actively involved in determining regulatory framework
- Ensure new nanotechnologies are developed in a safe and responsible manner
- 50+ members in 12 member states
- Supported by scientific advisory board

ENTA
The European Nanotechnology Trade Alliance
www.euronanotrade.com

2

5. Integrating the Societal Dimension: Addressing Expectations and Concerns

strategy

- *Due attention should be paid to the integrating societal aspects into nanotechnology R&D*
- *Europe should pursue an open and proactive approach to governance in nanotechnology R&D*
- *A dialogue with EU citizens and consumers should be encouraged to promote informed judgement*
- *The Commission reaffirms its commitment to ethical principles*
- *The responsible and transparent development of nanotechnology is essential for public confidence*

SOURCE: European Commission

3

Member Activities

- ENTA members such as NanoCover who develop novel coatings, Thomas Swan who manufacture single walled nanotubes for energy storage applications and QinetiQ Nanomaterials who are studying how to combat bird flu with nanoparticles are making new innovative products and devices which have the potential to greatly benefit society. One of newest members, NanoGap are making exciting new materials.

NanoCover — Keeps nice things nic
QinetiQ
NANOGAP SUBnm POWDERS

- They are all taking considerable care to ensure that these activities are managed and monitored in a responsible way.

4

In Conclusion…

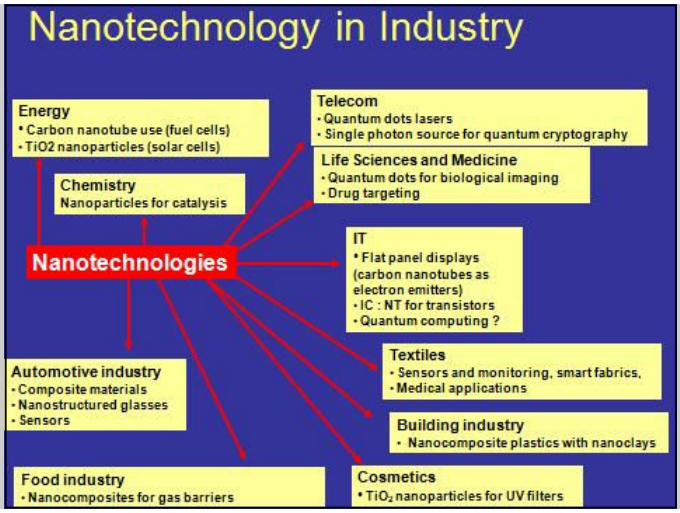
- ENTA represents nanotechnology businesses across Europe and governments should support nanotechnology research and development and recognise the business and societal benefits. Nanotechnology regulation frameworks should not stifle innovation.

Message to Industry:

- The coming months will be a vital period in shaping the future development of policy and applications of nanotechnologies…
  - It's an excellent time to invest in ENTA.

5

Nanotechnology in Industry



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ENTA's View

Relationship with the European Commission:

- It is the intention of ENTA to provide expert opinion and advice regarding the European Commission's Action Plan for Nanosciences and Nanotechnologies.
- Offer input to EU projects when needed and speaking on behalf of industry.

7

ENTA's View

- **Safety is a necessity and industry is working in a responsible manner.**
- **Industry feels current regulations are working and review is a necessary process.**
- **New policies, statutes, legislation, regulations and or amendments must be evidence based and proportionate.**

8

ENTA's View

- **Industry is open to discuss concerns with NGOs and we are open to meetings and open debate.**
- **It would be nice if the NGOs would come to the table as they often decline invitations to participate in talks.**
- **NGO views are important and we value their input to the process in the development of responsible nanotechnology.**

9

Moving forward: reaping the rewards and all the benefits

- Policy Makers Note:
  - Any new policy must provide a fair framework that enables the EU to compete effectively on the world stage
  - Policy must assist with the harmonization of environmental, health, and safety issues related to nanomaterials and must be evidence based
  - ENTA will be here to give the industry perspective while:
    - *promoting the benefits of nanotechnology*
    - *mitigating regulatory and reputational risk for the whole industry*
    - *supporting all actions that ensure new nanotechnologies are developed in a safe and responsible manner*
    - *supporting innovation*
- Industry:
  - The coming months will be a vital period in shaping the future development and application of nanotechnologies…

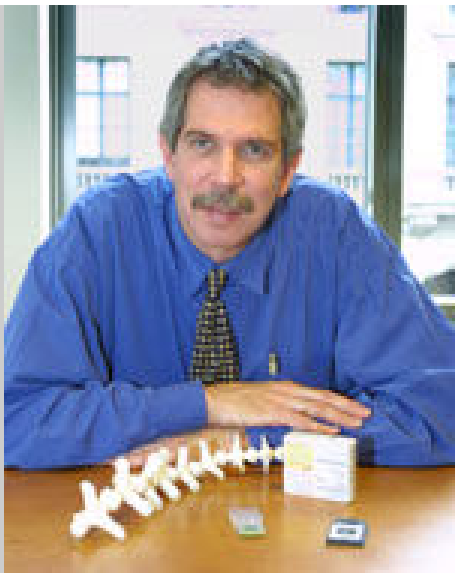
It's an excellent time to invest in ENTA.

10

General Conclusions

- Current thinking is that today's regulations are working yet review is necessary
- Companies are acting responsibly and are willing to provide more information
- Public perception is positive, sales steady
- Media could pay more interest in the science and facts – always seem interested in knowledge gaps and "fear factor"
- Nano harmonisation required and is in the works
- Will there be a regulatory battle ground with the NGOs and regulators (in the UK at first?) – I hope not as there will be no winners – only casualties and we will spend a long time thinking about lost opportunities.

NanoInside: Building a new social contract for 21st century products



David Rejeski, Woodrow Wilson Center, USA

Building a new social contract for 21st century products

David Rejeski
Woodrow Wilson Center, USA

Today, governments and industry are investing over $12 billion annually in nanotechnology research and development. There are now over 500 manufacturer-identified, nanotech-based commercial products on the market from 25 countries, ranging from cosmetics, to dietary supplements, sporting goods, and clothing (see: www.nanotechproject.org/consumerproducts). By 2014, nanotechnology is expected to account for over $2.6 trillion of global economic production, or about 15 percent of total output.

Despite these significant investments and the increasing flow of nanotech products into the marketplace, recent surveys have shown that 70-80 percent of Americans have heard nothing or very little about this technology, despite its likely transformative impacts on medicine, agriculture, computation, defense, and energy production. Nano is an invisible technology with big impacts that nobody is talking about.

This presentation will explore emerging approaches to nano oversight (from local regulations to voluntary agreements) and their intersection with public perceptions and expectations. We will look at the emerging social contract between the public and the scientific and business communities that will help define mechanisms for oversight, industry disclosure, risk research, and public engagement. The talk will draw on multiple regulatory analyses, national polls, and over two dozen focus groups conducted by the Project on Emerging Nanotechnologies that have explored public attitudes towards nanotech and public trust in government and industry to manage the introduction of this new technology.

Note: Unfortunately, David Rejeski was not able to hold his presentation at the conference due to family reasons.

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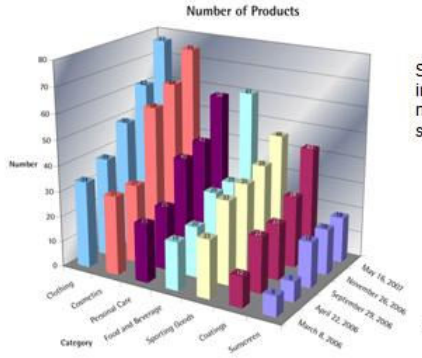
Product Introductions are Growing Rapidly



Significant increases in products using nano-engineered silver

Nano Teddy Bear

Number of products doubled in under 14 months

2

Generic Deficiencies in Regulations

- Many regulations do not adequately address size- and structure-dependent novel properties of nanosubstances
- Reliable and inexpensive technologies do not exit to monitor emissions of nanomaterials (either in the workplace or the environment)
- Mass-based standards/thresholds of many regulations will not work (mass will not translate into toxicity; no adequate scientific basis for setting thresholds; no enough risk research)
- Reporting exemptions will exclude many nanotech manufacturing facilities with small production quantities (< 10,000 kg)
- Technologies for pollution control (BATs) are not available

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Gaps in Regulatory Authority FDA

In areas of significant product penetration:

-Cosmetics
-Dietary supplements

4

Gaps in Regulatory Authority EPA

LEGAL ADEQUACY OF EPA PRODUCT PROGRAMS FOR NANOTECHNOLOGY OVERSIGHT

Function	TSCA	FIFRA	Fuel Additives
Requiring toxicity and use data	Weak	Strong	Strong
Placing burden to prove safety on manufacturer	None	Strong	Strong
Reviewing safety prior to marketing	Moderate	Strong	Strong
Requiring needed monitoring	Moderate	Moderate	Moderate
Requiring timely adverse event reporting	Strong	Moderate	Weak
Prohibiting initial marketing	Weak	Strong	Strong
Limiting uses or conditions of use	Weak	Strong	Weak
Requiring product withdrawal from market	Weak	Strong	Moderate

Note: TSCA = Toxic Substances Control Act; FIFRA = Federal Insecticide, Fungicide, and Rodenticide Act; Fuel Additives refer to section 211 of the Clean Air Act (CAA).

TSCA: "…a small step forward, but far too weak, giving the illusion of progress." Comment made in 1976 when the Toxic Substance Control Act was introduced.

