4th International
NanoRegulation
Conference
2008

the
innovation
society

Voluntary Measures in Nano Risk Governance

4th International „Nano-Regulation“ Conference
16. – 17. September 2008,
St.Gallen (Switzerland)

Conference Report

Christoph Meili, Peter Hürzeler, Stephan Knébel, Markus Widmer

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

September 2008

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We would like to thank our partners and sponsors for their support.

Preface

This report summarises the contents and results of the 4th International NanoRegulation Conference which took place from September 16-17, 2008 in St. Gallen (Switzerland). The conference was organised by the Innovation Society in cooperation with NanoEurope. This year's focus were Voluntary Measures in Nano Risk Governance.

The conference highlighted the following topics:

- The current state of voluntary measures in different legislations
- The concrete benefits and contributions of voluntary measures
- Experiences with voluntary measures in different industries
- The opportunities and requirements for international collaboration

The annual "Nano-Regulation" conference in St.Gallen is part of the multi-stakeholder platform "Nano-Regulation" which was launched in 2005 by the Innovation Society and is supported by several governmental, industrial, 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 **August 27-28, 2009**. Please reserve these dates.

For further information, please visit www.nanoregulation.ch

Content

This report consists of abstracts and selected slides of the presentations held at the 4th NanoRegulation Conference.

Introduction

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

Introduction

The topics of safety, risk and regulation have become very relevant for all involved stakeholders and are of utmost importance for a successful and sustainable development of nanotechnologies all over the world. Nanoproducts are coming onto the markets globally with enormous speed and many consumers are asking whether all these products are safe.

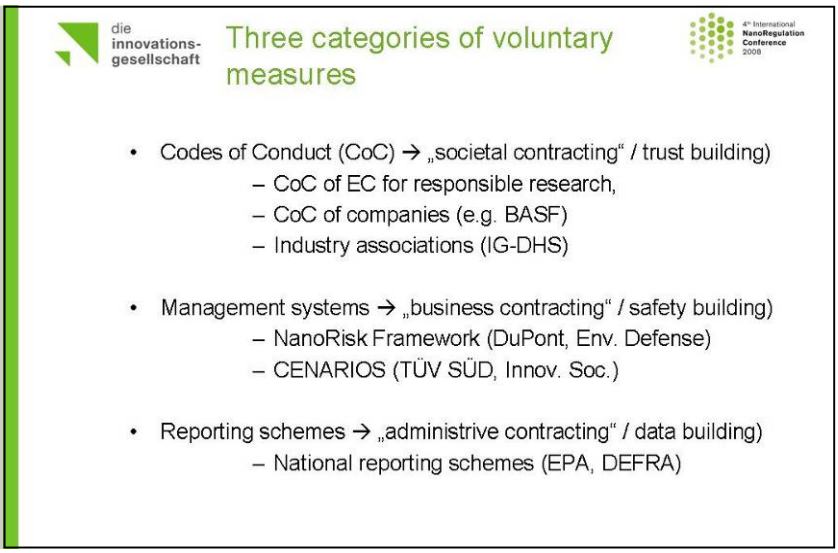
The Woodrow Wilson inventory of nano consumer products listed 803 nanoproducts by the end of August 2008. A list which was published by Migros and COOP (2 major Swiss retailers) also in August 2008 listed *53 products* (Coop 36; Migros 17) most of them belong to the categories of home & garden, automotive and some sunscreens. What seems striking is that there are interesting differences. In the list of Woodrow Wilson more than 50 % of the analysed products contain nano silver, a high-efficient antimicrobial agent, that is used in colours, packaging material and even childrens goods as pacifiers. In Switzerland there are no nano silver products sold by Migros and Coop. It can be assumed that they are both aware of the possible negative impact of nano silver on the environment. Another example are carbon nanotubes or fullerenes. In the US there are numerous consumer products on the market containing these materials.

Migros and Coop, on a voluntary basis, both do not sell products with carbon nanotubes even though there are products which contain carbon nanotubes.

Do we need Nano-Laws?

When this conference was first organised in 2005, one of the key-questions was, whether we would need „Nano Laws“ or whether the existing regulatory framework would be sufficient. The answer then was - and still is today - that we probably would not need „Nano-Laws“ but we should look at the nanomaterials and their applications very carefully and apply a „case by case“ approach. Additionally we should strengthen the precautionary principle and the self-responsibility of producers. The existing chemical laws normally do not take into account the nano-specific properties of chemicals such as size or changed physical or chemical behaviour. On some national or even regional level we see approaches of

nano-specific regulation as in the US where the EPA has declared some nano silver devices as „pesticides“. As there are no nano-specific regulations in place the role of „voluntary measures“ has become more and more important. In the absence of legally binding regulations concerning the special properties of novel nanomaterials, voluntary safety standards represent a promising



Categories of Voluntary Measures

approach to protect human health and the environment while using the time to clarify the needs and develop the required scientific and methodological database.

Today, there are several voluntary measures which are being taken internationally. Some of them are more specific than others – but all of them should be looked at in the light of the precautionary principle and the industry’s self-reliance. Some of the speakers of the first and partly the second conference day will elucidate voluntary measures in more detail.

Questions to be discussed

If we are looking at the voluntary measures presented during the next days we certainly have to discuss specific questions as for example:

Committment or anything goes? How strong is the binding character and the commitment of voluntary measures? If such measures are really voluntary can the consumers really rely on it? And if not: What can or must be done to increase the binding character of such measures?

Responsibility or risk? Who is responsible if anything goes wrong even when such voluntary measures were fulfilled?

Reward or penalty? Is it necessary to reward voluntary engagement of certain stakeholders or is the principle of self-responsibility a duty of the industry which is part of the normal compliance and can be punished in the case of non-compliance?

Trade barriers or opportunity? Do voluntary measures put an additional economic pressure on companies and industries in a country or are such measures in contrast an opportunity in the sense of „safety first because safety sells“.

Legal Perspectives - Significance of Voluntary Measures in the International Legal Context

Stefanie Merenyi, RA, sofia Darmstadt, Germany

Legal Perspective – Significance of Voluntary Measures in the international legal context

Stefanie Merenyi, Attorney at Law /
Information Scientist Chemistry
University of Applied Sciences, Darmstadt, Germany

Voluntary measures can be seen under a number of influences and interests. First of all, voluntary measures enable industry to operate proactively, to demonstrate its knowledge about a new technology and its ideas of its safe use. Against this backdrop, voluntary measures can express the realization of industry's individual responsibility. Moreover, voluntary measures may be used in order to prevent governmental regulation which may narrow economic freedom, entrepreneurial initiative and in the worst case regulate the new technology "into pieces". In addition, voluntary measures are publicized where already existing legislation is considered to be sufficient. Indeed, this constellation creates the need to identify the corresponding legal elements applying to the new technology – a question that will be answered differently by different experts. Likewise, no exhaustive answer can be given regarding the ratio between the compliance of voluntary measures and potential product liability issues. At this point where it comes to the question of legal certainty the possibilities of voluntary measures may be limited.

Nevertheless, it has to be considered that also public authorities are more and more subject to economy measures and have limited resources and, in consequence, limited knowledge. So effective administration may require even voluntary measures.

Thus, also the voluntary code of conduct for nanotechnology is to be reflected in this field of diverse tensions.

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4th International "Nano Regulation Conference"
September 16th – 17th 2008, St. Gallen/Switzerland

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University of Applied Sciences Darmstadt, Germany

Legal Perspective – Significance of voluntary measures in the int. legal context

Attorney at Law, Information Scientist Chemistry
Stefanie Merenyi

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Survey

1. **Characteristics of** voluntary measures
2. Nano specific voluntary measures
   a. EC: Voluntary code of conduct for nanotechnology
   b. US: Nanoscale Materials Stewardship Program (NMSP)
3. Significance of voluntary measures

3

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1. Characteristics of voluntary measures

1. Voluntariness ? → "Certain kind of Inducement" !
2. Who is acting 'voluntarily' ?
   - Industry
     e.g. agreement on waiver of dangerous substances
   - Governments
     - Specification of a certain (environmental) goal, e.g. certain purity of air, water, etc.
     - waiver of a specific regulation
   - Authorities
     (case by case under existing legislation)

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1. Characteristics of voluntary measures

3. Is more than one party involved ?
   - Unilateral measures
     - declaration of the actor only, e.g.
       - Asbestos industry 1982 (D)
         reduction of asbestos cement fraction (50 %)
       - Commission Recommendation (89/349/EEC) on the reduction of chlorofluorocarbons (CFCs) by the aerosol industry

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1. Characteristics of voluntary measures

3. Is more than one party involved ?
   - Bilateral measures
     - mutual engagement between industry and government / authorities:
       - Industry imposes certain obligations on itself
       - Public agency surrenders / delays regulations

"E. g.: Nuclear power phase-out (Germany)".

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1. Characteristics of voluntary measures

4. Is the voluntary measure legally binding?
   - Unilateral measures:
     No, but the actor raises expectations ("politically binding").
   - Bilateral measures:
     - In Europe: possibly (environmental contracts).
     - In US: No
       ban on ex parte communications
       Only: *Negotiated Rulemaking* .

From a legal point of view: High degree of uncertainty !

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1. Characteristics of voluntary measures

5. Who is represented by the committing parties?
   The identification of actors can be difficult:

- On behalf of certain authorities: competences!
- On behalf of industry: associations (mostly) → members and non-members
  Members may face challenges from anti-trust legislation !

From a legal point of view: High degree of uncertainty !

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2. Nano specific voluntary measures

a. EC: Voluntary code of conduct for nanotechnology
b. US: Nanoscale Materials Stewardship Program (NMSP)

The voluntarily acting party:

a. The European Commission
b. US-EPA

} "authorities"

Both programmes can be seen as unilateral declarations (even though there was dialogue with industry before)
→ they are not legally binding.

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3. Significance of voluntary measures

Depending on the details:

- **Initiator (public/private)**
- **Unilateral / bilateral → legally binding?**
- **Identifiability of members of a voluntarily acting group (e. g. associations)**
- **…**

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3. Significance of voluntary measures

Depending on the details:

- **Initiator (public/private)**
  Can a company expect to be free of liability / reduced liability because it complies with a public voluntary measure, e. g. with the EC code of conduct for nanotechnology ?

  Relationship to existing regulations / interfaces ?

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3. Significance of voluntary measures

In general:

The significance of voluntary measures is the larger, the smaller the remaining uncertainties are.

A way to decrease uncertainties:

Establish defined types of voluntary measures.

(Discussed for the new German Environmental code UGB, but not realized).

Aim:
Transparent standard of due diligence!

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3. Significance of voluntary measures

- **Motives for voluntary measures (here): uncertainty**
  - **about the object of regulation ("Nano") [Industry] as a consequence**
  - **about the necessity of regulation [gov/auth].**
- **In the centre: Cooperation principle !**
  - **Voluntary measures enable authorities to get insight into highly sophisticated techniques.**
  - **Voluntary measures contribute to establish just the appropriately necessary regulation and therewith legal certainty.**

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Nano Liability Risks

Dr. Gerhard Schmid,
Munich Re, Germany

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Nano Liability Risks:
Voluntary Measures from the Viewpoint of Liability Law
Dr. Gerhard Schmid
Munich Re, Munich, Germany

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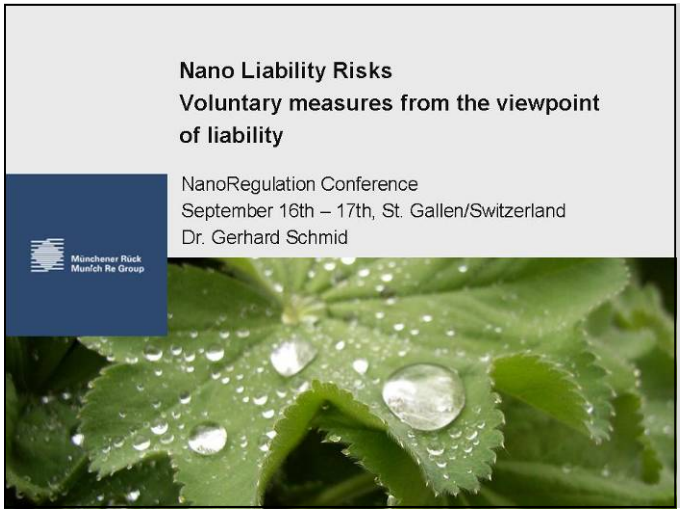

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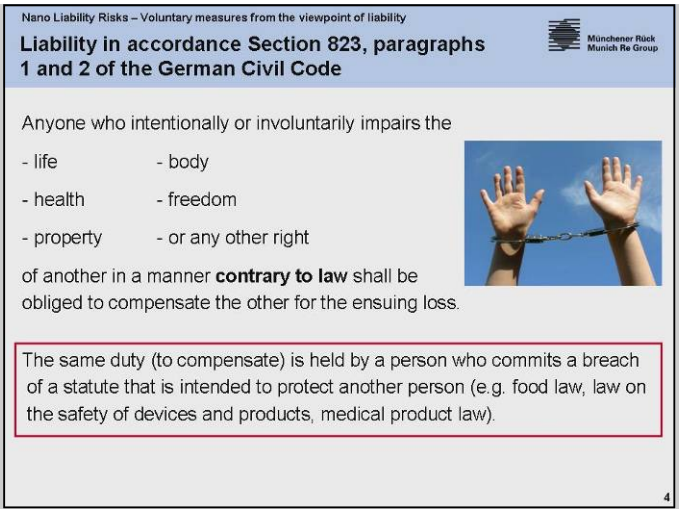

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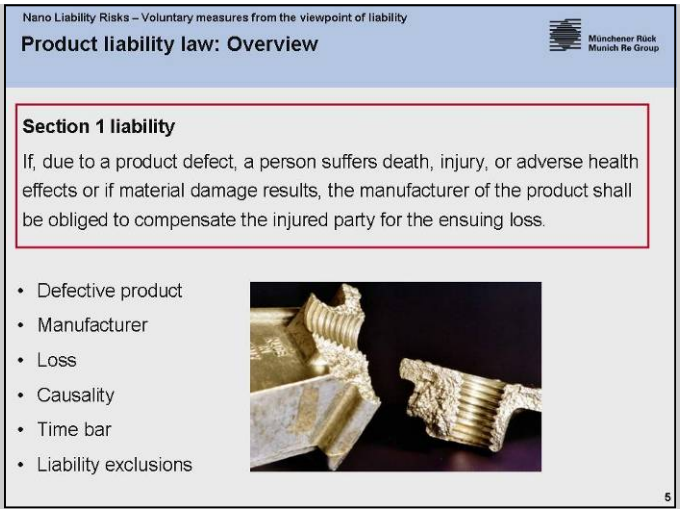

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Product liability law: Defective product, definition of manufacturer and loss

Product: Any movable object

Defects: Any negative deviation from the objective safety standard at the time of delivery

Manufacturer is

- Producer of final/component products and raw materials
- EU importer
- Quasi producer
- Any dealer that cannot name the real manufacturer or importer to the injured party (catchall element).