5

Lack of Resources (Financial and Human)

- **Environmental Protection Agency:** EPA's budget today is *less* than EPA's budget in 1973, with inflation adjustments.
- **Food and Drug Administration:** FDA's budget is around 50 percent below 1996 levels while demands on the agency have increased.
- **Consumer Products Safety Commission:** 440 employees to oversee 15,000 types of products, one half the number the CPSC had in 1980.
- **Occupational Safety and Health Administration:** In 2005, OSHA had 2,200 employees, about 800 fewer than in 1980 to deal with issues of workplace safety and inspections.

You don't have to change laws to limit effective oversight, just cut budgets.

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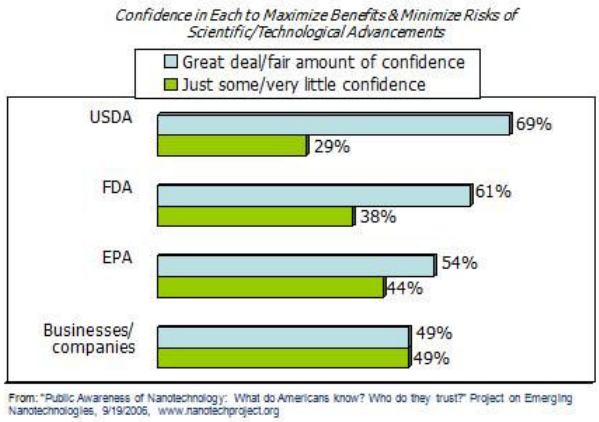
Trust in Government and Industry is Weak



From: "Public Awareness of Nanotechnology: What do Americans know? Who do they trust?" Project on Emerging Nanotechnologies, 9/19/2006, www.nanotechproject.org

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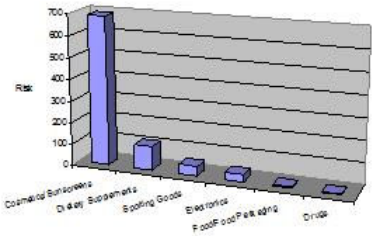
Perceptual Risks Increasing

$$\left[\frac{P \times E}{G \times S}\right]^{Ps} = Risk$$



	Cosmetics/ Sunscreens	Dietary Supplements	Sporting Goods	Electronics	Food/ Food Packaging	Drugs
Number of Products (P)	78	36	45	49	7	10
Potential for Exposure (E)	2	2	1	1	2	3
Government Oversight (G)	1	1	1	1	2	3
Industry Stewardship (S)	2	1	1	2	2	3
NGO Scrutiny (Ps)	1.5	1.1	1	1.1	1.5	1
Risk	689	110	45	34	7	3

Asset or Liability?

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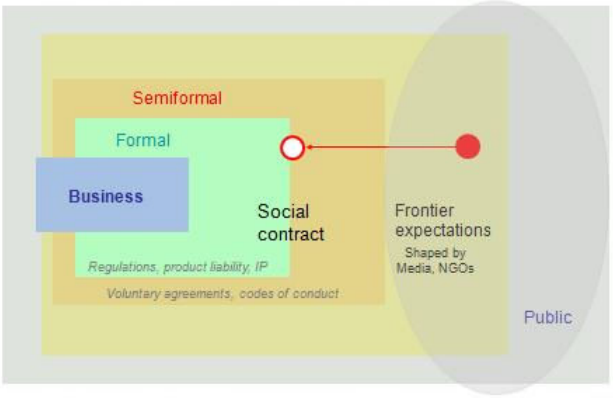
Opportunity For A New Social Contract



Bonini, Bielliet a. (2008). "When Social Issues Become Strategic," *McKinsey Quarterly*, Number 2.

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Public Expectations Are Consistent

Little public support for:

- A moratorium on nanotechnology research and development
- Industry self-regulation

When asked "How can public confidence in nanotechnologies be improved?" people converge around three recommendations:

1. **Greater transparency and disclosure**
2. **Pre-market testing**
3. **Third-party testing and research**

Results from 30 hours of focus groups conducted by the Project on Emerging Nanotechnologies between 2005 and 2007.

10

Social Contract Negotiations Have Begun

Dupont & Environmental Defense
NanoRisk Framework

EPA (Performance Track) & NanoFilm
Recognize and reward facility performance (2008)

UK/DEFRA Voluntary Program
Voluntary Data Collection for nano-based substances

Cambridge, Massachusetts, Nanotech Ordinance
Develop an approach to nanotech oversight for a municipality (6 month process to end in early 2008)

11

Observations

- Next 2-3 years will be crucial to the long-term success of nanotechnologies (success is not preordained).
- Social oversight (based on an emerging social contract) will be more important than government oversight during this period (and possibly beyond).
- How the public learns about nano, from whom, and with what message(s) could have large downstream impacts on consumer confidence and market growth.
- Industry will have to deal with both real and perceptual risks; brand equity and firm reputations will be at stake.
- An accident involving nano could change the equation.
- Hubris is dangerous.

12

A Little Luck

1st Nano-based Blockbuster Drug
Cash in Stock

A NO-NANO Label Appears
Cut profits by 50%

Nanoparticle Spill in Los Angeles
Loose Face

The NanoFood Battles Begin in Europe
Loose Sleep and Vacation

Code of Conduct: A suitable tool for the sustainable development of nanotechnologies - the BASF experience

Dr. Carolin Kranz, BASF AG, Germany

Code of Conduct: A suitable tool for the sustainable development of nanotechnologies – The BASF experience

Dr. Carolin Kranz
BASF AG, Germany

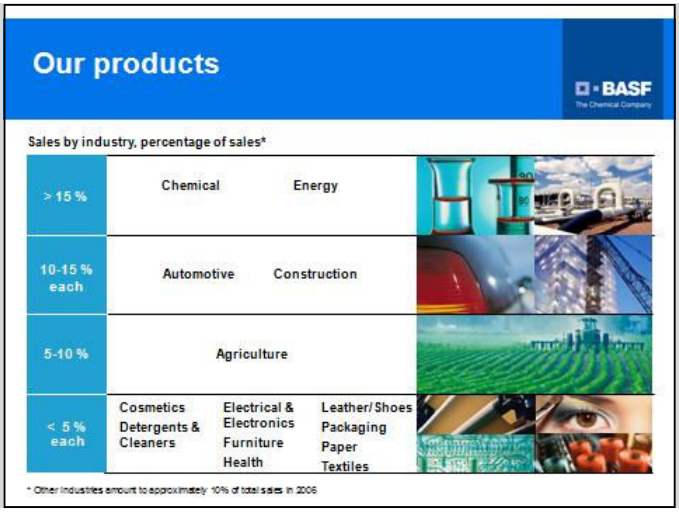
Nanotechnology is one of the key technologies of the 21st century, fascinating experts and lay people alike. The hopes and expectations placed in it as a driving force for innovation and sustainability are enormous. Nanotechnology is also an important technology for the chemical industry in general and for BASF in particular. With the growth cluster nanotechnology, BASF is investing €180 million in research and development alone in the period between 2006 and 2008. What drives innovation is on one hand the technology push that allows the production of nanotechnology enhanced products. On the other hand it is the marked pull for light-weight materials, functional packaging, scratch-resistant coatings, functional textiles, insulation materials, efficient lighting and new solutions for energy generation, conversion and storage, to name a few. BASF is focusing its R&D activities in the production and formulation of nanoparticles, as well as in the development of nanostructured surfaces, materials and systems. Our guiding principle: we use nanotechnology wherever it offers benefits for our customers. Newly developed products are eco-efficient engineering plastics, nanocomposite dispersions for more weather-resistant exterior paints and self-cleaning textiles.

Along with the development and marketing of our new products goes our environment, health and safety risk management. In own projects or by participating in national and international networks we are generating a scientifically well-founded database for the assessment of potential risks of exposure to free nanoparticles not incorporated in a matrix. We are also among the pioneers in the field of occupational safety and also among the pioneers when it comes to an open communication and a transparent dialogue with the public.

In 2006 BASF introduced its Code of Conduct Nanotechnology. Deduced from BASF's Values and Principles and the company's commitment to Responsible Care® it is a set of rules outlining the responsibility to protect employees, customers and business partners, to protect the environment, to participate in safety research, to communicate openly and to strive for a public dialogue. The Code of Conduct is not a stand alone document. It reflects corporate philosophy and is integrated into BASF's corporate policy and management.

1

2



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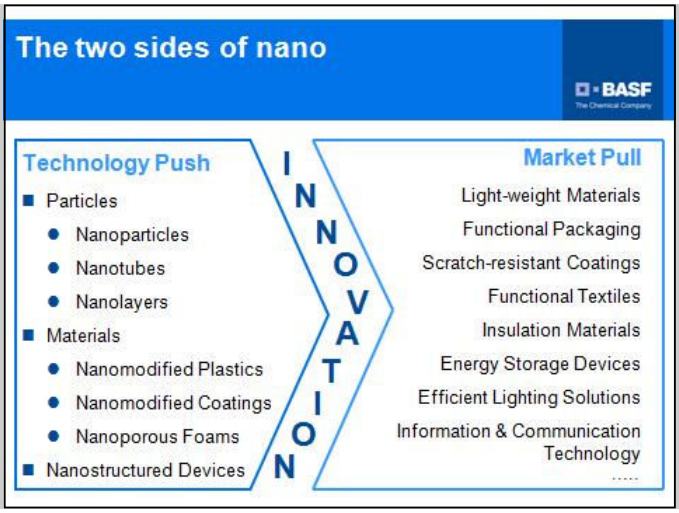

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5

Self-commitment instead of regulation: Code of Conduct Nanotechnology

- The Code of Conduct is a voluntary commitment to responsible action based on our Values & Principles:
  - protection of employees, customers and business partners
  - protection of the environment
  - participation in safety research
  - commitment to open communication and dialogue

The Code of Conduct gives guidance to all employees worldwide. It is published on the internet at:
www.basf.de/dialogue-nanotechnology

6

Implementation of the Code of Conduct Nanotechnology: Occupational Safety

It considers the particular situation of nanoparticles:

- A standardized occupational exposure measurement method is not yet available.
- A specific legal requirement apart from the existing occupational exposure limit values for dust is not yet existing.

Our approach is to work as far as possible in closed systems. If this is not possible, technical and organisational measures are additionally taken. Working areas subject to nanoparticle emissions are monitored by exposure measurements.

7

Implementation of the Code of Conduct Nanotechnology: Product Stewardship

- BASF has decades of experience in managing the risks of new technologies: we evaluate carefully and comprehensively any potential risks and take the appropriate measures to safeguard humans and the environment.
- BASF only markets products if their safety and environmental impact can be guaranteed on the basis of all available scientific information and technology.
- We provide our customers and logistics partners with information about the safe transportation, storage, safe use, processing and disposal of our products.

8

Implementation of the Code of Conduct Nanotechnology: Safety Research

We are actively involved in the ongoing development of a scientifically based database for the assessment of potential risks as well as in improving and refining product-based testing and assessment methods. In addition, we actively debate the opportunities and risks of nanotechnology with partners from all areas of society.

9

Implementation of the Code of Conduct Nanotechnology: Transparency and Dialogue

- In our Values and Principles, we have committed ourselves to pursuing a dialogue with society based on openness and trust.
- We regard it as our duty to provide information about both the opportunities and the potential risks of nanotechnology.
- We are committed to transparency and to an objective and constructive public debate.

10

What are the success factors?

- The effectiveness depends on the support of the management
- Should reflect corporate philosophy
- Should be embedded in the corporate policy
- Should be integratable into existing management systems
- Its external acceptance depends on the transparency of the implementation

CENARIOS®: A nano risk management system as a business and safety opportunity

Thorsten Weidl, TÜV SÜD Industrie Service GmbH, Germany

CENARIOS® – A nano risk management system as a business and safety opportunity

Thorsten Weidl[1], Gerhard Klein[1], Christoph Meili[2]

[1]TÜV SÜD Industrie Service GmbH, Germany
[2]The Innovation Society, St. Gallen Switzerland

Nanotechnology means fast-growing future markets and many new business opportunities. Numerous big companies and a lot of start-up companies provide many new and exciting products for industrial and consumer applications. Nanomaterials and nanoproducts offer new possibilities in product development. Adopting nanotechnology can therefore significantly improve product properties. However, these new properties could also pose potential risks, since mid - and long-term effects of nanosized materials on human health and the environment have not been fully understood. In addition, there are many legal uncertainties, as it remains unclear to which extent nanomaterials can be treated under regulations similar to "traditional" chemicals. To meet these new challenges, The Innovation Society Ltd. (St. Gallen, Switzerland) and TÜV SÜD (Munich, Germany) have developed CENARIOS®, the first certifiable nano-specific risk management and monitoring system. CENARIOS® provides a "State-of-the Art" hazard and risk assessment, encompassing risk monitoring tools to minimise the potential risks. The system will be implemented by mid 2007 at the first industry company and can be applied sector independent in industry, retail and research organisations.

What is CENARIOS®?

“Nano Labelling” is a common phrase at the moment. The discussion starts at “Nano Inside” Labels, in the US “Nano Hazard” labels are discussed. Well known are the Nano Product labels of the Hohenheimer Institute. CENARIOS® is not a product certificate, it is a certificate for a risk management and monitoring system for nanotechnology. The system was developed in 2006 to meet the particular requirements of nanotechnology risk assessment. The concept of CENARIOS® ensures that HSE-risks of products and processes are assessed according to "State-of the Art”-standards and new findings from science and technology are continuously included in the risk management process. An up–to-date evaluation will be

applied and combined with a foresight element, monitoring strategic and relevant risk areas (toxicity, regulation, consumer attitude, etc). It sets the basis for strategic decision making processes under conditions of high uncertainty. CENARIOS® is certified and audited regularly in an independent quality standard process in which a TÜV SÜD certificate is awarded. This certificate testifies a foremost safety level for the risk-management system. It documents the company's great safety efforts towards customers, authorities and the public.

The CENARIOS® Risk Management System

CENARIOS® does not reinvent the wheel, it rather considers all the well-known steps of a Risk Management System.

The special needs for a Risk Management for nanotechnology show up in the way these steps are performed. This becomes transparent in the approach of CENARIOS® with four distinct elements. These elements provide a coherent fundament for strategy and product decisions and serve as benchmarks.

- Risk and Hazard Assessment / Risk Evaluation
- Risk Monitoring System
- Issues-Management and Communication
- Certification

For the industry the CENARIOS®-Certificate is a possibility to differ from the black sheep, which produce without considering any safety standards.

The Certificate includes certification criteria with special requirements to

- Staff
- Organisation
- Risk Assessment and Monitoring
- Risk Coverage

For these requirements a base of certification was developed (TÜV Standard CENARIOS®). This base consists of 5 documents, one for each of the issues above and one general list of criteria which serves as customer's information, e. g. as help for the preparation for the certification.

1

Nano Labelling (2)

Nano Inside Labels
A label, which informs about whether nanoparticles or not are inside a product

Nano Hazard Labels
A competition of the ETC Group (Action Group on Erosion Technology and Concentration) whether nanoparticles or not are inside a product

Nano Product Labels
Special product properties – like self cleaning – are tested and certified. Reliable certificates include toxicological investigations.

Nano Quality Labels
General Information about the Quality of nanoproducts. We found 1 (one) label with a low reputation.

Nano Competence Labels
Information if the companies have the general competence to produce safe products in a given quality. Similar to Quality Management Systems

2

Co-operation

joint competence and expertise

Approved methods and instruments for Risk Assessment and Risk Evaluation

Providing Networks of experts, data research and publications

Engagement in committee work and broad industrial relations

Monitoring instruments for trends in science, technology and regulations

Assigning a globally acknowledged certificate: The CENARIOS® Certificate

Providing tools and instruments for coping with and communicating of risks

3

Targets of the Project

1. Establishing a safety standard
2. Continuously improvement of product and process safety
3. Minimise potential liability risks
4. Evaluation of the state-of-the-art in science and technology (not pushing in)
5. No over-reaction: requirements no one can fulfil will stop progress and will cause refusal of the system
6. Establishing a responsible practice with nanotechnology - Increase of market opportunities if a proof of safety is provided

4

Four elements of CENARIOS®

Element 1
Risk Assessment and Risk Evaluation
comprehensive risk survey related to products and processes

new insights

Element 2
Risk Monitoring System
Foresight-instrument for trends in science, technology and regulations

pro-active | in case of crisis

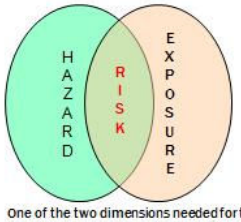
Element 3
Issue Management and Communication
Tools and instruments for the efficient and effective coping of risk

Element 4
CENARIOS® Certification
Globally acknowledged certificate providing certainty and added value

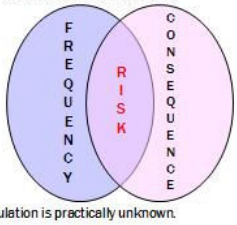
5

Assessing Nano-Risks (2)

In toxicological context, risk is often defined in the following way:



CENARIOS® requires a semi-quantitative risk evaluation, so the following definition is more sensitive:



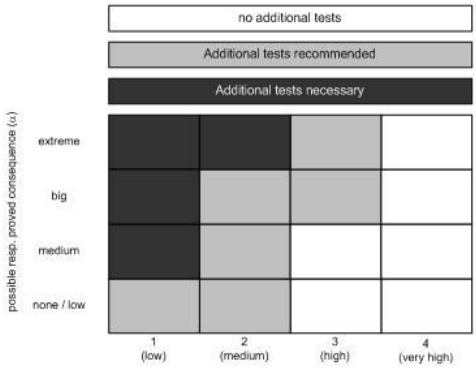
One of the two dimensions needed for the risk calculation is practically unknown.

The CENARIOS® Risk Management System replaces the concrete dimension *consequence* by a weak dimension *possible consequence*, which is judged considering the latest findings in science and technology.

Therefore the latest publications, referring to the product, are taken into account. Each publication is checked with respect to to its credibility and transferability.