Loss in accordance with the product liability law is

- Bodily injury including damages for pain and suffering
- Material damage (only for final consumers)

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Product liability law: Causality, time bar

Causality is the link between a defective product and the damage/injury that has occurred (as in Section 823 of the GCC).

The time bar comes into effect 3 years after the injured party knows or should have known of the

- loss
- name of the liable party

However, under no circumstances later than ten years after sale of the product.

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Product liability law: Liability exclusions

Liability exclusions for the manufacturer exist if

- it has not marketed the product
- the defect arose after the product was marketed
- the product was not intended for sale
- the product conforms to strict legal regulations
- the defect was unavoidable given the status of science and technology at the time
- the defect is attributable solely to the final producer

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Contractual liability in accordance with Section 280 of the GCC

Compensation due to a breach of duty

If the obligor breaches

- a duty
- arising from the obligation,

the obligee may demand damages for the damage caused thereby.

This does not apply if the obligor is not responsible for the breach of duty.

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Fundamental objectives of the law on the safety of devices and products

Article 1: Scope of application
This law applies to the marketing and issuing of products in the course of commercial operations.

- Greater safety for private consumers
- Greater transparency of market supervision
- Authorisation basis for official bodies vis-à-vis manufacturers
- Duty on the part of manufacturers to inform authorities about the risk of personal injury, safety risks and the preventive measures taken
- Duty of disclosure on the part of the authorities (Section 5, paragraphs 2 and 3, Section 10 of the law on the safety of devices and products)
- Obligation to establish preventive recall management (Section 5, paragraph 1, item 1c of the law on the safety of devices and products)

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Quality management

- Origin of all quality management systems is ISO 9000 ff
- Numerous supplementary standards
- Still no explicit standard regarding quality management of nano-products
- ISO/TC 229 Nanotechnology
  - WG 1 Terminology and nomenclature (Canada)
  - WG 2 Measurements and characteristics (Japan)
  - WG 3 Health, safety and environment (USA)

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Nanocluster

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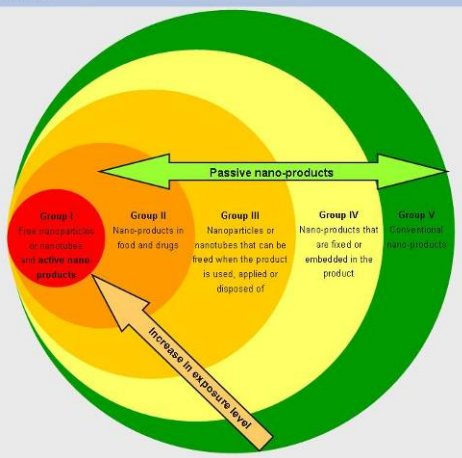

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Impact of nanoproducts

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- **Design faults**
  Production period, annual working days, number of shifts per day, number of items per shift, service life, temporal limit of the insurance cover
- **Production errors**
  Typical batch size, number of identical products, estimated return rate
- **Quantifiable unit costs**
  Removal and installation costs, other costs
- **Recall costs**

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Loss prevention through Enterprise Risk Management (ERM)

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- Theoretically at least, loss prevention starts in the laboratory and in research
- Practised within the production process through QS/QM for incoming goods, production itself and outgoing goods
- Ongoing handling through risk management and in-depth risk analysis
- Constant monitoring on the basis of ERM and early-warning systems (EWS)

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Analysis of the entire risk spectrum

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Elements of risk analysis

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- Organisation and planning of measures
- Methods and requirements
- Documents and documentation
- Quality controls
- Auditing and certification
- Transparency
- Laboratories and testing means

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

Occurrence probabilities Aspects for the insurer

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- Company and management
- Product and product environment
- Research and development, construction and design
- Production
- Operating environment
- Quality assurance
- Purchasing
- Sales and services
- Risk and loss management

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

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Conclusion and outlook

- Nanotechnology is an area of enormous economic significance
- Risk analyses have to be continuously further developed
- Before production starts, manufacturers of nano-products have to carry out loss prevention
- Risk management and life-cycle management are essential in the manufacture of nano-products
- Quality assurance and quality management must be seen as an integral part of research, development, production, and use by the consumer

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Nano Liability Risks – Voluntary measures from the viewpoint of liability

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Conclusion and outlook

- Safe, certified nano-products guarantee a high level of confidence in products.
- A risk dialogue must be established which can help to ensure that nanotechnology does not suffer the same fate as genetic engineering, stem cell therapy and other technologies.
- Risk dialogue and information programmes can make an important contribution to raising public awareness and to risk management.

Nano Ethics in Science and Research

Recommendation to the Member States on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

Pēteris Zilgalvis, J.D.

European Commission, Brussels, Belgium

Pēteris Zilgalvis, J.D., European Commission, Brussels

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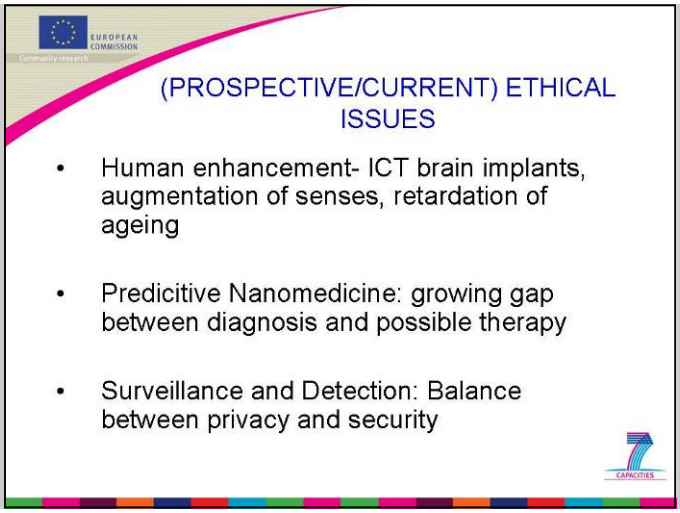

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(PROSPECTIVE) CURRENT RISK ISSUES

- Mainly: Safety of nanoparticles
- Application of Precautionary Principle
- Implementation of Code of Conduct

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FUTURE SCIENCE/SOCIETY ACTIONS AND CHALLENGES

- Involving civil society actors in nanotech research
- Acceptability of Technology: consumer product satisfaction is crucial
- Map regulatory needs at EU and international levels

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3- Why a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research?

A Recommendation from the Commission to the Member States in the field of N&N research constitutes a **strong political signal** in line with its previous commitments.

The harmonisation of laws of the Member States being excluded from research policy, the Community can use **non-binding instruments**, such as recommendations (Art. 211 of the EC Treaty), to fulfil the tasks and obligations enshrined in the Treaty.

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3- Why a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research?

The Recommendation, through the Member States, addresses **all stakeholders** in N&N Research,

Proposes the **adoption and promotion of a Code of Conduct** for Responsible N&N Research (both private and public laboratories)

Calls for the application of the Precautionary Principle to N&N Research.

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4- The Code of Conduct

GENERAL PRINCIPLES

(1) Meaning
(2) Sustainability
(3) Precaution
(4) Inclusiveness
(5) Excellence
(6) Innovation
(7) Responsibility

8

EC recommends Member States

–be used as an instrument to encourage dialogue at all governance levels among policy makers, researchers, industry, ethics committees, civil society organisations and society at large

–Inform the EC on first results by 30 June 2008

–Cooperate with EC to monitor and review the Code biannually

9

4- The Code of Conduct

ACTIONS TO BE TAKEN

– Good governance of the N&N research
- Stakeholders awareness,
- Favouring an inclusive approach
- Key priorities
- Prohibition, restrictions or limitations

– Due respect of precaution
- Protection of people
- Reduction of uncertainty

– Wide dissemination and monitoring

10

4- The Code of Conduct

ACTIONS TO BE TAKEN

– Stakeholders awareness,
Open and pluralistic forum for discussion
- Make information accessible and understandable
- Share best practices in N&N research
- Scientific peer-review
- Scientific integrity
- Application of existing laws and regulations
- Applying ethical review requirements

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Applying ethical review requirements

How to approach proposals involving Nanosciences and Nanotechnologies (N&N) in Ethical Review?

The Ethical Review Panel should report in the ERR:

– Any violation of fundamental rights or fundamental ethical principles, at either the research or development stages;
– Fundamental rights implications of any possible restrictions on informed consent and on publication of research results related to human health;
– Particularly relevant for ethical review of dual-use linked to N&N research.

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Applying ethical review requirements

Nanosciences and Nanotechnologies (N&N) and Ethical Review

–Specific research activities aiming to gain a better understanding of ethical, legal and societal impacts of the new fields opened by N&N;
–Degree of awareness of researchers of the Code of Conduct for Responsible N&N Research itself and of the opinion of the EGE on the ethical aspects of nanomedicine;
–The extent to which the future implications have been taken into account, notably through participatory foresight processes involving ethical committees;

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The Code of Conduct

ACTIONS TO BE TAKEN

– Favouring an inclusive approach
- Inclusive discussions
- Participatory foresight exercises
- Open N&N research

14

The Code of Conduct

ACTIONS TO BE TAKEN

–Key priorities
- N&N standards (terminology, measurement, reference)
- Risk assessment, metrology and standardisation
- Priority to protection
- Balanced assessments

15

The Code of Conduct

ACTIONS TO BE TAKEN

–Prohibition, restrictions or limitations

– Violation of fundamental rights or fundamental ethical principles

- Non-therapeutic enhancement of human beings leading to addiction or if illicit (cheating in sports etc.)
- As long as risk assessment on long-term safety not available, deliberate intrusion of nano-objects into the human body

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The Code of Conduct

ACTIONS TO BE TAKEN

– Protection of people

- Specific health, safety and environmental measures
- Apply existing good practice in classification and labelling
- Risk assessment and funding
- Monitoring potential social, environmental and human health impacts

17

The Code of Conduct

ACTIONS TO BE TAKEN

– Reduction of uncertainty

- Understanding the potential risks
- Understanding fundamental biological processes
- Understanding ethical, legal and societal impacts

– Wide dissemination and monitoring

- Wide dissemination of the Code of Conduct
- Awareness of all relevant legislation
- Monitoring at national level and synergies

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References

FP7: http://cordis.europa.eu/fp7/home_en.html
FP7 Calls: http://cordis.europa.eu/fp7/dc/index.cfm
http://cordis.europa.eu/nanotechnology/src/eu_funding.htm

Nanotechnology Homepages:
http://ec.europa.eu/nanotechnology/index_en.html
http://cordis.europa.eu/nanotechnology/

Nanotechnology and Society:
http://ec.europa.eu/research/science-society/

Nanosciences and Nanotechnologies Policy :
http://cordis.europa.eu/nanotechnology/actionplan.htm

More on nanotechnology: nanoforum.org European Nanotechnology Gateway

The Nanoscale Material Stewardship Program at EPA

Jim Alwood, Environmental Protection Agency (EPA), USA

The Nanoscale Material Stewardship Program at EPA
Jim Alwood
Environmental Protection Agency, Washington, USA

On January 28, 2008, the United States Environmental Protection Agency (EPA) launched the Nanoscale Materials Stewardship Program (NMSP) as part of its oversight of nanoscale materials under the Toxic Substances Control Act (TSCA). Companies that manufacture, import, process, or use nanoscale materials for commercial purposes, were invited to participate in the NMSP. Others, including researchers who develop or study engineered nanoscale materials, were also invited to participate. Any participation in the program is voluntary.

As an introduction the presentation will give background on why EPA embarked on a stewardship program and what it hoped to accomplish including providing a firmer scientific foundation for regulatory decisions. Then the presentation will briefly discuss outreach activities before and after the program announcement and will include a discussion of key participation issues such as confidentiality, format, deadlines, scope, and why companies would participate.

Next the presentation will summarize results of the stewardship program to date including how many participants, numbers of nanoscale materials, information typically submitted and what EPA knows about companies that did not participate.

The presentation will then discuss next steps for oversight of nanoscale materials under TSCA which include continued outreach to new NMSP participants, follow-up with existing NMSP participants, measuring NMSP results with some objective standard, and future regulatory or other oversight activities of nanoscale materials under TSCA.

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Nanoscale Material Stewardship Program at EPA

The Innovation Society 4th International Nano Regulation Conference

Jim Alwood - September 16, 2008
US Environmental Protection Agency

2

Scope

- Scale of approximately 1 -100 nm
- Size dependent properties and new functions of matter at the nanoscale
- Manipulate or control material at the nanoscale

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Nanoscale Materials (NMs)

- Chemical substances as defined by the Toxic Substances Control Act (TSCA)
- NMs not on the TSCA Inventory are new chemicals
  - TSCA definition based on molecular identity, not on other properties
  - Examples are fullerenes and carbon nanotubes
- NMs on the TSCA inventory are on existing chemicals
  - Some metal oxides as an example
- EPA paper on TSCA Inventory status of NMs
- Different tools available depending on whether a chemical is "new" or "existing".