6

Evaluation scheme (1)



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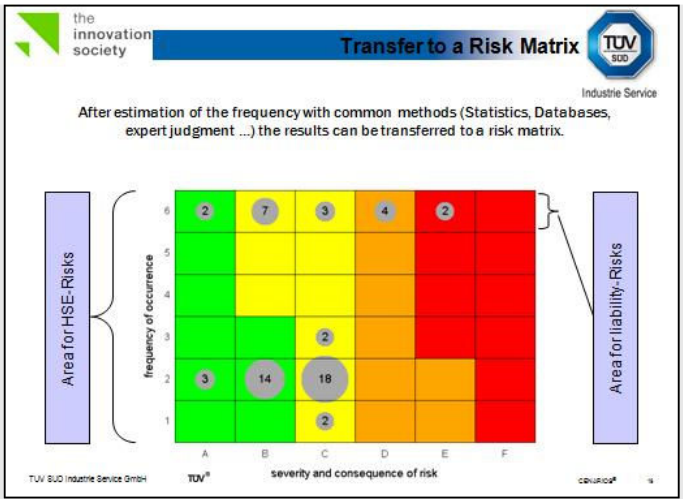
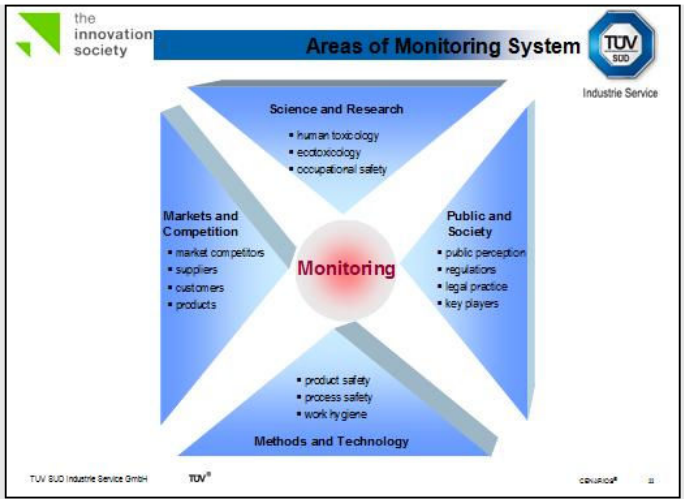
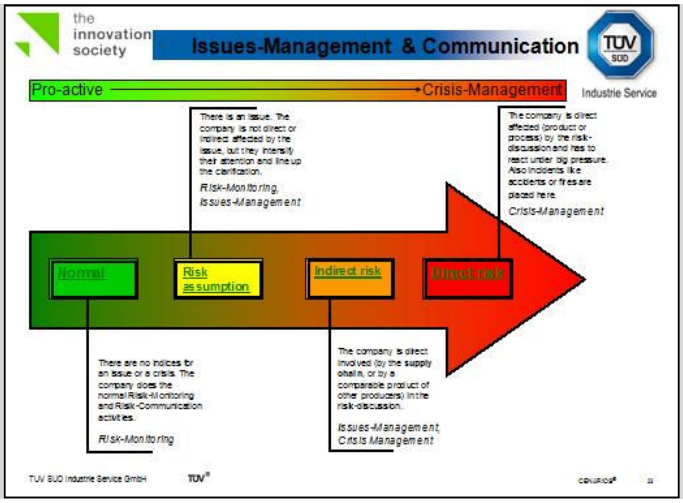

the innovation society
Transfer to a Risk Matrix
Industrie Service
After estimation of the frequency with common methods (Statistics, Databases, expert judgment ...) the results can be transferred to a risk matrix.
Area for HSE-Risks
frequency of occurrence
Area for liability-Risks
A B C D E F
severity and consequence of risk
TÜV SÜD Industrie Service GmbH

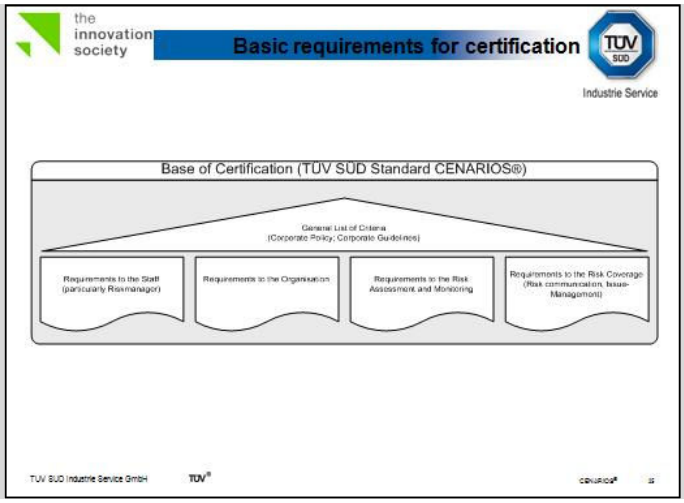
8


the innovation society
Areas of Monitoring System
Industrie Service
Science and Research
human toxicology
ecotoxicology
occupational safety
Markets and Competition
market competitors
suppliers
customers
products
Monitoring
Public and Society
public perception
regulations
legal practice
key players
product safety
process safety
work hygiene
Methods and Technology
TÜV SÜD Industrie Service GmbH

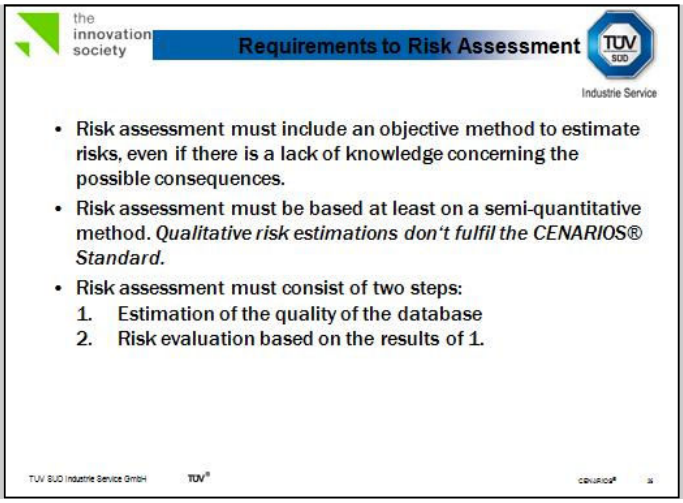
9


the innovation society
Issues-Management & Communication
Industrie Service
Pro-active
Crisis-Management
Normal
Risk assumption
indirect risk
Direct risk
Risk-Monitoring, Issues-Management
Crisis-Management
There are no indices for an issue or a crisis. The company does the normal Risk-Monitoring and Risk-Communication activities.
Risk-Monitoring
The company is direct involved (by the supply chain, or by a comparable product of other producers) in the risk-discussion.
Issues-Management, Crisis Management
TÜV SÜD Industrie Service GmbH

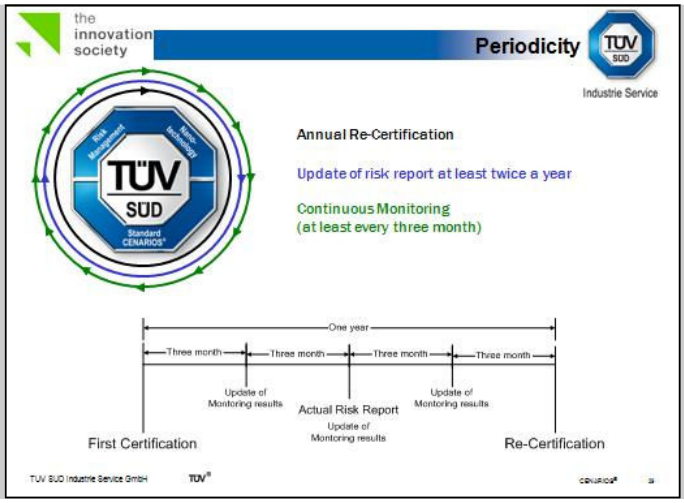
10


the innovation society
Basic requirements for certification
Industrie Service
Base of Certification (TÜV SÜD Standard CENARIOS®)
General List of Criteria (Corporate Policy; Corporate Guidelines)
Requirements to the Staff (particularly Risk-manager)
Requirements to the Organisation
Requirements to the Risk Assessment and Monitoring
Requirements to the Risk Coverage (Risk communication, Issue-Management)
TÜV SÜD Industrie Service GmbH

11


the innovation society
Requirements to Risk Assessment
Industrie Service
Risk assessment must include an objective method to estimate risks, even if there is a lack of knowledge concerning the possible consequences.
Risk assessment must be based at least on a semi-quantitative method. Qualitative risk estimations don't fulfil the CENARIOS® Standard.
Risk assessment must consist of two steps:
1. Estimation of the quality of the database
2. Risk evaluation based on the results of 1.
TÜV SÜD Industrie Service GmbH

12


the innovation society
Periodicity
Industrie Service
TÜV SÜD
Standard CENARIOS®
Annual Re-Certification
Update of risk report at least twice a year
Continuous Monitoring
(at least every three month)
One year
Three month
Three month
Three month
Three month
Update of Monitoring results
Actual Risk Report
Update of Monitoring results
Update of Monitoring results
First Certification
Re-Certification
TÜV SÜD Industrie Service GmbH

Nano Risk Framework

Dr. John M. Balbus,
Environmental Defense, USA

A Framework for Responsible Nanotechnology Development
Dr. John M. Balbus, MD, MPH
Environmental Defense, USA

Environmental Defense, an environmental advocacy organization, and DuPont, a science-based products and services company, have developed a comprehensive, practical, and flexible framework for evaluating and addressing the potential risks of nanoscale materials. The intent of this framework is to define a systematic and disciplined process for identifying, managing, and reducing any environmental, health, and safety risks of engineered nanomaterials across all stages of a product's lifecycle. Our framework offers guidance on the key questions an organization should consider in developing applications of such materials, and on the key information needed to make sound risk-evaluation and risk-management decisions. The framework allows users to move ahead despite areas of incomplete or uncertain information, by using reasonable assumptions and by compensating for knowledge gaps with appropriate risk-management practices. Further, the framework describes a system to guide information generation and update assumptions, decisions, and practices with new information as it becomes available. And the framework offers guidance on how to communicate information and decisions to key stakeholders.

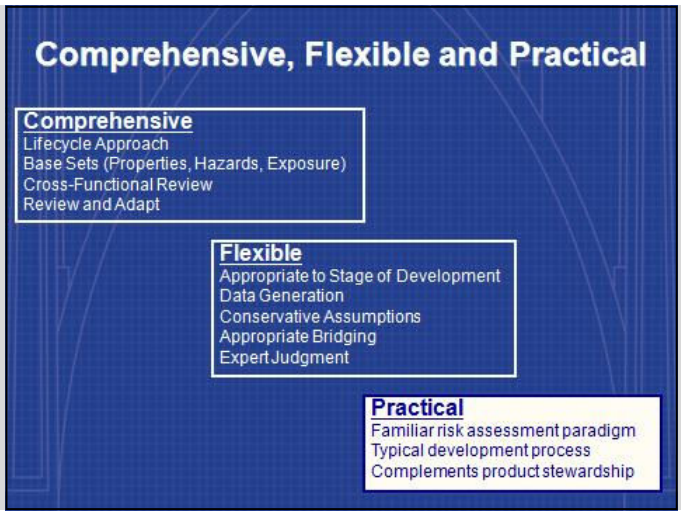
We believe that the adoption of this framework can promote responsible development of nanotechnology products, facilitate public acceptance, and support the development of a practical model for reasonable government policy on nanotechnology safety. We have solicited and incorporated feedback on our overall approach from a wide range of international stakeholders, and we have pilot-testing the framework on several materials and applications, at various stages of development. These case studies demonstrate how the framework can be adapted to different phases of the product lifecycle and can help support decisions to proceed or not proceed with product development. We expect that the framework itself will evolve as it is used by a variety of stakeholders in a variety of settings for a variety of applications.

Participants in the workshop on the framework will be able to review the framework documents in more depth, including an output

template for organizing information and the three case studies that demonstrate use of the framework. They will then begin the first step in the framework on a product with which they are familiar, and discuss the advantages and disadvantages of the framework for their own application.

1

2



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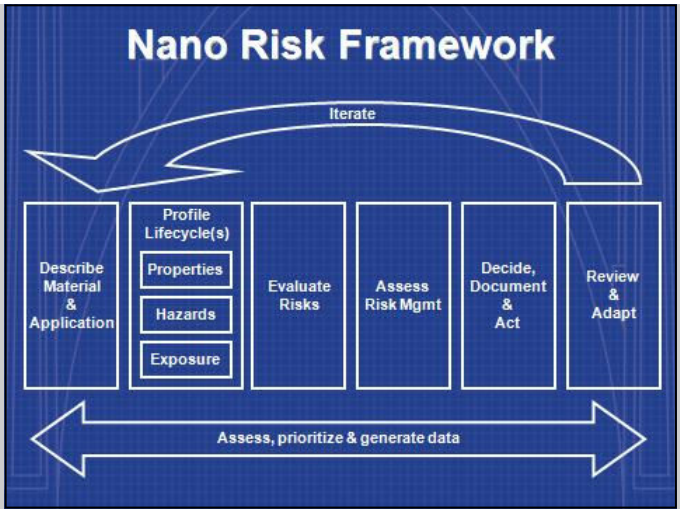

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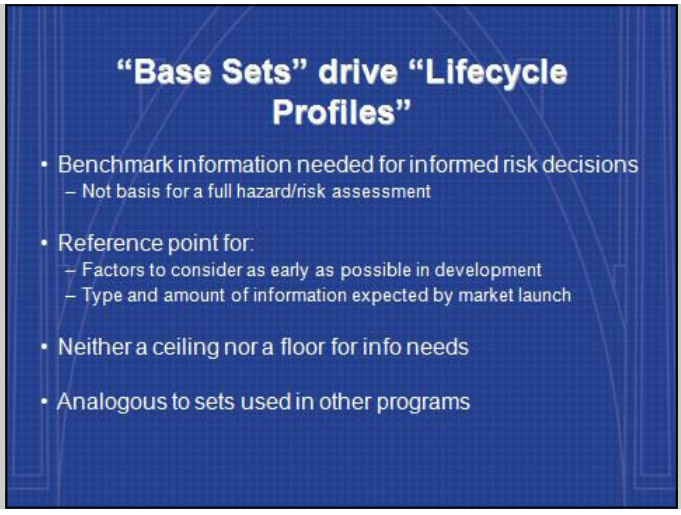


5

Base Set Physical & Chemical Properties

- Particle Size
- Size Distribution
- Surface-Area
- Particle Density
- Solubility
- Dispersability
- Bulk Density
- Agglomeration State
- Chemical Reactivity
- Surface Reactivity
- Porosity
- Surface Charge
- Technical Name
- Commercial Name
- Common Form
- Chemical Composition
- Molecular Structure
- Crystal Structure
- Physical Form

6

Base Set Health Hazard Data

- Short-term Toxicity:
  One or more of the following, depending on conditions:
  - Single-dose instillation study
  - 28-day inhalation study
  - 28-day repeated-dose oral toxicity test

  Each with full histopathology, over a 90-day observation period
- Skin sensitization/irritation
- Skin penetration
- Genetic toxicity tests

7

Triggers for Additional Testing

- High exposure potential
- High inherent hazard potential
- Results of base set studies
- Significant changes
  - e.g., in production or use pattern
- Compensating for lack of data or uncertainty

8

Additional Health Hazard Data

- Biological fate and behavior
- Chronic (≥1 year) inhalation/ingestion toxicity
- Chronic dermal irritation/sensitization studies
- Developmental and reproductive toxicity
- Neurotoxicity studies
- More extensive genotoxicity studies
- Focused toxicity studies, e.g.:
  - Susceptibility studies — animal models
  - Allergenicity and immunotoxicity
  - Organ function bioassays

9

Case Studies

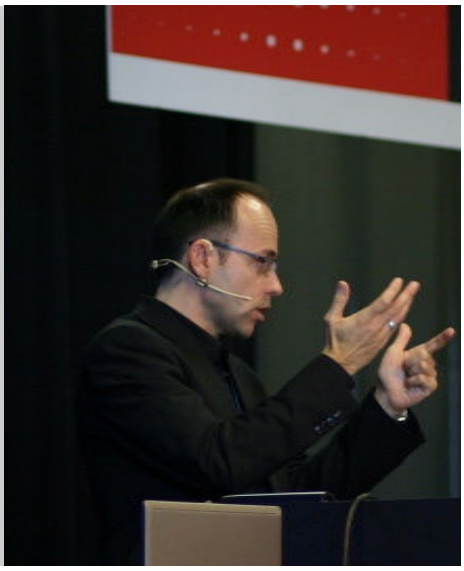
Material	TiO2	CNTs	ZVI
Application	Light Stabilizer	Polymer Additive	Waste Remediation
Role	Producer	User	Customer
Stage	Commercial	R&D	Concept
Result	Proceed	Limit	Hold
Cost	125 hours $170 K	80 hours $5 K	40 hours $0

10

Desired Outcomes

- Comprehensive, practical, and flexible
- Evaluates and addresses the potential risks of nanoscale materials across the lifecycle
- Promotes responsible development of nanotechnology products
- Facilitates public acceptance
- Contribute to the development of government policy on nanotechnology safety

Walking the molecules - Europe's fist NanoRobot



Prof. Dr. Daniel J. Müller, University of Technology Dresden, Germany

Walking the molecules – Europe's first NanoRobot

Prof. Dr. Daniel J. Müller
Center of Biotechnology, University of Technology Dresden, Germany

Molecular interactions drive all processes in life. They determine the molecular crosstalk and build the basic language of biological processes. To detect these interactions we have developed a fully automated robot taking single machines of the biological cell to the line. To do so the robot crosses dimensions: A macroscopic cantilever exhibiting a microscopic tip contacts a nanometer sized protein to detect and locate interactions at the subnanometer scale. The invented technology allows to locate molecular interactions of cellular machines at subnanometer resolution and to observe how these molecular interactions drive the functional state of these machineries. Applied to drug screening the robot detects and locates ligand- or inhibitor-binding to a protein and detects the functional states of receptors.

1

Proteomics

In the **post-genomic** era of the 21st century, **proteomics** now characterizes the function of proteins as they are involved in every process of life

Directing proteins in biotechnology, medicine and pharmacology requires a detailed understanding of **fundamental principles** in the **molecular world** (structure, function, and interactions of proteins and other biomolecules)

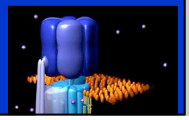
Needed are new tools for research and application

2

Diseases have molecular origins

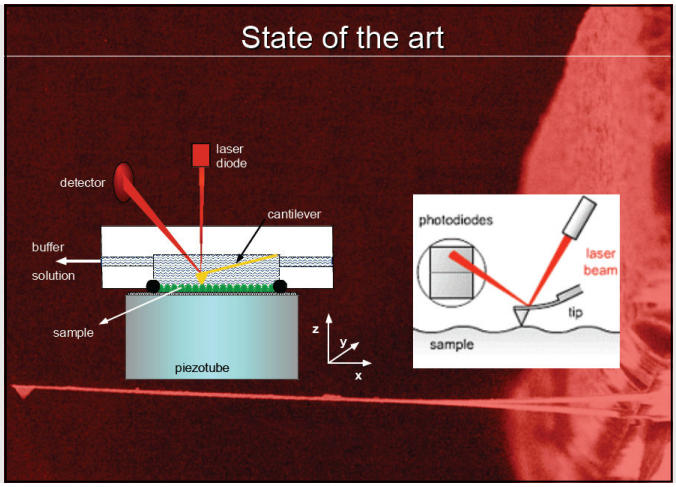
- If proteins fail they cause characteristic diseasese
- This holds true for Alzheimer, diabetes II, cataract, brain stroke, Retinitis pigemntosa, cystric fibrosis, …