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General Approach

- Both regulatory and voluntary components
- Regulatory:
  - New Chemicals Program
  - Issue targeted SNURs for specific NMs or categories where there is evidence of
    - Risk concerns
    - Significant exposure/release potential
  - Data Development
    - Section 4 test rules
  - Information gathering
    - Section 8(a) – report use and exposure data
    - Section 8(d) – report health and safety studies
    - Section 8(e) – report substantial risk info

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Nanoscale Materials Stewardship Program Objectives

- Complement regulatory approach
- Compile data on NMs in commerce
- Increase experience with risk assessment/ mitigation
- Provide insight on data to be developed
- Generation of data to provide sound scientific basis for decision-making
- Encourage risk management practices

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NMSP Development

- Initial public meeting in June 2005
- National Pollution Prevention and Toxics Advisory Committee developed "Overview Document" and forwarded to EPA for review/consideration November 2005
- Peer consultations
  - risk management practices October 2006
  - materials characterization September 2007
- Concept paper, inventory paper, information collection request released for public comment July 2007
- EPA announced program on January 2008

6

7

Key Issues

- Confidentiality of submitted data
- Deadlines
- Scope of participants and materials
- Benefits and incentives for participation
- Metrics for evaluation

7

8

NMSP Design

- Designed for participants who already manufacture, process, use, or import NMs
- Researchers or PMN submitters may also participate
- Did not attempt to rigidly limit or define participants or nanoscale materials
- Allow for confidentiality but encourage as much public data as possible

8

9

Basic Program

- Encourage participants to report existing information during first six months - deadline was 7/29/08
- Encourage use of optional data submission form but may use any reporting format.
- Report physical and chemical properties, hazard, exposure, use, and risk management practices or plans.
- Encourages participants who do not have a risk management plan to consider developing one and submitting it

9

10

In-Depth Program

- Sponsors would develop data on a smaller set of representative nanoscale materials
- Entities or consortia with an interest in developing data should notify EPA.
- EPA will facilitate data development process
- EPA will begin in-depth follow-up with interested stakeholders after they identify themselves

10

11

Outreach

- Strategy to encourage early and active participation in the basic program
- Outreach sessions and meetings with stakeholders during the first six months
- Major trade associations alerted membership and encouraged participation

11

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NMSP Submissions

- *Submitted under the Basic Program (22 organizations covering more than 93 nanoscale materials)*
  - Arkema
  - BASF Corporation
  - Bayer Material Science
  - Dow Chemical
  - DuPont
  - Evonik/Degussa
  - General Electric
  - International Carbon Black Association
  - Nanofilm
  - Nanophase Technologies Corporation
  - Nantero
  - Office ZPI
  - PPG Industries
  - Pressure Chemical
  - Quantum Sphere
  - Sabic Plastic Innovations
  - Strem Chemicals
  - Swan Chemicals Inc.
  - Synthetic Amorphous Silica and Silicate Industry Association
  - Unidym
  - Two companies claimed as Confidential Business Information

12

13

NMSP Commitments

- *Additional Commitments to Submit Information under the Basic Program (10)*
  - Angstron Materials
  - eSpin Technologies
  - Evident Technologies
  - Luna Nanoworks
  - Nanocyl North America
  - MicroTechNano
  - Sasol North America
  - Showa Denko KK
  - SouthWest NanoTechnologies, Inc.
  - One company claimed as Confidential Business Information
- *Commitments to Participate in the In-depth Program (3)*
  - SouthWest NanoTechnologies, Inc.
  - Swan Chemicals Inc.
  - Unidym

13

14

NMSP Data

- Information typically submitted
  - characterization, risk management practices, hazard data, use
- Range of participants
  - large companies, small or start-up companies, trade associations
- Some companies notified EPA why they did not participate

14

15

Follow-Up Activity

- Continued outreach
  - Focus on smaller start up companies
  - In-depth program
- Questions for existing participants
- Measuring results with objective standards
- Regulatory actions or other oversight

15

16

Evaluation

- Interim report approximately one year from initiation based on first six months reporting
- Detailed report and program evaluation in approximately two years
- Determine future direction of NMSP at two-year evaluation
- May adjust or decide future steps earlier if experience or data warrant
- Always considering use of regulatory authorities under TSCA

16

DuPont Participation in the Nanomaterials Stewardship Program of the EPA - The Perspective of DuPont

Terrry L. Medley, J.D., DuPont, USA

DuPont Participation in the Nanomaterials Stewardship Program of the EPA - The Perspective of DuPont

Terry L. Medley, J.D.
DuPont, USA

This presentation discusses support for and participation in the NMSP by DuPont; perspective on characterization and analysis of participation in the program after the first six months; and the identification of key elements for a voluntary program that meet the agency's objectives.

The first section of this presentation discusses the key considerations that were involved in making the decision to participate in the basic program of the NMSP. These include program objective and clarity (what is expected of participants), the considerations for protection of confidential business information; how the information gathered in the program will be utilized and what form do you use to submit the information. This first section also discusses utilization of the Nano Risk Framework for the Responsible Development of Nanoscale Materials as a tool to document the information requested under the NMSP.

The presentation then takes a close look at participation in the NMSP after the first six month sign-up period. It includes a review of important assumptions about the number of nanotechnology companies as well as the number of different nanoscale materials entering or soon to enter commerce. This section also describes the steps taken by an industry trade association group to support the NMSP and encourage wide participation in the program.

Lastly, the presentation highlights those key elements that are critical to voluntary information programs that meet the Agency's stated objective of providing a firmer scientific foundation for regulatory decisions. These elements include: clarity of scope and objectives; reasonableness of information requested; and timeliness of agency actions.

1

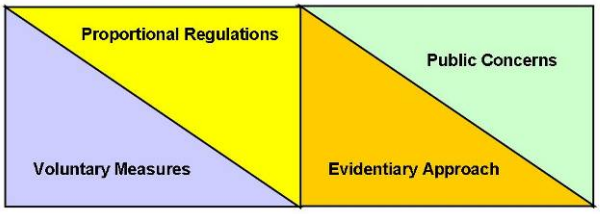
DuPont Participation in the Nanomaterials Stewardship Program of the U.S. EPA

Terry L. Medley, J.D.,
Global Director Corporate Regulatory Affairs
September 16, 2008
The Innovation Society 4th International Nano Regulation Conference
St. Gallen, Switzerland

DUPONT
The miracles of science

2

Being Responsive to Informational Needs



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U.S. Environmental Protection Agency (EPA) Nanoscale Materials Stewardship Program (NMSP)

- Program launch - Federal Register notice January 28, 2008
  http://www.epa.gov/fedrgstr
- Scope: Companies or others including researchers who develop or study engineered nanoscale materials.
- Objective: To provide a firmer scientific foundation for regulatory decisions.

4

News Release – DuPont Supports NMSP

Wilmington, Del,, January 29, 2008 – DuPont today submitted documentation related to DuPont™ Light Stabilizer 210, a new titanium dioxide product with a sizeable percentage of particles in the nanoscale, as a demonstration of its support for the new U.S. Environmental Protection Agency (EPA) Nanoscale Materials Stewardship Program (NMSP). This submission is the first received by the EPA under the new program, which was launched Monday.

5

Decision Points Considered for Participation in EPA Nanomaterials Stewardship Program

- What is expected of program participants?
- Is there protection of confidential business information?
- What is the stated objective for the information?
- Is the program practical and flexible?

6

Internal Actions that Aided Participation in the NMSP

- Adopted definitions
- Inventory of nanomaterials
- Consultation process
- Commitment to workplace safety and product stewardship
- Framework for responsible development

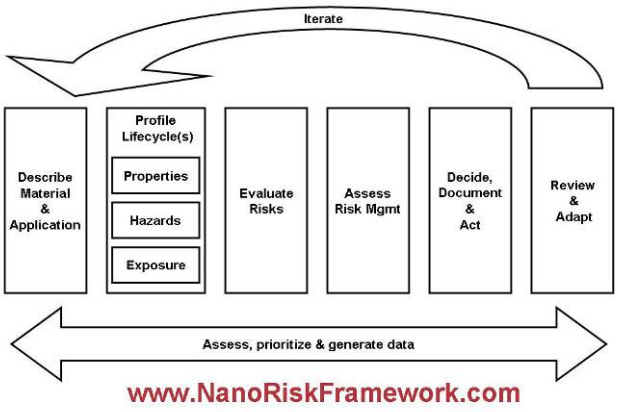
7

Nano Risk Framework for the Responsible Development of Nanoscale Materials

A Joint effort by Environmental Defense Fund and DuPont

8

Environmental Defense Fund – DuPont Nano Risk Framework



www.NanoRiskFramework.com

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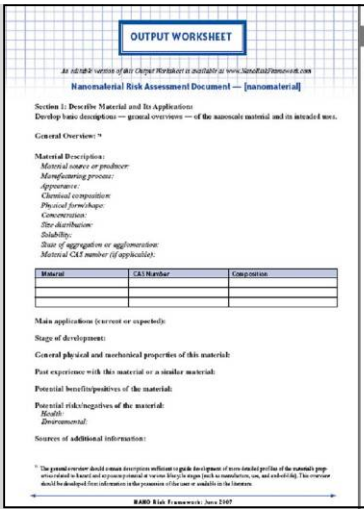


Output Worksheet

- Organize
- Record
- Share

10

Information Collection Request (ICR) for NMSP Assumptions by EPA

Basic Program

- 240 total responses over three year approval period
- 120 small/medium companies (1 per company)
- 60 large companies (2 per company – 120 total)

In-Depth Program – 15 responses over three year approval period

11

EPA NMSP has Received Information on a Significant Number of Nanoscale Materials

- Basic Program Submissions – 20 organizations covering more than 90 nanoscale materials.
- 10 additional commitments to submit under basic program

As of August 5, 2008

12

Different Views after Results of Initial 6 Month Sign-up Period

Environmental NGO

"EPA not only appears to have received limited information, but worse, EPA is saying almost nothing about it. The information being received appears to be entering a black hole," ....

Chemical Industry Association

" We told EPA in 2007 that their estimates were too high," .... the EPA has since revised its estimates and expects to receive information under the basic program for about 100 materials. "They are close to that goal now and will likely exceed it,"

Chemistry World – August 5, 2008

13

Nano Reg News NMSP Survey

What do you think of the EPA's Nanoscale Materials Stewardship Program, a program to voluntarily collect information on nanomaterials?

- The information won't be sufficient to learn about the potential risks of nanomaterials. 18%
- This is a reasonable approach. 29%
- It's a great start! 35%
- We need new laws to deal with nanomaterials. 5%
- It's too little, too late! 10%

Total Votes: 37

Results as of Aug 28, 2008

http://www.nanoregnews.com/

14

Industry Associations are Supporting the NMSP Through Outreach Efforts

- Encouraged American Chemistry Council (ACC) and non-ACC members to participate through its web-based NMSP information.
- Issued joint statements with the Synthetic Organic Chemical Manufacturers Association (SOCMA) and the NanoBusiness Alliance to encourage participation in the NMSP.
- Encouraged trade associations representing other businesses (aerospace, electronics, paints and coatings, paper) to encourage its members to participate in the NMSP.
- Engaged further discussions with EPA on the In-Depth portion of the NMSP to clarify participation issues.

15

OECD Aids Information Gathering Programs

OECD Working Party on Manufactured Nanomaterials establishes sub-group for co-operation on voluntary schemes and regulatory programmes.

Objectives

- To identify common elements of the various information gathering initiatives, in place or planned.
- To identify applicable current and proposed regulatory regimes and how they address information requirements, ...

Status

- Initial comparisons conducted
- Developing a model " template"
- Developing a clearinghouse for International sharing and comparison of data on manufactured nanomaterials

16

OECD Considerations and Recommendations for Information Gathering Initiatives

- Should clearly indicate how they intend to measure progress and the success of the programme.
- When and how information submitted will be assessed, and the steps that will be taken if objectives are not met.
- Should require respondents to submit all available information.
- Should indicate specific types of information eligible for protection as confidential business information.
- Should identify clearly how information collected under the initiative will be made public.
- Should ensure appropriate communication of the information gathering initiative.
- Should consider providing tools to respondents to facilitate their response.

17

Elements Critical to Voluntary Information Programs

- Clarity of Program Scope and Objective
- Reasonable Information Request
- Affords Appropriate CBI Protection
- Responsiveness to Public Concerns
- Timely Agency Actions
- Adequate Agency Resources

18

Concluding Thoughts

- A Good Start/Reasonable Approach
- Generating significant information on nanomaterials
- Encourages collaboration and engagement amongst stakeholders
- Information can be used for oversight assessment
- Provides a basis to build upon

The UK‘s Voluntary Reporting Scheme for Engineered Nanoscale Materials

Steve L. Morgan, Defra, UK

The UK’s Voluntary Reporting Scheme for Engineered Nanoscale Materials

Steve L. Morgan
Defra, London, UK

The UK’s Voluntary Reporting Scheme for Engineered Nanomaterials has now been running for 2 years. Steve Morgan of the UK’s Department for Environment, Food and Rural Affairs will describe the UK experience, the lessons learned from it and set out some of the options for future reporting in the UK.

1

Experience and reflections on the UK’s Voluntary Reporting Scheme for Engineered Nanoscale Materials

4th International Nano Regulation Conference
St Gallen, Switzerland, 16th -17th September 2008

Steve Morgan
Nanotechnologies Policy
Steve.L.Morgan@defra.gsi.gov.uk

defra

2

Presentation Outline

- Background
- About the UK VRS
- Issues affecting the success of the VRS
- Where next for nano reporting in the UK?
- Questions

defra

3

THE ROYAL SOCIETY

ROYAL ACADEMY of ENGINEERING

“Nanoscience and nanotechnologies: Opportunities and uncertainties”

- “In assessing and managing risks it is necessary to understand both the hazard and exposure pathways”
- “There is virtually no evidence available to allow the potential environmental impacts of nanoparticles and nanotubes to be evaluated”
- “There are uncertainties about the risks of nanoparticles currently in production that need to be addressed immediately to safeguard workers and consumers and to support regulatory decisions”

defra

4

About the scheme

- 2-year scheme, launched on 22/09/2006
- VRS submissions invited from industry and academia
- Scheme subject to regular reviews

5

VRS Data Package

- Information about the reporter
- Identity of the nanomaterial – CAS no, composition, detection methods, shape, size, surface area
- Use, benefits, exposure pathways
- Physico-chemical properties – melting, solubility, flashpoint, oxidising properties, etc.
- Risk management practices, safety precautions
- Toxicology – Inhalation, skin, mutagenicity, reprotox, etc
- Ecotoxiclogy – organisms, degradation, adsorption,etc

6

Too many objectives, too little focus...

The aims of the VRS were:

- to find out who is working with nanomaterials
- to build an inventory of nanomaterials manufactured, imported and used in the UK
- to gather information on nanomaterials, their characteristics and hazards and to use this information to fill gaps in our knowledge
- to identify data gaps which may require further research
- To provide provide reassurance and build consumer confidence

7

Issues affecting participation in the VRS

Small and medium sized commercial enterprises have limited resources

Uncertainty: Does the scheme apply to me?

Confidentiality of data

Incentivisation: What's in it for me?

8

Options for future of voluntary reporting schemes in the UK

- Continue with the VRS in its present form
- An 'enhanced' VRS, with varying data requirements
- Voluntary registration scheme
- Responsible care initiatives

9

Some mandatory reporting options

- Introduce a simple registration scheme
- Make the current Voluntary Reporting Scheme mandatory;
- Introduce REACH early for UK companies

Systematic Risk Management in the Manufacturing Industry

Samuel Schär, Bühler PARTEC, Switzerland

Systematic Risk Management in the Manufacturing Industry

Samuel Schär
Bühler PARTEC, Switzerland

The business unit PARTEC of Bühler AG manufactures nanodispersions of mainly metal oxides with a current production capacity of 500 tons per year. It’s the first entity worldwide that has obtained the CENARIOS® certificate from TÜV Süd one year ago and underwent a successful recertification in August 2008.

The present talk will cover hands-on and in a pragmatic way how PARTEC implemented the new risk management system for its entity within a large corporate structure and successfully brought it to life at reasonable cost.

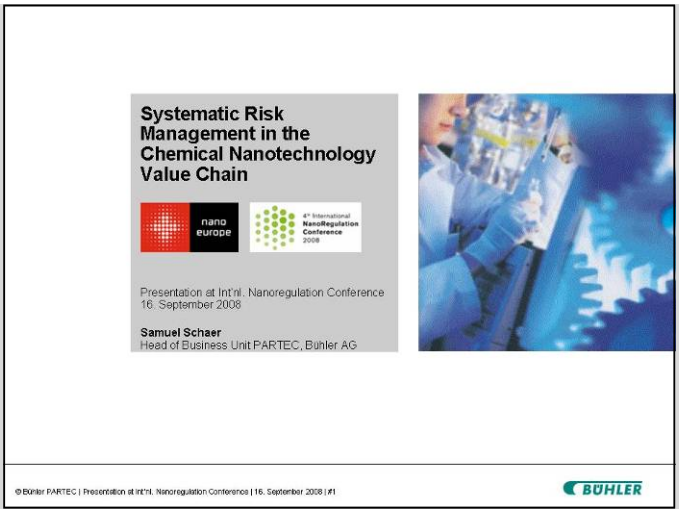
Starting from a simple MSDS, PARTEC compiles an extended nanospecific “MSDS” called RAS – Risk Assessment Sheet – for every product. The RAS includes a complete assessment of risks going far beyond HSE, combining conventional root cause – extent of damage industrial risk analysis for secure production, storage, transport and application techniques with an assessment of the current state of science and technology pertaining to the known and anticipated risks of the respective nanomaterial used in the product of the RAS by an independent board of experts in the field.

Regular monitoring cycles several times a year reconsider the RAS issued formally with respect to new consolidated findings, making the RAS an ideal stoplight decision tool for management and communication with the stakeholders likewise.

Talking implementation, the talk will discuss how the system could easily be integrated into the corporate landscape of existing certified management systems without the need to reinvent the wheel by making it part of the corporate QM documentation on the one hand, and simply by clear definition of the interfaces and responsibilities with respect to the event and alarm organization and the crisis management and communication system through active involvement of the respective bodies concerned.

As a conclusion, the talk shows how the nanospecific risk management system is far from being a recurring analysis disjoint from operative business activities, but an integral part of it, from initial product development to scale-up, to market introduction and monitoring during its product life cycle, and in that respect therefore has become a core business process in the industrial nanodispersion manufacturing.

1



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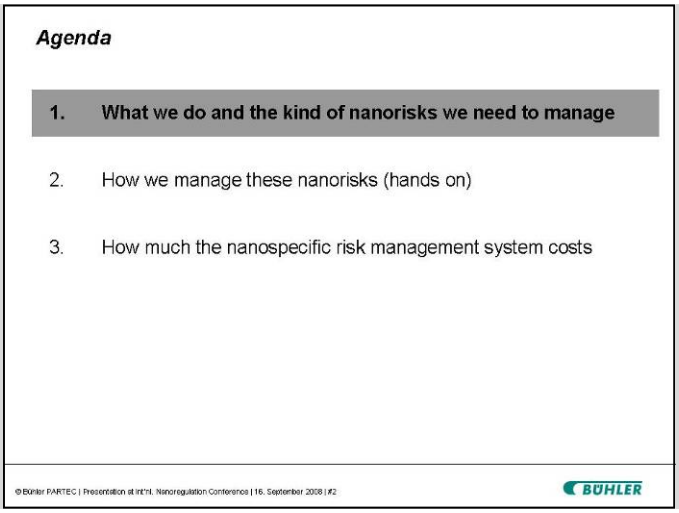

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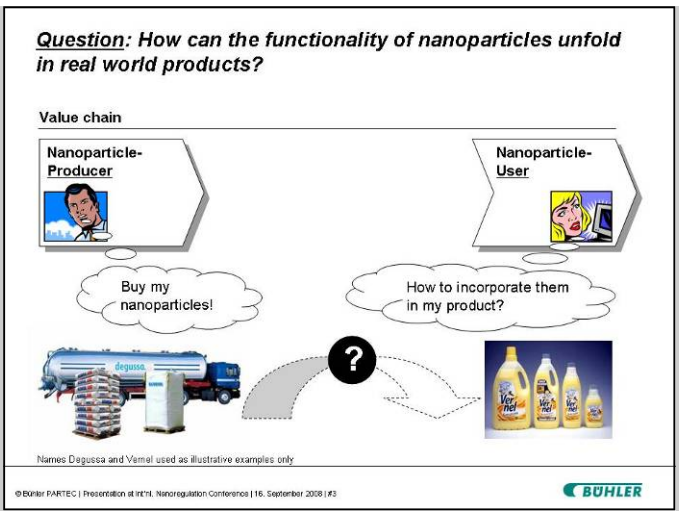

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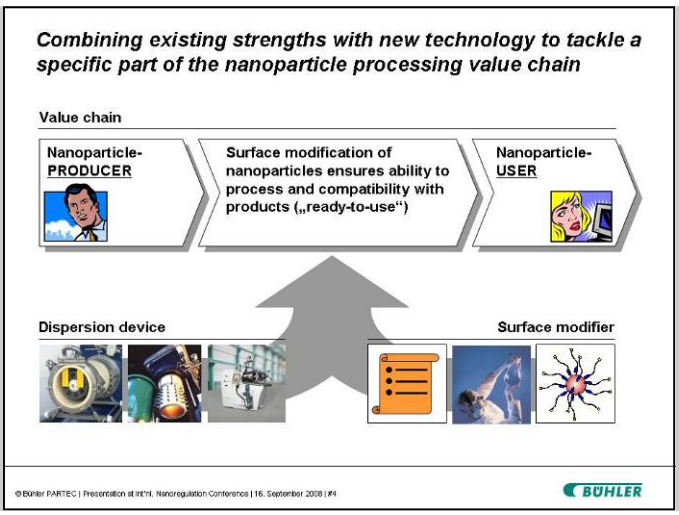

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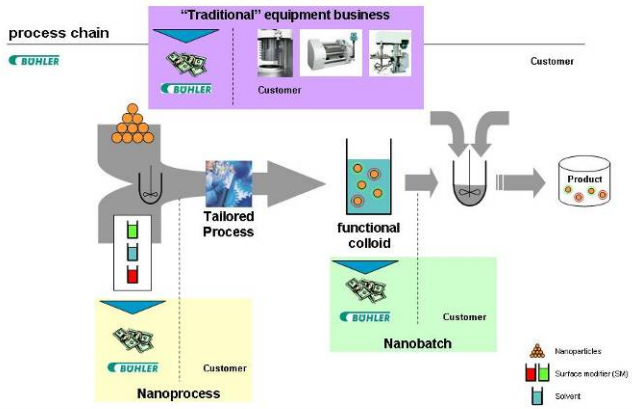
Business model Buhler PARTEC



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The same dispersion produced with various production technologies – the properties DO CHANGE when going nano

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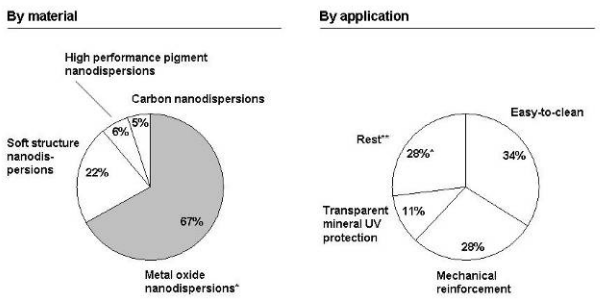
Buhler PARTEC main fields of activity
Revenue breakdown by type of business



* Mainly ZnO, TiO_2, Al_2O_3, ZrO_2 and also SiO_2
** Emerging applications

8

Agenda

1. What we do and the kind of nanorisks we need to manage
2. **How we manage these nanorisks (hands on)**
3. How much the nanospecific risk management system costs

9

Corporate Buhler as equipment and plant manufacturer does not intrinsically have a HSE department

10

Risk management ≠ risk elimination, but the management to keep the risks As Low As Reasonably Possible

RISKS ARE ALARP

=

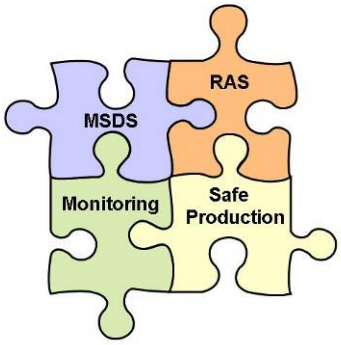
RISK MANAGEMENT

≠

RISK ELIMINATION

11

Our risk management system is based on 4 elements



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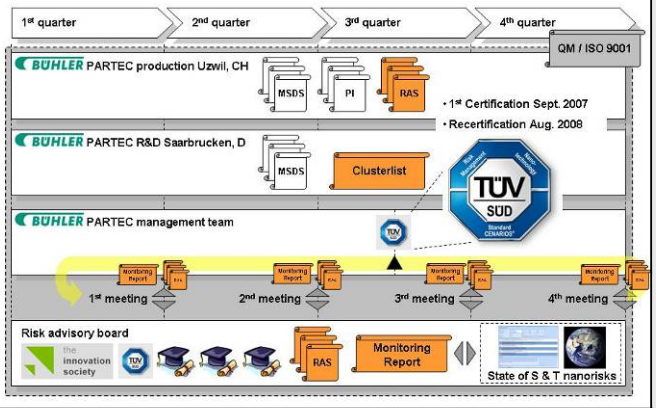
How we practice our nanospecific risk management at a glance



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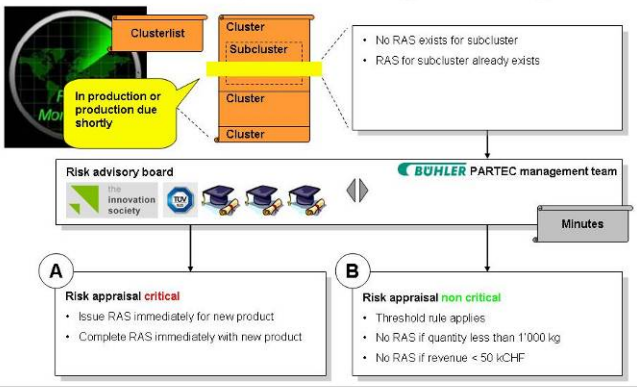
The RAS define the input for the monitoring radar, the Clusterlist defines the input for the foresight monitoring radar



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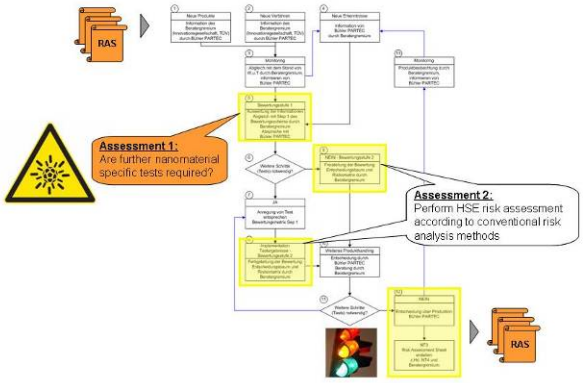
RAS are issued with a two step assessment process



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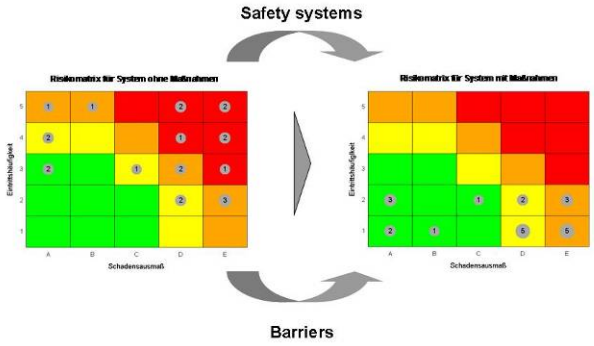
Consideration of safety systems and containment barriers rounds off the picture of the risk assessment matrix



16

What you always wanted to know but never dared to ask

- Time required from idea to first certification: **1.5 years**
- Setup cost (internal & external): **250 – 500 kCHF**
- Running cost per year: **50 – 250 kCHF**

We are very glad we did it, the reasons why were presented in the conference

Guidance of the German chemical industry association VCI for a responsible production and utilization of nanomaterials

Dr. Hans-Jürgen Klockner, German Chemical Industry Association (VCI), Germany

Guidance of the VCI for a responsible production and utilization of nanomaterials

Dr. Hans-Jürgen Klockner
German Chemical Industry Association (VCI), Germany

The German chemical industry is committed to a responsible production and use of nanomaterials under the core principles and commitments of the “Responsible Care Global Charter” of the International Council of Chemical Associations.