- At the same time applying these machines biotechnically requires their control



3

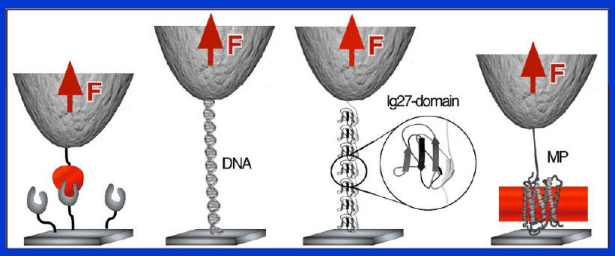
State of the art



4

Single-molecule force spectroscopy

Detecting molecular interactions



5

Single-molecule force spectroscopy

Bottlenecks

- Spectroscope needs specialized operator (PhD)
- One spectra is recorded after the other (low throughput)
- Thermal drift problems
- Force calibration needs improvement
- No objective criteria for experimental standards
- No objective criteria for data analysis
- No solid statistics possible in reliable time
- No control of environmental conditions as required for life sciences
- No automated exchange of experimental conditions (required for screening)

6

ForceRobot^{R}

New

- Approaching molecular interactions directly
- Fully automated data acquisition
- Full environmental control
- Fully automated data analysis

Reproducibility

- Requires no specialized personnel (sample standards and platforms
- Automated calibration
- No drift

Higher sensitivity

- Of force and of distance

Higher throughput

- By a factor of 1000

nAmbition

7

Focus: The global drug market

Fundamental insights needed are drug - target interactions

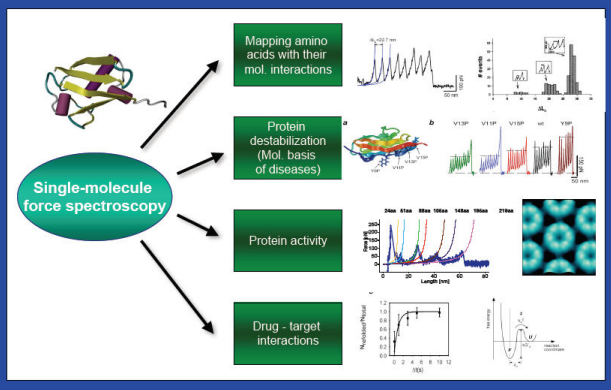
- Location at which drug interacts with target
- Insights into functional implication (active, inactive, modulation, …)
- Binding affinity, strength, competition of drugs, …

Pharma research requires several high technology approaches to reveal these insights

ForceScreener^{R} serves all these information within one experiment, in real time, label free, native environment and requires pico-molar amounts

8

New developments, insights and patents - all processes in life are steered by molecular interactions



Nanotechnology and sustainability - Precautionary approaches and public participation

Ulrich Petschow, IOEW, Germany

Nanotechnology and Sustainability – Precautionary approaches and public participation

Ulrich Petschow
Institute for Ecological Economy Research, Germany

Nanotechnologies and sustainability are interwoven in good as well as in bad terms. While sustainability might in general be interpreted rather broadly, our main focus with respect to nanotechnologies is mainly on their positive and negative effects on environmental sustainability. To shape nanotechnologies we focus on technology assessment as well as public participation.

Technology assessment analyzes predicted or to-be-anticipated positive and negative effects of technologies, processes, and products using a well-established set of methods, including cost-benefit analysis, risk analysis, (eco-) toxicology, and life cycle assessment (LCA). These methods unfortunately require detailed information not only on the technology being investigated but also on the specific situation or application. In the case of an emerging technology such as nanotechnology, such information is generally lacking; therefore a *prospective assessment* of nanotechnologies (opportunities as well as hazards) must find ways to adequately deal with the unknown. Striving to meet this challenge, we[1] developed an approach which is based on four pillars:

1. Technology characterization: Prospective assessment of nanotechnologies with respect to opportunities and hazards with a focus on the technology itself (in analogy to substance characterization in toxicology)

2. Eco-profiles: Evaluation of eco- and resource-efficiency potentials by application of LCA methods (extrapolating) to typical applications and comparison with existing products and processes

3. Orientation through *Leitbilder*: Influencing the development of technologies, processes, and products through discursive explication of existing *Leitbilder* or vision statements that integrate the aspects of health, safety, and environment.

4. Communication with the *public*. While the first three approaches focus on experts, the involvement of the public and its acceptance and opinion is essential for the perspectives of nanotechnologies.

[1] The knowledge base of this presentation are research activities of IOEW and University of Bremen (A.v..Gleich)

1

Sustainability

What is new in sustainability debate?

- Scale (global, next 50 years, irreversible)
- Three dimensions (social, economic, ecologic)
- Carrying capacities

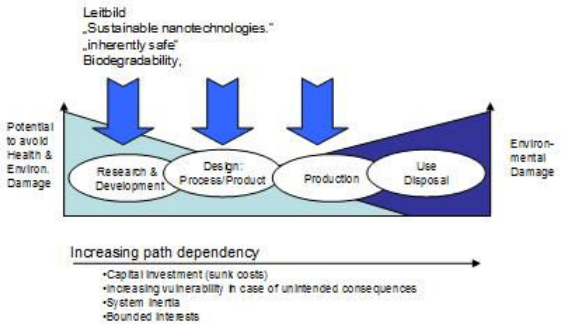
A pathway into the future without far reaching system crashes

=> (Re)Sources, sinks, material and energy streams, risks

- Technological innovations will play an important role on the way to sustainability

2

Developmental time window in the life cycle



Source: Rejeski 2004

3

Hazard characterization I

Nano-Quality	Effect/Problem	Approach of assessment	Type of risk, Non-nano examples
Particle size and mobility	Suspended in air, dusty, Entering alveoli, cells, membranes (persistence?)	Models of dissemination, (Eco)Toxicology	PM from diesel engines Asbestos CFCs?
New functionalities and effects Ratio surface /volume	Reactivity, Catalytic effects Selectivity Solubility Phase transition	Models of dissemination, (Eco)Toxicology	Metal Ions in soil; Enzymes in detergents

4

Hazard characterization II

Nano-Quality	Effect/Problem	Approach of assessment	Type of risk, Non-nano examples
Quantum effects	Malfunction, Depending on highly purified and defined conditions	Risk analysis FMEA	Chip-technology
Self-Organization	Potential for self-replication?	Risk analysis Scenarios	GMOs

5

Hazard characterization III

Production requirements and 'type of usage':

⇒ Well defined particle size and purity
(energy and material requirements, waste, clean room)

⇒ Production technology **(e. g. Flame-Assisted-Deposition, CVD, PVD, sol-gel process, precipitation, molecular imprinting, lithography, SAMs…)**

⇒ Type of substances **(heavy metals, rare earth…)**

⇒ Open use, closed use

⇒ Inherent safety **(e. g. adhesion, aggregation…)**

6

Guiding principles (Leitbilder)

- Important role of ‚images' and ‚guiding principles'

Philosophy of science (paradigms)
Development of technological pathways (trajectories)
Innovation research

Extremely important role in 'NanoTechnoScience':

7

Guiding Principles (Leitbilder)

- Function:
  Orientation, motivation, synchronization,
  reduction of complexity, structuring perception
  constitution of group identity
  => Possibility for management by guiding principles
- Requirements:
  Pictorial quality, emotional and value content, irritation, resonance, feasibility
- Successful examples:
  Closed loop economy (Kreislaufwirtschaft)
  Green chemistry

8

Leitbilder

- *Leitbilder* may have a guiding effect and help to define the aims and direction of innovation
- in this respect, it is possible to explore opportunities for influencing innovation toward sustainable development with the help of *Leitbilder*
- In the past *Leitbilder* such as "Solar Economy", "Closed-Loop Economy" (Kreislaufwirtschaft) or "Green Chemistry" did and still do play an important role for progress
- Some first steps conc. "Green Nanotechnologies"

9

Public Participation

- New technologies and the public
  - History of green biotechnology
    - Non-communication, new technology: self-convincing
  - The need to communicate „upstream"
    - Information and consultation of the public
    - Taking consumers seriously

10

Public Participation

- Consensus conference on nanotechnologies concerning consumer goods in Germany
  - Project funded by BfR, carried out by UfU/IOEW
  - Participants: 20 citizens
  - Three weekends – Information by experts
  - Developing own questions and asking experts in a public hearing

11

Public Participation

- Main results
  - No general caveat conc. nanotechnologies
  - Positive effects of nanotechnologies welcome
  - Possible adverse effects (not-yet-knowledge) proposal of precautionary approaches
    - Not too much difference to scientific discussions
  - Active involvement of representatives of firms important (pro-active: textile industry, hesitant: food and cosmetics)
  - Pro-active textile industry: acknowledgement by participants – less caveat and example of good practice
  - Constraints: „something to hide?" - distrust

12

Summary

- Characterization of nanotechnology proofs to be an approach for 'prospective TA' and a knowledge base for measures according to 'precautionary principle'
- Effects of nanoparticles in the short run and a switch from self-organization to self-replication in the long run are to be looked at as sources of 'new risks'
- In most cases the expected risks of (current) nanotechnology seem to be similar to those of chemical technology
- Case studies in prospective LCA show varying prospects for nanotechnology based eco-efficiency gains
- Guiding principles ('Leitbilder') play an important role in the development of nanotechnology and its applications
- Public participation and involvement are essential for the acceptance of new technologies (confidence with reference to the mentioned approaches)

Workshops on voluntary measures

The goal of this part of the conference was to compare and evaluate three different voluntary industry measures:

- Code of Conduct (Caroline Kranz, BASF)
- CENARIOS® (Thorsten Weidl, TÜV SÜD / Innovation Society)
- NanoRisk Framework (John Balbus, Environmental Defense / DuPont)

Each of these approaches represents a unique way of dealing with the many unknowns and the uncertain regulatory situation in the field of nanotechnology. The participants had already been introduced to the different voluntary measures during the detailed presentations in the morning. They were asked to form three groups, each of them discussing another voluntary measure. The corresponding speakers of the morning presentations acted as the discussion moderators.