Good product stewardship is a key pillar of Responsible Care and is the chemical industry’s key mechanism for managing the health, safety and environmental aspects of a chemical throughout its life cycle. Product stewardship is a shared responsibility between chemical producers, their suppliers and their customers. It requires the development of close, sustained dialogue and working relationships with suppliers, customers, and others in relevant value chains. These parties should share information up and down the value chain to ensure that chemicals are used and managed safely throughout their life-cycle. In doing so, they will meet the increasing demand for safe and environmentally-sustainable uses of chemicals.

Product stewardship provides the platform for companies to identify risks at an early stage and manage those risks along the value chain, thereby enabling adequate protection of human health and the environment. Evaluation and avoidance of risk reduces the potential for harm and potential liabilities, making product stewardship a “value added” business proposition.

The German chemical industry is committed to establish and disseminate best practices for a responsible production and use of nanomaterials. VCI has, therefore, issued a series of guidance documents and recommendation papers to help companies in the sustainable and responsible development of nanotechnology-based applications and to manage the health, safety and environmental aspects of nanomaterials throughout the life cycle.

These documents provide guidance on all aspects of a good product stewardship on nanomaterials and cover aspects like fulfilling the requirements of the REACH Regulation, gathering of hazard information for the risk assessment of nanomaterials, handling and

use of nanomaterials at the workplace, passing on of information along the supply chain, and safety research.

Additionally, the German chemical industry has expanded its dialogue with society to address societal expectations and concerns relating to nanomaterials. The activities include stakeholder workshops, public fora and an active participation in the “Nano-Dialog” of the German environment ministry.

1

Responsible Production and Utilization of Nanomaterials

NanoRegulation Conference
16 – 17 September 2008, St. Gallen
Hans-Jürgen Klockner, VCI

2

Good product stewardship with nanomaterials

General statements in laws vs. Codes of Conduct

- **REACH:** “Manufacturers, importers, downstream users must ensure that substances do not adversely affect human health or the environment.”
- **German Dangerous Substances Ordinance:** “Manufacturers / importers must classify substances / preparations according to their dangerous properties (with obligation to take efforts to gather information).”
- **German Worker Protection Law:** “Employer must take the necessary measures for occupational health and safety (with obligation to verify the efficiency of the measures and, if needed, to adapt the measures).”
- **German Product Safety Law:** “No marketing of products if there are risks for users at typical uses. Users must be provided with the necessary HSE information.”

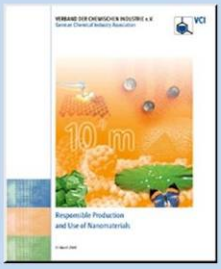
Language of laws is similar to that in Codes of Conduct.
Industry associations often write guidelines how to implement laws.

3

Good product stewardship with nanomaterials

8 VCI documents for a comprehensive but modular approach

- **Principles document**
  - Implementing Responsible Care® on Nanomaterials
- **Regulatory documents**
  - Nanomaterials and REACH
  - Data Gathering for Risk Assessment
  - Occupational Safety and Health
  - Communication in the Supply Chain
  - Standardization
- **Documents on Safety Research**
  - Human Health
  - Environment
- **This is VCI’s approach for responsible nanotech use – reflecting the European legal environment and REACH**



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Good product stewardship with nanomaterials

Implementing Responsible Care© on Nanomaterials

- **Responsible Care® applies to all products of the chemical industry**
  - **also to nanomaterials**
- **The global Responsible Care® principles require to:**
  - **continuously improve HSE-knowledge and performance** of technologies, processes and products over their life cycles
  - **report openly on performance, achievements and shortcomings**
  - **listen, engage and work with people** to understand and address their concerns and expectations
  - **cooperate with governments and organisations** for effective regulations and standards, and meet or go beyond them
  - **provide help and advice to foster the responsible management of chemicals along product chain**

5

Good product stewardship with nanomaterials

Nanomaterials and REACH (1)

REACH

- **regulates chemical substances, in whatever size, shape and form,**
- **therefore also regulates nanomaterials,**
- **and provides the necessary legal instruments for their regulation.**

⇨ **This is the common understanding of VCI and German Competent Authorities**

6

Good product stewardship with nanomaterials

Nanomaterials and REACH (2)

- **Legal requirements without volume thresholds and independent of registration timelines:**
  - **Classification and labelling**
    - **Different products with the same chemical identity can have different classification / labelling**
  - **Risk Assessment for all uses**
    - ⇨ **Nanospecific VCI recommendation on gathering HSE information**
  - **Information in the supply chain according to Title IV of REACH**
    - ⇨ **Specific VCI guidance on how to fill in the Safety Data Sheet for nanomaterials**

7

Good product stewardship with nanomaterials

VCI

Nanomaterials and REACH (3)

- REACH Registration:
  - Mandatory for all substances >1 t/a per registrant
  - Precautionary Principle already implemented in REACH (Article 1)
  - Substances, not uses or forms, must be registered
  - All uses / forms of the substance must be identified in the registration dossier
    - also uses / forms of the substance at nanoscale
    - even if they are < 1 t/a!
  - Obligation for update, if a registered non-nanoscale substance is to be manufactured also at nanoscale

⇨ VCI guidance on the requirements of REACH for nanomaterials

8

Good product stewardship with nanomaterials

VCI

Data Gathering for Risk Assessment

⇨ Nanospecific VCI guidance for gathering of hazard information

- Tiered gathering of HSE information according to REACH Annexes VI – X to ensure product safety
- Recommendation for additional physicochemical information on top of REACH requirements:
  - surface chemistry/coating, morphology, crystalline phase, shape, surface structure, particle size/size distribution, agglomeration/aggregation in native material or in preparation, specific surface area, known catalytic activity
  - in special cases: dustiness, porosity, dispersion stability in water (or in other media), zeta potential (surface charge), radical formation potential, photocatalytic activity

9

Good product stewardship with nanomaterials

VCI

Occupational Safety and Health

⇨ Specific VCI / BAuA guidance for handling and use of nanomaterials at the workplace

- Especially targeted to SMEs
- Explanation of legal requirements for workplace safety
- Checklist and recommendations for procedures to ensure workplace safety using nanomaterials
  - Substitution, information of workers, technical safety measures, personal safety equipment
  - Overview on exposure measurement techniques
  - Recommendation to minimise exposure at the workplace, until specific limit values are laid down for nanoparticles or certain nanomaterials

10

Good product stewardship with nanomaterials

VCI

Communication in the Supply Chain

- Legal requirement to submit information to downstream users
  - ⇨ Nanospecific VCI guidance for the information flow in the supply chain by means of the Safety Data Sheet (SDS)
- Common practice in the German chemical industry:
  - Safety Data Sheets for all substances/preparations
    - i.e. also for those not classified as dangerous

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Good product stewardship with nanomaterials

VCI

Standardisation and Safety Research

⇨ VCI strategy paper on the standardisation of nanomaterials

- Terminology, definitions
- Implementation of new testing methods
  - with focus on exposure measurement

⇨ DECHEMA / VCI roadmaps for

- Safety research on nanomaterials [human health] and
- Environmental aspects of nanoparticles
- Overview on current and finalised projects on safety research
- Gives rise to new research projects in FP7 and national programmes

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Good product stewardship with nanomaterials

VCI

Some voluntary measures in the VCI guidance documents

- Above legal requirements:
  - For Risk Assessment **quite a number of additional physicochemical information** on top of REACH requirements
  - **In special cases** (specific toxicity and/or widespread use and repeated exposure) **gathering of HSE information beyond REACH Annex VII** (i.e. from Annex VIII, IX und X)
  - **Minimise exposure at the workplace,** until specific limit values are laid down for nanoparticles or certain nanomaterials
  - **Safety Data Sheets for all substances/preparations** (i.a. also for those not classified as dangerous)
  - **Intensifying safety research with specific projects**
  - **Stakeholder dialogues**

Approaches in Retailing: The Code of Conduct of the IG DHS

Dr. Thomas Gude, IG DHS and SQTS, Switzerland

Approaches in Retailing: The Code of Conduct of the IG DHS
Dr. Thomas Gude
Swiss Retailers Association (IG DHS)
Swiss Quality Testing Services (SQTS), Switzerland

In recent years, when consumer products based on nanotechnology entered the market, not only consumers but also consumer organisations requested more information from retailers about the safety of this type of products. Therefore, as a first step in April 2008 the Swiss Retail Association (IG DHS – Interessengemeinschaft Detailhandel Schweiz) published a Code of Conduct (CoC) Nanotechnology. This is worldwide the first document of retailers, which takes account of the growing importance of nanotechnologies in consumer products. This CoC serves as a guideline not only for retailers but also for stakeholders like consumers, manufacturers, suppliers etc. Due to the absence of binding definitions and regulations, a guideline was assumed to be necessary.

On the one hand the CoC lists obligations of the IG DHS members like personal responsibilities, the procurement of information and finally information for consumers. On the other hand the CoC lists requirements for stakeholders like providing information on company specific quality systems and especially on product specifics. Furthermore, companies should also provide information on safety aspects, i.e. concerning the environment and manufacturing staff.

When putting the CoC into action, a challenging task among others is dealing with missing information. How retailers or others could find out, which product contain nano particles, if manufacturers and suppliers do not or could not sufficiently inform about their products. Maybe they also face a lack of information by their suppliers. The easiest products to handle are those, which carry in their names the acronym “Nano”. Here it is possible to request general data or data of safety assessments. For all other products it depends on “goodwill”.

This information deficit makes evident that the CoC can only act as

a first step in improving the really needed discussion within the stakeholders. For manufacturers, suppliers and retailers it is mandatory to share information in an efficient way, because they are all in the same boat – selling safe and good products. Therefore, discussions with several interest groups like cosmetic, textile, packaging associations etc. have started or will be started soon about the way of sharing data under necessary secrecy agreements.

If data on products containing nano particles are provided by a manufacturer or supplier, the retailers currently will independently check the quality of those data and will perform a risk assessment. The problem here is, that for the moment no binding rules exist for the risk assessment of such new products. One open question here is, how to deal with toxicological data, which are based on classical study design – is that sufficient for nanoparticles?

As a first step the temporary risk matrix, provided by the Swiss Action Plan “Synthetic Nanomaterials”, will be taken to classify products. On the top of this risk list are products which are able to set free synthetic nanoparticles; on bottom of this list are products with modified surfaces having nanoeffects like the Lotus effect.

The definite challenge to put life into the CoC is the way to inform consumers on nanobased products by declaration. For those products already carrying “Nano” in the product name a kind of declaration is given, but a risk classification is not given. For all other products there also is a need for declaration, but the way of implementing is still questionable. First rules for a possible declaration will be worked out by ISO groups, but they will not be available so soon. In the meantime the retailers try to fill the gap between new and promising consumer products with advantageous properties versus possible risks emanating from synthetic nanoparticles by the above described process.

The CoC at its present form is only the beginning of the process to find a widely accepted way of dealing with nanobased consumer products. New perceptions on products will be permanently included into current risk assessments, which will lead directly to adequate consumer information.

The CoC of the IG DHS is a first and important step on dealing with nanotechnologies, but it must be clear that retailers can not be made responsible alone for all nanobased product related issues. Generally, the expectations of any stakeholder should be realistic and pragmatic and not driven by any ideology.

1

SQTS – Swiss Quality Testing Services

IG DHS
Interessengemeinschaft Detailhandel Schweiz

Approaches in Retailing: The Code of Conduct of the IG DHS

Dr. Th. Gude
16 September 2008

ZURICH, FRIBOURG, HONG KONG

2

Code of Conduct Nanotechnologies

- Published end of April 2008*
- IG DHS: Swiss Retailer Association:

Vögele · coop · DENNER · MANOR · MIGROS

* www.igdhs.ch

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3

Outline

- Why a Code of Conduct?
- Definition
- Obligations of IG DHS members
- Requirements for manufacturers an suppliers
- Conclusion

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CoC: Obligations IG DHS

- **Personal Responsibility**
  - Product safety first
- **Action**
  - Screening of products on the market, which contain nanomaterials or which advertising with „nano“
  - New products:
    Statement on “nano” is needed from supplier
- **Discussion**
  - Unknown Status of Products

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CoC: Obligations IG DHS

- **Procurement of information**
  - Requesting information about nanotechnologies
- **Action**
  - Questionnaire is developed
  - Will be published soon on IG DHS web page
- **Discussion**
  - Manufacturers/Suppliers providing inadequate information – using a different definition

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CoC: Questionnaire – Important Elements

- **Product basis**: What is special about the product that distinguishes it from a comparable, “non-nano” product? Provide evidence of effectiveness. What is the added benefit for the customer?
- **Additional information about the ingredients** with respect to particle size, technical function, method of use, recipe:
- Potential risk in the individual **cycles of the product’s life** (production, use, disposal):
- **Potential risk for the user** in applying, using and in the event of conceivable misuse or excessive use of the product. Does it require special customer instructions?
- **Risk to the environment or organisms** (soil, air, water): acute or long-term; degradability or change of the substance or substances in the environment. Persistence or accumulation in the environment:
- At what stage (Production, Use, Disposal) **are nanoscale particles released**?
- **Product already on the market**: Where, since when and how many products have been sold? What customer complaints/problems have been received in connection with the product?

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CoC: Obligations IG DHS

- **Procurement of information**
  - Assessment of Data
- **Action**
  - Assessment done by IG DHS members
  - Assessment done by external, independent organisations
- **Discussion**
  - No final ruling for i.e. performance of toxicology studies and the assessment of such studies
  - The current regulatory framework and the subsequent technical guidance documents do not specifically address nanomaterials.

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CoC: Obligations IG DHS

- **Information for Consumers**
  - Retail Trade is responsible for informing consumers openly about products that incorporate nanotechnologies
- **Action**
  - Ensuring that products advertising nanotechnologies actually contain components or mode of actions
- **Discussion**
  - No existing and binding declaration rules
  - Products with nano-effects

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CoC: Requirements for Manufacturers and Suppliers

- **Company Specific Requirements**
  - Risk Assessment
- **Action**
  - Manufacturers/Supplier should follow a risk assessment approach, i.e. ……
    incl. occupational health and safety during production, storage and transport
  - Outcome of risk assessment should be communicated
- **Discussion**
  - Which risk assessment is valid for nanotechnologies?
  - We do not have a common standard!

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CoC: Requirements for Manufacturers and Suppliers

- **Product Specific Requirements**
  - Disclosing and Forwarding decision–relevant **Product Data** throughout the production and distribution chain
  - New health-related or environmentally relevant findings on products that come to light must be communicated quickly

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CoC: Requirements for Manufacturers and Suppliers

- **Action**
  - Starting dialogue with stakeholders
  - Cosmetics within `08 (SKW and COLIPA)
  - Further meetings planned: Textile, Packaging, Consumers, Authorities etc.
- **Discussion**
  - Achieving common understanding

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Conclusion – Code of Conduct

- CoC is a guideline
- CoC is a starting point
- CoC sets basic rules
- CoC is not a final solution
- CoC is a tool for further developments
- CoC has initiated and will initiate
  - Dialogue with Stakeholders incl. Consumers
  - Product Assessments

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Voluntary Measures in Nano Risk Governance: The CENARIOS® Approach

Dr. Peter Langer, TÜV SÜD, Germany

Voluntary Measures in Nano Risk Governance: The CENARIOS Approach

Dr. Peter Langer
TÜV SÜD, Germany

In recent years "Nano Risks" have become an intensively discussed topic. Certainly it depends on the interests of different stakeholders, whether Risk Management in Nanotechnology is necessary or not. Many researchers point out Risk Management to be necessary, just because there are so many uncertainties in this (still) new field of technology. But Risk Management is expensive and for many Small and Medium Enterprises (SMEs) it seems to be more reasonable to spend the money on product development. So the question arises, what requirements a Risk Management System must fulfil that also reflects the interests and needs of SMEs.

It is generally agreed that Risk Management should be integrated in the existing safety and quality culture of companies. Therefore, a Risk Management System can be organized as part of an existing Quality Management System.

Since Quality Management Systems are usually certified acc. to ISO 9000 / 9001 the question arises, whether a certification of a Risk Management System makes sense and realises advantages in the market. Our answer to this question is that an explicit certificate by a third party guarantees compliance with given standards and shows that risks have been thoroughly analyzed and are continuously monitored thus assuring a "living" RMS. So a certificate is a confidence-building measure for industry and consumers.

There are a number of relevant generic standards for Risk Management like ONR 49000 - ONR 49003 (Austria), FERMA (UK), AS/NZS 4360:2004 (Australia/ New Zealand). What is needed then is an adoption and tailoring to the specific needs of nanotechnology.

The CENARIOS® Approach was created to establish this adoption. It was developed in close contact with the requirements of industry and includes requirements for risk evaluation, risk monitoring, communication and knowledge management.

1

Industrie Service

Voluntary Measures in Nano Risk Governance the CENARIOS® Approach

4th International NanoRegulation Conference 2008

Dr. Peter Langer, TÜV SÜD Industrie Service GmbH, St. Gallen, 17 Sept. 2008

2

Industrie Service

Content

- Risk Management and Certification in the overall context
- Generic and specific standards
- Risk Assessment – methods and definitions
- Knowledge Management
- Conclusion and summary

3

The context of "Nano Risk Management"

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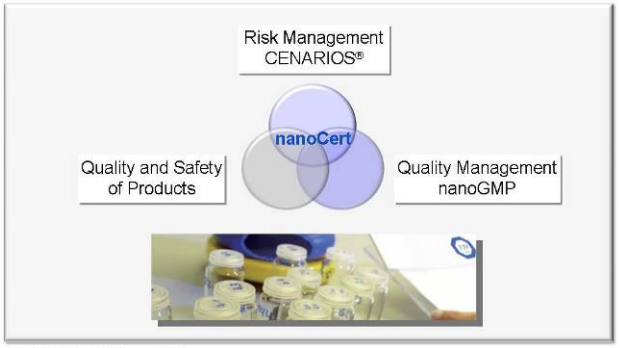

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What is (not) certifiable?

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Risk Management System
- (generic standards are existing, nano-specific standard developed by TÜV SÜD)

Production Processes (GMP)
- (Production- und Quality Management Processes are able to improve product properties. Generic standards, e.g. for medical products, are existing)

Product Properties
- Nanomaterials or
- Products containing Nanomaterials?
  - physical-chemical Properties of Nanomaterials
  - verifiable Product Properties
  - toxicological Harmlessness

5

Certification in Nanotechnology?

Industrie Service

The question:

Implementing a Risk Management System (RMS) for NT is a good idea, but why a certification?

Our answer:

A certification is a kind of control mechanism. Simply stating "We have a RMS" allows no conclusion regarding the content of this RMS. A certification should assure compliance with given standards; annual re-certification assures a "living" RMS

- *A certificate is no "general absolution", but it is a confidence-building measure!*

6

Industrie Service

Content

- Risk Management and Certification in the overall context
- Generic and specific standards
- Risk Assessment – methods and definitions
- Knowledge Management
- Conclusion and summary

7

Basic Requirements to a Risk Management System

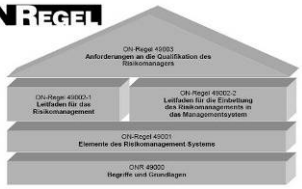
Industrie Service

We didn't re-invent the wheel, our work is based on existing, international standards for Risk Management:

The Orange Book
Management of Risk - Principles and Concepts
HM TREASURY
October 2004

ON REGEL

Risk management
AS/NZS 4360:2004



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Actual situation

Industrie Service

Most of the existing standards are not mandatory

- For some important fields of interest mandatory standards for risk management are existing (e. g. *DIN EN ISO 14971 Risk Management for medical products*)
- There are some national and international activities to develop standards which explicit include Nanotechnology (NT)[1]

For small and medium-sized enterprises (SME) the following questions are of interest:

- Are our products safe?
- Are our product lines „fit for the future"?
- Endanger upcoming regulations our business plan?
- Can we handle possible cases of liability?

A Risk Management Standard for NT, which will be accepted as voluntary measure must comply with (3) and fulfil requirements from (4)

[1] ISO 31000 Risk management -- Principles and guidelines on implementation

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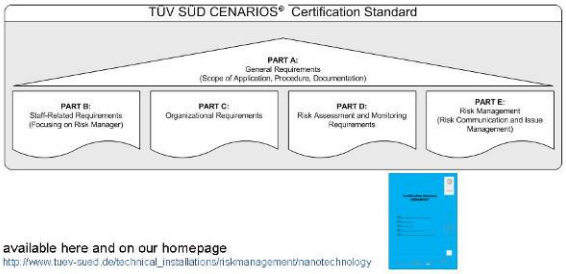
From generic to nano-specific standards

Industrie Service

Based on the existing international standards and on the requirements shown in the slide before, we developed the CENARIOS® certification standard, which includes nano-specific adaptations at the crucial points.



available here and on our homepage
http://www.tuev-sued.de/technical_installations/riskmanagement/nanotechnology

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Risk definition

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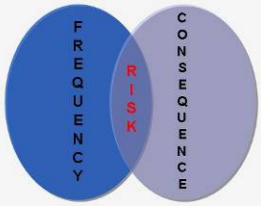
In toxicological context, risk is often defined in the following way:

Exposition based approach

We prefer an alternative approach, so we use the following definition (following ISO/IEC 73):



Event based approach

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Approaches

Industrie Service

The different definitions of risk lead to different approaches in Risk Assessment:

■Event based
A damage (consequence) can only occur, if caused by a technical, human or organisational error dangerous material is released. We assume that in such cases basically for humans dangerous concentrations are available.

■Exposition based
A damage can occur, if humans are exposed for a given period to a given concentration of toxic substance. The reason for this concentration is not in the focus of the exposition based method.

Both methods have their fields of application and complement each other: The exposition based method is used for the exact toxicological determination of the risk of a material.

The event based method uses the results of the exposition based method to define technical boundaries for a safe handling with the materials. If there is no exact knowledge about the toxicological effects of the material, a risk based safety-concept can be developed based on conservative assumptions.

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Scope of the CENARIOS Approach

Industrie Service

Companies will produce products containing nanomaterial, if the commercial success outweighs possible dangers.

A risk management system should be able to highlight the dangers, preferably in the development phase of the product.

All these business decisions are time critical.
For SME's it is not possible to wait until we are 100% sure about possible toxicological effects.

They need a decision based on existing knowledge of the state of the art in science and technology.

Essential:
Assessment of the state of the art in science and technology by Knowledge Management

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Criteria for the evaluation of publications

Industrie Service

1 **Base of knowledge**
PC data, in vitro or in vivo data, longtime experiences

2 **Transferability of the database**
in vivo: principle of similarity (similarity to hb)
in vitro: exposition relevant information, general information

3 **Comparison of publications**
How many publications are available? Are the results similar?

4 **Rating of the publication**
Reputation of journal and author(s)

5 **Transferability to the product**
Are the possible incorporation paths discussed properly?

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Evaluation criteria for the reliability of the publication

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Development of the strategy for the evaluation of publications is an ongoing process

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Reliability of evaluated database (2)

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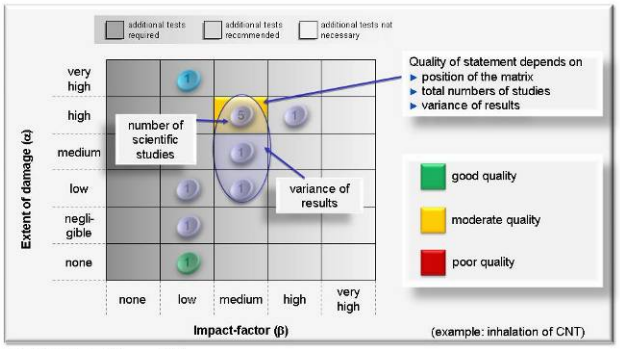

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Risk Assessment Process

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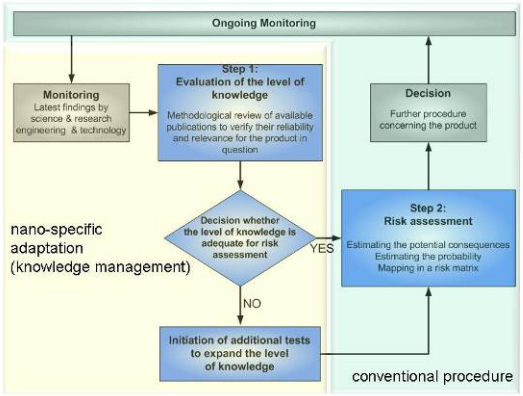

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Summary

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- A Risk Management System must be integrated in an existing safety and quality culture of the company
- Certification including annual re-certification lead to a higher safety level
- Risk Management is not new; new technologies just require some adaptations
- CENARIOS is an *event based* approach, but it needs input from *exposition based* risk assessment
- The difference to ‚conventional' risk assessment is knowledge management. It is an integral part of each RMS, but especially for nanotechnology it is of utmost importance
- Gathering data does not automatically mean an increase of knowledge
- An intelligent Knowledge Management must be able to handle the last point

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TÜV SÜD. Choose certainty. Add value.

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The Situation in Switzerland: An Action Plan for responsible development and application of nanotechnology

Dr. Roland Charrière, Federal Office of Public Health (FOPH), Switzerland

The Situation in Switzerland: An Action Plan for responsible development and application of nanotechnology

Dr. Roland Charrière
Federal Office of Public Health, Switzerland

The Federal Office for the Environment FOEN and the Federal Office of Public Health FOPH drew up an action plan for the assessment and management of the risks of nanoparticles. The action plan indicates the work required in Switzerland in order to deal safely with nanoparticles. The Federal Council approved the Action Plan Synthetic Nanomaterials on 9 April 2008.

The Action Plan's objectives are:

- Creating framework conditions for responsible handling of synthetic nanoparticles;
- Creating scientific and methodological conditions to recognise and prevent possible harmful effects of synthetic nanomaterials on health and the environment;
- Promoting public dialogue about the promise and risks of nanotechnology;
- Better use of existing promotional instruments for the development and market launch of sustainable applications of nanotechnology.

The involvement of industry, authorities and the public in the debate on opportunities and risks must be an integral part of technological development. For an integrational approach, this debate should be as broad as possible and not restricted to individual levels or topics (scientific, psychological, sociological).

One important condition for regulation is the presence of validated and standardized methods to measure and to test the properties of synthetic nanoparticles, including the toxicological properties. The Organization for Economic Cooperation and Development (OECD) and the International Standardization Organization (ISO), in particu-

lar, are in charge of developing uniform terminology, nomenclature and standardized meth-ods of measurement and testing in the a-reas of health, the environment and safety.

Regulatory measures

Synthetic nanomaterials do not receive special treatment under current legislation. Basically it can be considered that in Switzer-land, at the level of laws, the prerequisites are in place to regu-late nanoparticles. It will be necessary to adapt at the level of ordinan-ces, and in the area of norms and guidelines. Existing gaps in the regulations could contribute to the industry's uncertainty about how to act or what investments to make. Despite this, precautiona-ry safety measures must be taken where necessary, taking into ac-count the development of international legal measures, particularly in the European Union (e.g. REACH).