	Figures	Countries	Products	Nanotechnology
A Food Company	sales: 82 bn USD employees: 265'000	Europe, America, Africa, Asia	beverages, dairy products, ice cream, chocolate, pet care	nanoscale food ingredients, nano-encapsulation
B Car Manufacturer	sales: 205 bn USD 360'000	Europe, America, Asia, Africa	passenger cars, commercial vehicles, components, financial services	scratch resistant paint, ultrastrong composites, water- and stain-repelling coatings, plastics
C Cosmetics Company	sales: 4 bn USD	Switzerland, Germany, Spain, Austria	creams, fluids, serums, etc.	water-soluble ingredients, nano-emulsions, nano-encapsulated agents
D Packaging Company	sales: 930 Mio USD employees: 1'800	Germany	specialty sheet, extrusion products, automotive, components, composite materials	composites, flame retardants, intelligent packaging
E Pharmaceutical Company	sales: 956 Mio USD	Europe	medical nutrition, vaccines, pharmaceuticals	nanoscale drug delivery systems, water-soluble agents

Five cases have been given for the workshop discussions.

The workshops were organised as open discussion rounds with specific questions and tasks given. There were five case studies descri-

bing different industries (a car manufacturer, a food and a packaging company, a cosmetic and a pharma company). The participants were given specific questions concerning the implementation of the measure, the benefits to the stakeholder, the communication and the overall appropriateness. They were asked to discuss these issues in the group and mark their conclusion with a coloured sticker (red / orange / green) on the main poster.

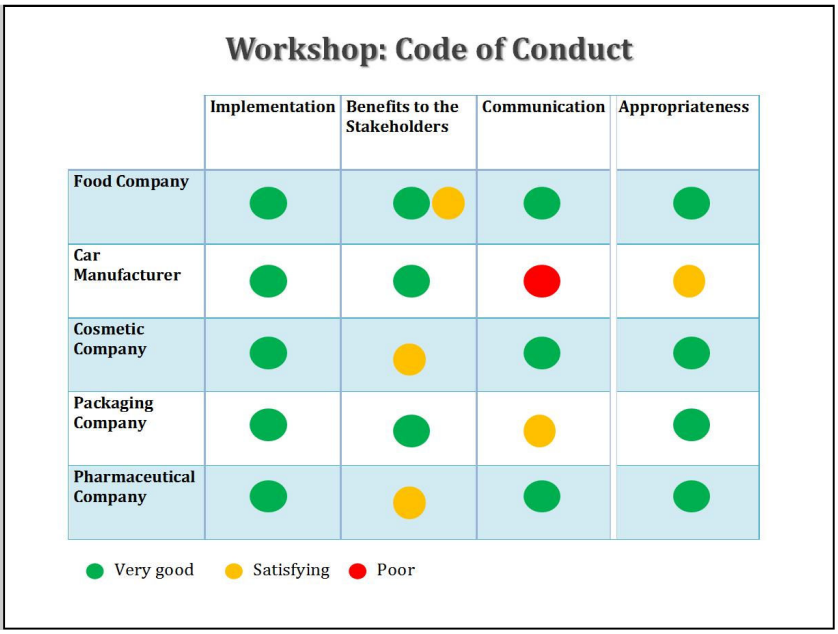
In the following plenum discussion, all the posters were collected and presented. The following pages summarise the findings corresponding to each voluntary measure.



Discussion

Code of Conduct-Workshop A

The outcome of this workshop has been the conclusion that a voluntary Code of Conduct is a very useful and helpful measure, and that it is appropriate in most of the discussed cases. Implementing a Code of Conduct has generally been estimated to be beneficial for almost all stakeholders. However, the workshop participants explicitly stated that a Code of Conduct must not only consist of empty phrases but has to be meaningful.



This poster summarises the results from the Code of Conduct workshop. The participants discussed the given issues for five different scenarios (food-, cosmetic-, packaging-, pharmaceutical company and a car manufacturer).
The column at the right (appropriateness) represents the overall suitability of the measure for the corresponding case.

In the first case, the food company, the Code of Conduct would be very appropriate, because it would be easy to implement and communicate and the stakeholders would benefit. In contrast, however, the question has been raised whether a Code of Conduct would be enough for such a company or not; finally, the participants came to the conclusion that a food company has to do more than implementing a Code of Conduct. The issue of consumer sensitivity in

terms of nanotechnology in foods was also mentioned.

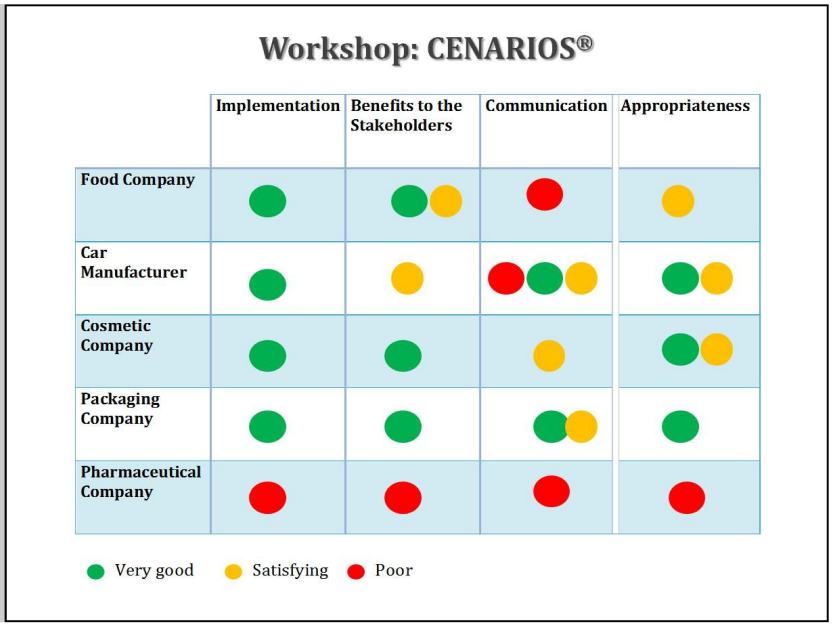
The pharmaceutical and the cosmetic company case turned out to be similar and the results were almost the same. The main point was that trust in these companies is of particular importance. Therefore a Code of Conduct would be very beneficial for consumers, with easy implementation and communicability. However, the additional benefit would be comparatively minor in a highly regulated sector such as the pharmaceutical industry.

In the scenario of the car manufacturer, a Code of Conduct would be more difficult to communicate since the issue of “nano” in cars does not seem to be relevant to consumers. That is why a Code of Conduct would only be satisfyingly appropriate. On the other hand it could still be useful for the company in terms of occupational safety.

The stakeholders of the packaging company would benefit from the implementation of a Code of Conduct and the tool was rated very appropriate for this type case. However, the packaging company would probably also encounter problems with the communication of a Code of Conduct. Consumers would possibly lack the understanding why a packaging company needs a Code of Conduct and where nanotechnology or nanoparticles are used. In particular, nano food packaging would suffer from consumer concerns.

CENARIOS®-Workshop B

CENARIOS® (certifiable, nanospecific risk management and monitoring system) was in general rated to be well suitable for all kinds of industries. However, the size of the company was indicated as important, because large companies particulary in heavily regulated areas such as pharmaceuticals, usually already have the necessary risk management structures. This makes it less probable that such companies would implement a second system according to the CENARIOS® standard. In contrary to this, the risk monitoring tool of CENARIOS® was estimated to be a valuable tool even for these companies and branches.



Poster summarising the results from the CENARIOS® workshop. The participants discussed the given issues for five different scenarios (food-, cosmetic-, packaging-, pharmaceutical company and a car manufacturer).
The column at the right (appropriateness) represents the overall suitability of the measure for the corresponding case.

Especially in the case of the car manufacturer, the inclusion of the supply chain was identified as being important, since car manufacturers would only use prefabricated (nanotechnological) compo-

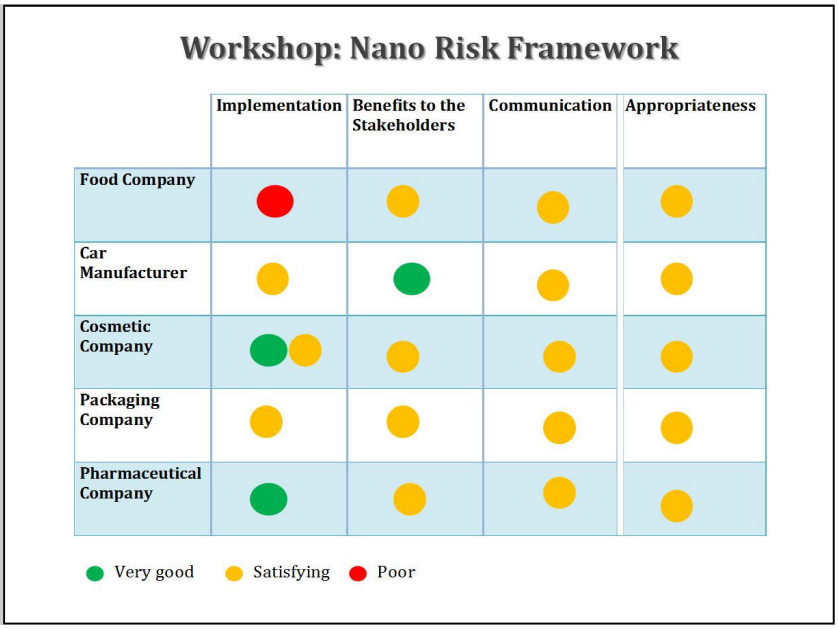
nents. Communication was controversely disussed and the difference between the communication of nanotechnology benefits and risk communication became evident.