Strengthening the industry's own responsibility

A safety matrix will help business and the authorities to identify applications with associated risk, and to take the necessary safety precautions. It provides a tool that should be applied in self-monitoring by the produc-ers and importers of synthetic nanoma-terials and the products based on them. Voluntary measures by the industry will be described in a specific to the particular branch of industry Code of Conduct (CoC) and Risk management systems (RMS).

Further information:

http://www.bag.admin.ch/nanotechnologie

1

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Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Consumer Protection Directorate

The situation in Switzerland

An action plan for responsible development and application on nanotechnology

Roland Charrière, Federal Office of Public Health

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Swiss Action Plan „Synthetic Nanomaterials"

approved on April 9, 2008 by the Swiss Federal Council

"..... strategy to control the risks of synthetic nanomaterials **on base of existing legislation** despite existing scientific knowledge gaps ....."

www.bag.admin.ch/nanotechnologie

NanoRegulation 2008
Roland Charrière
17.9.2008

3

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Basic report:

State of knowledge about the risks of synthetic nanomaterials

- Current applications
- Health and environmental risks
- Physical chemical hazards
- Safety at work
- Analysis of areas to be regulated
- Technology assessment and communication
- Need for research

Download from: www.bag.admin.ch/nanotechnologie

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17.9.2008

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Basic report: key results

- Knowledge of the effects of synthetic nanomaterials on humans and animals is currently inadequate. This lack of **scientific** knowledge prevents a well-founded risk analysis
- There is a lack of authoritative **definitions, standards of measurement** or **guidelines for testing the properties** of synthetic nanomaterials, even though these are important prerequisites for regulation
- **Current regulation** does not take into account the special properties of synthetic nanomaterials

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Objective of the Action Plan

- To **minimise the** risks of synthetic nanomaterials and their use for human health and the environment; to protect society and the economy from **wrong investments and unnecessary follow-up costs**
- To draw up the **scientific and methodological foundations** for risk assessment
- To promote **public** dialogue on the opportunities and risks of nanotechnology (communication, TA activities)
- To promote **sustainable nanotechnologies** (Federal funding instruments: CTI, FOEN)

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Communication and promotion of public dialog

Measures:

- *Communication*
  joint communication plan, collate specific and updated information on oportunities and risks for public, politics and economics.
- *Dialogue platforms*
  analysis and support of existing existing platforms: "NanoConvention" (EMPA), "Nanopublic" (Uni Lausanne), "Nanoregulation"
- *Technologie Assessment*
  identify opinions, wishes and fears of the population, use of participatory processes.

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17.9.2008

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Scientific and methodological foundations for risk assessment

Measures:

- *Increased support for independent risk research in nanotechnology*
  Swiss Nation Research Programme " Opportunities and Risks of Nanotechnology", participation in the current 7th Framework Programme of the EU
- *Terminology, standards, methods of measuring and testing*
  strengthen participation/collaboration with current programmes of ISO and OECD

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17.9.2008

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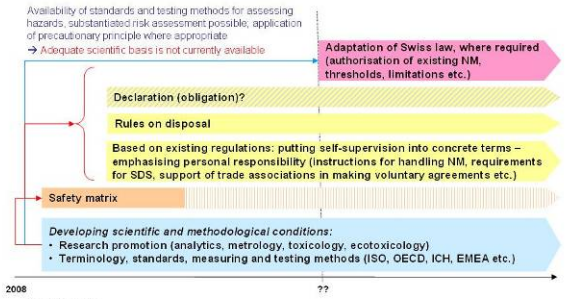
Regulatory framework for the responsible handling of synthetic nanomaterials



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Regulatory framework for the responsible handling of synthetic nanomaterials

Measures:

- Safety matrix for products and applications with synthetic nanomaterials
- Self-supervision and measures of occupational health protection (Guidance)
- Provision of safety information to the processing industry (Guidance)
- Informing consumers about synthetic nanomaterials in products
- Regulation for the disposals containing synthetic nanomaterials

NanoRegulation 2008
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17.9.2008

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Federal Office of Public Health FOPH
Consumer Protection Directorate

Safety Matrix:
Screening the potential risks of synthetic nanomaterials and their uses

- Allows differentiated dialogue/public communication about the risks of synthetic nanomaterials
- Helps industry and authorities to identify applications with associated risk, and to take the necessary safety precautions
- Provides a tool that should be applied in self-monitoring by the producers and importers of synthetic nanomaterials and the products based on them

NanoRegulation 2008
Roland Charrière
17.9.2008

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Federal Department of Home Affairs FDHA
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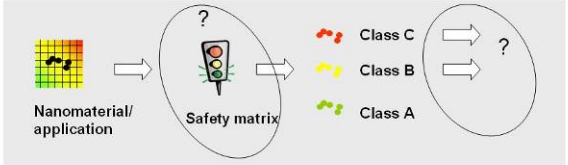
Consumer Protection Directorate

Safety Matrix:



A: nanospecific risks may be considered as low, even without further clarifications.

B: nanospecific risks may not be excluded. Further clarifications are needed.

C: nanospecific risks have to be considered. Taking into account the precautionary principle more detailed clarificationes are required before production, use and commercialization.

NanoRegulation 2008
Roland Charrière
17.9.2008

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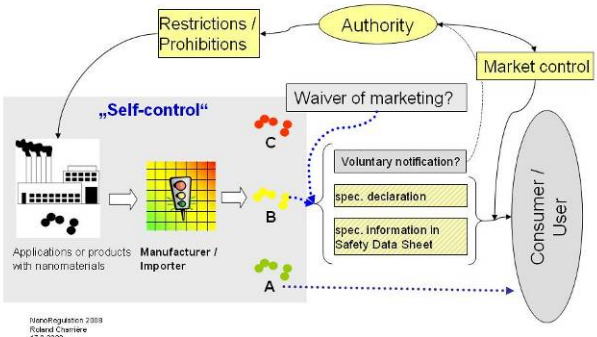
Distribution of products with synthetic nanomaterials
„nanospecific" measures



NanoRegulation 2008
Roland Charrière
17.9.2008

The Situation in Germany: NanoDialogue - Opportunities and Risks of Nanomaterials

Prof. Dr. Klaus Günter Steinhäuser, Umweltbundesamt (UBA), Germany

The Situation in Germany: NanoDialogue - Opportunities and Risks of Nanomaterials

Prof. Dr. Klaus Günter Steinhäuser,
Umweltbundesamt (UBA), Germany

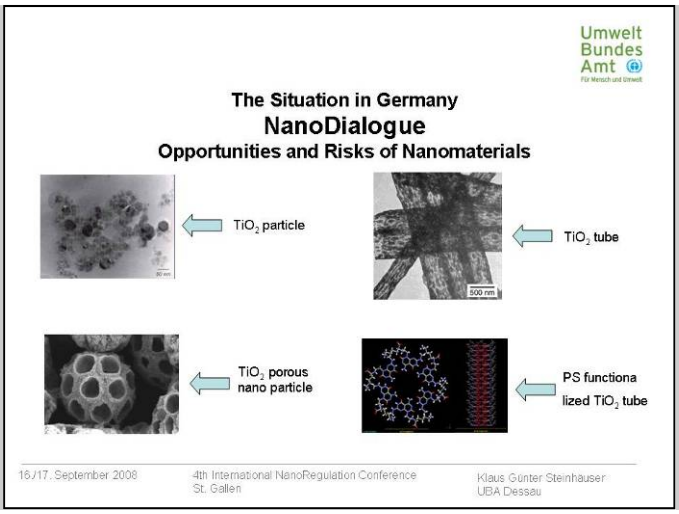
Nanotechnology is regarded as one of the most important future technologies. The world market of nano products is continuously growing; the number of products containing nanomaterials is increasing not only for professional use but also for consumers. This new technology offers great benefits for environment and health, while potential risks for humans and nature are still not yet elucidated.

In Germany the NanoDialogue was initiated by the federal government and a so-called Nano Commission was established where stakeholders from authorities, industry, trade unions and NGOs try to get a common understanding on opportunities and risks of nanotechnology. The Nano Commission has the mandate to develop a report within 2 years by the end of 2008. It is embedded into several other governmental activities in Germany and internationally. Three working groups discuss important aspects of the development of nanotechnology: WG 1 evaluates the opportunities of nanotechnology for environment and health and wants to identify criteria for sustainable and resource saving applications of nanotechnology. WG 2 is dealing with risks and safety aspects. Urgent research needs shall be identified and some exemplary applications will be evaluated in order to develop guidance how a responsible development of nanotechnology may happen taking into account existing knowledge gaps. The WG 3 (Guidance for Responsible Use of Nanomaterials) wants to develop a “Code of Conduct” proposing voluntary agreements as substitute for detailed legislative measures. Regulatory options like labelling and notification will be evaluated. The results of the dialogue will be presented at a final conference in November 2008 giving advice to politicians and information to the public. It is discussed whether the Nano Commission should continue its efforts for additional two years. The guiding ideas of the Nano Commission are *inter alia* to serve as an “early learning system” and to be transparent as possible in order to avoid a communication disaster like with other new technologies.

Regarding legislative measures on nanomaterials there is no reason and no basis for an own nano legislation. With regard to manage potential risks of nanomaterials the Federal Environment Agency (UBA) is regarding REACH as an appropriate legal basis. However, several open questions need to be resolved. A subgroup of the competent authorities (CASG) on REACH is currently established by the EU to discuss how REACH can be functionalized, interpreted and modified to serve as a legal basis.

UBA is also involved in the activities of the OECD Working Party on Manufactured Nanomaterials (WPMN). 8 projects are developed in order to get an international information exchange and common understanding of aspects of nanosafety. Most important is the sponsorship programme which is launched to get harmonized test results on 14 representative nanomaterials by examination of more than 40 endpoints. Germany will participate and sponsor the testing of titanium dioxide and co-sponsor the activities on nano-silver.

1



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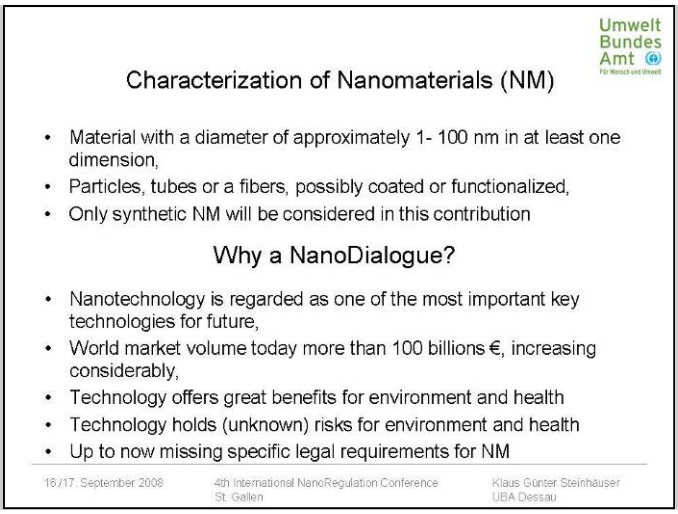

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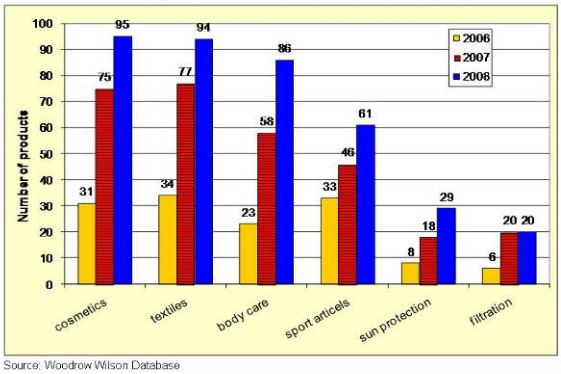
Nanomaterials for Health and Fitness



Source: Woodrow Wilson Database

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The NanoDialogue in the Context of Various Federal and International Activities

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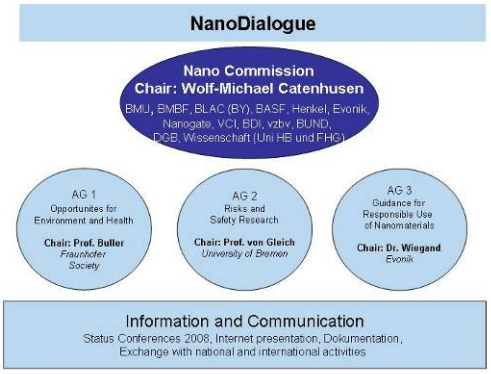

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Schedule of the Nano Commission

- Start in November 2006
- Interim Conference at 20th February 2008
- Working groups will deliver their results by September 2008
- Final Conference at 27th November 2008 with presentation of a concluding report
- Prolongation for additional 2 years ?

Goals of Nano Commission

- Establishment of a proven, science-based information basis
- Information of the public (via Internet)
- Discussion with stakeholders and experts
- Advice to politicians
- Involving and constraining producers and their associations by responsibility
- Identification of knowledge gaps and needs for action

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AG 1 Opportunities for Environment and Health

Tasks

- Identification of examples which demonstrate that nano products can contribute to resource efficiency and environmental health.
- Analysis of realistic perspectives for innovation in Germany by nanotechnological applications regarding the action field „Environment and Health".
- Carry out lifecycle assessments which indicate quantitatively the potential the actual contribution of nanotechnology for sustainability.

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AG 1 Opportunities for Environment and Health

Goals

- Development of a strategic paper „Sustainable nano products – central action fields".
- Development of criteria environmentally compatible and resource saving nano products and applications.
- Analysis of the most interesting development processes for innovation in Germany with respect to nanomaterial applications in the field „environment and health"
- Evaluation of the opportunities exemplified by 1 – 2 nanomaterials with emphasis to the lifecycle of the products. Advantages for sustainability should be identified.

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AG 2 Risks and Safety Research

Tasks

- Identification of short-term and mid-term research needs.
- Assessment of selected examples of nanomaterials where exposure of humans and environment are possible.
- Development of precautionary criteria for an assessment of nanomaterials taking into account existing knowledge gaps.
- Proposals for adaptation and development of testing procedures and methods of risk assessment and risk management of nanomaterials.
- Proposals for the development of a „green nanotechnology" → differentiated consideration of products and applications.