Between the food and the cosmetics sector, similarities in the stringency of regulatory requirements were identified and therefore CENARIOS® was rated to be about equally suitable in both cases. Problems were anticipated in the communication area, since the communication of nanotechnology (risks) in these branches is critical in terms of consumer acceptance.

The packaging sector, however, turned out to be an ideal case for the implementation of the CENARIOS® risk management system. Overall, it was concluded that CENARIOS® would particularly be suitable for business-to-business communication and represent an advantage if implemented along the supply chain. Implementation was generally assessed to be simple and in most cases there would be significant benefits to the stakeholders.

NanoRisk Framework-Workshop C

The NanoRisk Framework tool was estimated to be suitable for all kinds of industries. Accoding to this finding, the appropriateness of the tool has been rated „satisfying“ in all five scenarios. However, it became clear during the discussion that the NanoRisk Framework is best suitable for small and medium companies as a learning tool.



This poster summarises the results from the NanoRisk Framework workshop. The participants discussed the given issues for five different scenarios (food-, cosmetic-, packaging-, pharmaceutical company and a car manufacturer). The column at the right (appropriateness) represents the overall suitability of the measure for the corresponding case.

The tool‘s benefits depend on the stringency of existing regulation in a specific branch. One the one hand, the more stingent the existing regulatory framework is, the more companies could benefit from the NanoRisk Framework. On the other hand, more stringent regulation usually implies that a company already has effective structures to cope with it, making additional measures unnecessary. In the case of the pharma company, the workshop participants stated that there would be no need for the NanoRisk Framework, since pharma companies already face regulations going beyond the Nano-

Risk Framework.

Another important outcome was that the success of the NanoRisk Framework depends on the industry's practice of transparency and the willingness of a company to disclose potential risks. In the case of the cosmetic company, the communication of potential risks would be beneficial to consumers and would be supported through the implementation of NanoRisk Framework.

However, in the case of many other companies, the implementation was identified to be a problem because of the unwillingness to disclose information about potential risks and lack of information.

Although the NanoRisk Framework was rated to be satisfyingly implementable in the car manufacturer and the packaging company scenario, several barriers have been identified in the workshop discussion. Due to the strong dependency on suppliers, such companies would probably also have to rely on their suppliers regarding EHS risk knowledge. Although the car manufacturer's staff would benefit from less exposure to risks with NanoRisk Framework, implementation would be complicated in a non-expert environment.

Speakers and Participants of the 3rd NanoRegulation Conference

Speakers

Balbus	John	Environmental Defense	USA
Büning	Monika	Federation of German Consumer Organisations	Germany
Karlaganis	Georg	Federal Office for the Environment	Switzerland
Kuster	Martin	Novartis International AG	Switzerland
Kranz	Carolin	BASF Aktiengesellschaft	Germany
Müller	Daniel J.	University of Technology Dresden	Germany
Nohynek	Gerhard J.	L'Oréal R&D Worldwide Safety Evaluation	France
Petschow	Ulrich	Insitute for Ecological Economy Research	Germany
Rejeski	David	Woodrow Wilson Center USA	USA
Thomas	Treye A.	U.S Consumer Product Safety Commission	USA
Schmidt	Gerhard	MunichRe	Germany
Schneider	Paul	miVital AG	Switzerland
Stark	Del	European Nanotechnology Trade Alliance	Great Britain
Weidl	Thorsten	TÜV SÜD Industrie Service GmbH	Germany
van der Zandt	Peter	European Commission	Belgium

Conference Moderation

Kish	Susan	First Tuesday AG	Switzerland
Meili	Christoph	The Innovation Society Ltd, St.Gallen	Switzerland

Workshop Moderation

Balbus	John	Environmental Defense (NanoRisk Framework)	USA
Klein	Gerhard	TÜV SÜD Industrie Service GmbH (CENARIOS®)	Germany
Kranz	Carolin	BASF Aktiengesellschaft (Code of Conduct)	Germany

Participants

Bamberg	Klaus	Alcan Airex AG	Switzerland
Bellucci	Sergio	Zentrum für Technologiefolgen-Abschätzung (TA-Swiss)	Switzerland
Bernard	Daniel	Arkema	France
Bickel	Manfred	TVS Textilverband Schweiz	Switzerland
Buchard	Vincent	Debio RP	Switzerland
Büse	Hans-Ulrich	EOS GmbH	Germany
Burkhardt	Klaus	Allianz Global Corporate & Specialty AG	Germany
Butscher	Roland	Novoplast GmbH&Co.KG	Germany
Cameron	Patricia	Bund für Umwelt und Naturschutz Deutschland e.V.	Germany
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Concepcion	Carlos	Torrecid, S.A.	Spain
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d'Hondt	Christian	Syngenta Crop Protection AG	Switzerland
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Elbert	Helmut	Ciba Specialty Chemicals Inc.	Switzerland
Faunce	Thomas	ANU College of Law	Australia
Favier	Anne-Violaine	Université Pierre Mendes France	France
Freitag	Hans-Joachim	CiS Institut für Mikrosensorik GmbH	Germany
Funk	Caroline M.	Klöckner Pentaplast GmbH Ko. KG	Germany
Gamma	Richard	Schweizerische Gesellschaft für Chem. Industrie (SGCI)	Switzerland
Gandolfi, Jr	Aldo	Montana Quimica S.A.	Brasil

Geiger	Markus	Ratiopharm GmbH	Germany
Geister	Ursula	Ratiopharm GmbH	Germany
George	Jonathan	Finetex Technology	France
Goossens	Henk	Philips Research	the Netherlands
Grobe	Antje	Stiftung Risiko-Dialog	Switzerland
Habich	Edgar	Cham Paper Group	Switzerland
Han	JuTak	Nano Practical Application Center	Korea
Hansen	Jesper	Baudirektion Kanton Zürich (AWEL)	Switzerland
Hauser	Doris	Forma Futura Invest AG	Switzerland
Hermann	Andreas	Öko-Institut	Germany
Hilty	Florentine	ETH Zürich	Switzerland
Hofer	Brigit	Coop	Switzerland
Holthausen	Niels	Ernst Basler + Partner AG	Switzerland
Holzer	Andreas	Bank Sarasin & Cie AG	Switzerland
Hourman Ditlefsen	Laetitia	Oticon	Denmark
Huber	Heidrun	Universität Wien	Austria
Jaffres	Cristina	L'OREAL	France
Karasch	Gunda-Maria	Bundesministerium für Wirtschaft und Technologie	Germany
Kaufmann	Thomas	Credit Suisse	Switzerland
Kawaraya	Masahide	Graduate School of Toin University of Yokohama	Japan
Knöchel	Arndt	Universität Hamburg	Germany
Konrad	Franz	Siemens AG	Germany
Le Paire	Marjorie	WWF International	Switzerland
Lötscher	Markus	Bundesamt für Landwirtschaft	Switzerland
Lynch	Daniel	Exilica Limited	Great Britain
Meyer	Hans	Solvay GmbH	Germany
Möller	Martin	Öko-Institut	Germany
Montigel	Esther	Basler Versicherungen	Switzerland
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Müller	Rainer	Invest in Germany GmbH	Germany
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Ng	Amy	SGS (HK) Ltd.	Hong Kong
Pichler	Sonja	Polymer Competence Center Loeben GmbH	Austria
Pöll	Holger	SIG allCap AG	Switzerland
Polster	Steffen	Robert Bosch GmbH	Germany
Ragot	Jacques	Bayer MaterialScience AG	Germany
Rezaei	Rohollah	Tehran University	Iran
Rombouts	Jef	Janssen Pharmaceutica nv.	Belgium
Sacher	Hubert	TÜV SÜD Industrie Service GmbH	Germany
Schär	Samuel	Bühler PARTEC GmbH	Germany
Schirmer	Ralf	TÜV SÜD Industrie Service GmbH	Germany
Schröder-Oeynhausen	Frank	Center for Applied Nanotechnology GmbH (CAN)	Germany
Schubert	Mathias	Gen Re	Germany
Stabe	Matthias	Fraunhofer-Institut für Arbeitswirtschaft und Organisation	Germany
Studer	Christof	Bundesamt für Umwelt	Switzerland
Tanpipat	Noppawan	National Nanotechnology Center	Thailand
Thalmann-Manser	Andrea	Zurich Schweiz	Switzerland
Tricas	Nuria	Grupo Repol	Spain
Truffer	Marc	suva	Switzerland
van den Brink	Willem	Philips Research	the Netherlands
Vargas	Martin	Oticon	Denmark
Wengert	Steffen	Bundesamt für Gesundheit	Switzerland
Winter	Götz Hendrik	Grupo Repol	Spain
Yoo	Bong	Nano Practical Application Center	Korea


aquella
Swiss
Alpina