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AG 2 Risks and Safety Research

Goals

- Assessment of four examples:
  1. Photocatalysis on surfaces treated with nano-TiO2 → environmental exposure,
  2. Use of Nano-SiO2 in food,
  3. Lifecycle of CNT in composites,
  4. Nanosilver spray for indoor plants.
- Development of recommendations for risk assessment of NM.
- Drawing up of a catalogue of criteria of concern and of relief.
- Recommendations for research priorities.

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Risks and Safety Research

Current activities

- BAuA, UBA und BfR published a strategy for research on risks of nanomaterials in December 2007 .
- OECD pursues the adaptation of the Test guidelines to the testing of nanomaterials.
- OECD launches a worldwide testing programme on 14 selected nanomaterials.
- Guidance papers for safe handling of nanomaterials at workplace (OECD, BAuA).
- ISO develops definitions and methods for characterization of NM.
- BMBF promotes safety research (e.g. NanoCare, NanoNature).
- SCENIHR calls current risk assessment procedure for chemicals inadequate and recommends a „tiered case by case approach" (June 2007).

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AG 3 Guidance for Responsible Use of Nanomaterials

Tasks

- Development of a „Code of Conduct" with regard to a responsible production and use of nanomaterials basing on the precautionary principle as substitute for legal obligations.
- Sector-specific recommendations for the use of nanomaterials.
- Identification of uses where risks may dominate the benefits („No-Go-Areas") and of areas where future innovation should take place.
- Evaluation of currently discussed options for political action, e.g. labeling or notification.
- Evaluation of legal options, in particular by chemical legislation (REACH) – will be discussed by Nano Commission itself.

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AG 3 Guidance for Responsible Use of Nanomaterials

Goals

- Development of a super ordinate principle paper regarding responsible production and use of nanomaterials.
- Proposals für monitoring and reporting.
- Starting with the development of sector-specific guidance papers in order to put the principles concrete (e.g. varnishes, cosmetics).
- Identification of application areas with dominating risks („No-Go-Areas"), using criteria of concern and relief developed by AG 2.
- Evaluation of regulatory options like labeling and notification.

If no consensus will be achieved at least arguments for *pro* and *con* should be made transparent.

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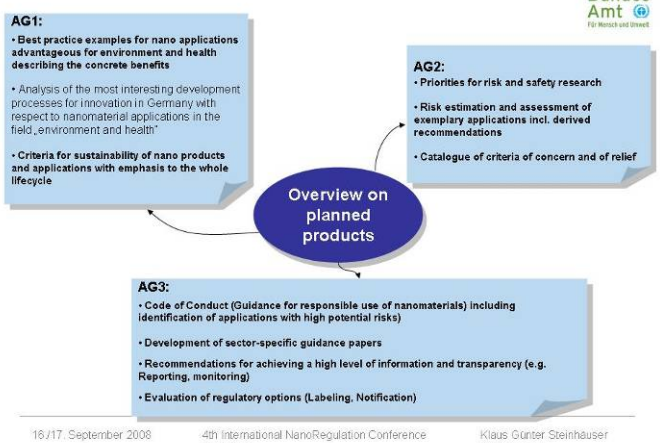

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Guiding Ideas of the NanoDialogue

- Involve all relevant groups of society in order to achieve a common responsibility.
- Be as transparent as possible to the public.
- Determine characteristics of an innovative development of nano technology of environment and health.
- Avoid a communication disaster like with green genetic engineering.
- Use the dialogue as „Early Learning System" (Catenhusen).

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Important aspects regarding legislative measures on nanomaterials

- There is no reason and no basis for an own nano legislation!
- REACH should be the regulatory basis for legal requirements; - some problems need to be resolved, however.
  - *Clear definition of nanomaterials is still missing.*
  - *Definition of substance within reach is based on the chemical formula and does not differ between bulk and nanoscale.*
  - *Therefore, most nanomaterials are "phase in" (existing) substances (except fullerenes).*
  - *Unambiguous nomenclature is still missing.*
  - *Test guidelines and analytical methods for determination of (eco)toxicity and exposure need to be adapted and completed.*
  - *Test results may depend on size and form of particles.*
  - *Adapted evaluation concepts must be developed.*
  - *Trigger values for data requirements based on production volume may be inadequate for nanomaterials.*

→ Competent authorities subgroup on nanomaterials (CASG) established in EU.

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REACH - Thesis of German Federal Environment Agency

- In principle, REACH as the central piece of chemical legislation is suitable for regulation of nanomaterials.
- Risk assessment of substances in nanoscale should be clearly separated from evaluation of bulk material. Advantages of separate registration dossiers for NM should be examined.
- Adequacy of trigger values based on production volume should be discussed.
- Where possible, nanomaterials should be grouped into categories.
- Adaptation and completion of test guidelines and analytical methods are necessary.
- Risk assessment principles should be amended.
- Evaluation of a higher percentage of nano registrations should be carried out by the authorities.
- Administrative burden should not be exaggerated in order not to impede the development of innovative solutions.

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OECD Working Party on Manufactured Nanomaterials (WPMN)

Objective: To promote international co-operation in human health and environmental safety related aspects of manufactured nanomaterials (MN), in order to assist in the development of rigorous safety evaluation of nanomaterials.

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OECD WPMN: Programme of Work

Work Area 1
Identification, Characterisation, Definitions, Terminology and Standards

-To provide the basis for establishing **criteria for the identification of nanomaterials**

-To develop a general working **definition** of nanomaterials within the context of human health and environmental safety for use by the Working Party.

-This will involve efforts to **harmonise standard reference materials and working definitions of manufactured nanomaterials among member countries**

Work Area 2
Testing Methods and Risk Assessment

-To **harmonise methods for human health and environmental testing of manufactured nanomaterials**

-To identify priorities for **reviewing, developing or modifying test guidelines for the assessment of nanomaterials.**

-**The development of agreed risk assessment approaches** is important.

Work Area 3
Information sharing, Co-operation and Dissemination

-To facilitate **harmonization of regulatory practices in the chemicals regulatory area**

-This will include initiatives to co-operate and share information on **risk assessment and exposure measurements, voluntary schemes programmes,** and **EHS research strategies on manufactured nanomaterials**

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OECD Working Party on Manufactured Nanomaterials (WPMN)

Current activities of UBA in context of OECD WPMN:

- Research Strategies: Facilitate international information exchange in fields where many research groups are working already.
- Fill in quality assured descriptions (summaries) of German research projects into the international database.
- Contribution to a guidance for sample preparation and dosimetry and commenting a review on the adaption of OECD test guidelines for nanomaterials.
- Participation in the international test programme for a representative set of 14 nanomaterials (> 50 endpoints)
- Germany will be sponsor for testing Titanium dioxide and co-sponsor for silver. It will contribute with existing test results to the test programmes for carbon black, single and multi-walled CNTs, aluminium oxide and cerium oxide. UBA will coordinate the Germen sponsorship.

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The Situation in Austria: Risk Dialogue, Nanoplatform, Voluntary Measures

Dr. Thomas Jakl, Lebensministerium, Austria

The Situation in Austria: Risk Dialogue, Nanoplatform, Voluntary Measures

Dr. Thomas Jakl
Lebensministerium, Austria

On the one hand there is no doubt that nanotechnologies offer a great potential for new, innovative products and thus for strengthening the competitiveness of Europe. On the other hand the public rightly claims reliable information on possible risks of nanomaterials. Environment policy is still searching for the adequate approaches as to how to deal with nanomaterials. A right mix of regulatory and voluntary instruments taking due account of the precautionary principle has to be developed ensuring the necessary level of protection while at the same time allowing companies to innovate.

The relevance of REACH must not be underestimated. Existing EU legislation and in particular REACH are in principle appropriate for covering the security aspects of nanomaterials. However in particular the registration threshold value of one tonne per producer/ importer is too high to be able to get nanomaterials registered to the necessary extent. Furthermore we have to address the gaps in test- and risk assessment methods which are leading to the fact that not all relevant properties and risks of nanomaterials are covered by the current regimes.

While the Austrian public still shows a positive perception of Nanotechnology as such (according to Eurobaraometer results) this attitude might change depending on the publicity, findings on potential risks will receive. As products containing nanomaterials are already at the shops' shelves people might change their mind if they do not get sound and reliable answers addressing their concerns. It is an absolute key target in nanomaterials policy to ensure transparency and communication with all groups of stakeholders, in particular with the public. This is why the Austrian Environment Agency together with Austria's largest broadcasting company launched the „Risk dialogue". In public conferences, and discussion fora in various media including the internet the topic was treated in an open and participatory manner.

Stakeholder Platforms on nanotechnology are regularly held at the Ministry for the Environment. In the Course of these events actors

from all fields exchange information and discuss possible fields of action at national and European levels.

A „stick and carrot“ situation where the threat of possible regulatory instruments triggers the development of sound voluntary approaches is what we might face also with regard to Nano materials. It is of utmost importance to emphasize, enhance and illustrate the responsibility of the producers of nanomaterials and in particular their obligation to provide sound information on properties and exposition. All means and in particular voluntary approaches put forward deserve accurate consideration as to their accountability and credibility.

In small economies like Austria however we realize that country specific instruments for voluntary approaches involving industry are unlikely to gain support and to deliver successful results. Stakeholder organisations themselves do not seem to have enough insight to bring the right players at the table what makes it difficult to even enter into a negotiating scenario.

During these days the conceptual work for an Austrian Nano - Action Plan is starting aiming at combining international, European and national approaches and instruments into a coherent and target-oriented package.

1

The Situation in Austria: Risk – Dialogue, Nano-platform – voluntary measures

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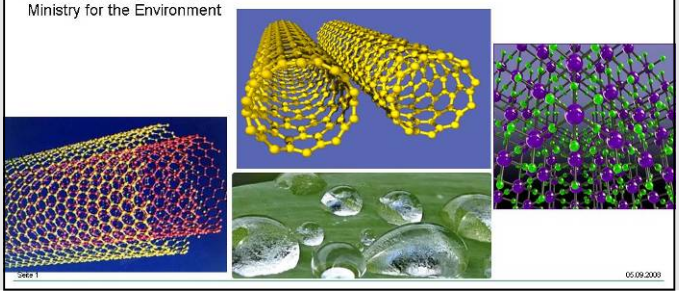
Dr. Th. JAKL
Chemicals Policy Directorate
Ministry for the Environment



2

The Nano - discussion in Austria

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- Acceptance of Nanotechnology in the Austrian public is still high (Euro barometer)
- Increasing number of spotlights on Toxicology
- The products are at the shelves
- Tailor made Chemical Legislation is lacking
- It is sexy to deal with Nano, write about Nano, bring Nano to the political Agenda

3

Areas for Action of the Government

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- Safety, Health and Environment Protection (EHS)
- Research, Development and Innovation
- Addressing Public Concern
- Cooperation between Stakeholders, ensuring Coherent Approach (national, EU, international)

4

Main Actions for Environmental Policy

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- **Review existing regulatory framework**
- **Finding the appropriate mix of instruments**
- **Application of the precautionary principle**
- **Improve knowledge base**
  - **Definitions**
  - **Toxicological and eco-toxicological test methods**
  - **Exposure, risk assessment**
  - **Measurement**

5

Existing „Nano-Legislation“

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- **Chemicals (REACH, GHS, etc.)**
- **Pharmaceuticals, Pesticides, Biocides**
- **Medical Devices, Cosmetics, Food additives and packages**
- **Occupational health**
- **Air, Water, IPPC, Seveso, Waste**
- **Product Safety, Product and Environment liability**

Regulatory review published by EC on 17 June 2008 [COM(2008)366]

6

Regulatory review – main conclusions

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- Environmental and health risks of nanomaterials are in principle covered by EU regulatory frameworks
- Implementation of the legal frameworks is a challenge

Scientific knowledge gaps
Guidance documents need to be reviewed

- Current legislation may have to be modified as new information becomes available (e.g tonnage thresholds)

7

REACH and Nano (1)

Chemicals on the market need to be "safe".

- Chemical Safety Report (CSR) for "intended use" (also for the use in Nanoform)
- Additional information (different C&L, different risk management measures) to be included in the registration dossier
- Risk management measures and operational conditions to be communicated in the supply chain

Main Challenges:

- Uses < 10 t/pa not covered by CSR, no definition of Nano, shortcoming in test methods, lack of data/transparency

8

REACH and Nano (2)

- In order to address the specific properties, hazards and risks associated with nanomaterials, additional testing or information may be required (substance evaluation)
- Current Test guidelines to be reviewed

EU working group on REACH and Nano deals with the above mentioned aspects (2008-2010)

„REACH-Nano-Guidelines" to be developed

9

Responsible Nano production

- Complying with codes of conducts, e.g.
  - Company specific CoC (e.g. in the field of worker protection)
  - EC CoC for responsible nanoscience and nanotechnologies Research
  - Swiss retailers CoC
- Production of "safe" nanoproducts
- Filling data gaps (e.g. identify exposures for workers, consumers, environment)
- Transparency, active communication

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Overview on Austrian Activities

- Coordination of Austrian Stakeholders („Nano-Plattform")
- Policy-related measures
  - *Studies (e.g Life-Cycle-Analysis of Nanoproducts)*
  - *Discussion of voluntary measures of producers*
  - *Participation in international and EU Working Groups (e.g. EU-Nano-REACH-Group, OECD)*
- Communication with public („Risk-Dialog", Brochure, etc.)
- Research (Nano-Initiative, Nano-Trust-Project, etc.)

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„Nano-Plattform"

- **Ministry for Environment coordinates regulary meetings with all Ministries, Environment Agency, Food Safety Agency and representatives of industry who are in charge of Nano**
- **Aim:**
  - **Exchange of information**
  - **Discussion of possible national activities**
  - **Coordination of positions for international and EU Working Groups**

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Policy-related measures (2)

- Possible Voluntary measures of producers
  - Discussions with representatives of Industry started June 2008
  - „Carrot and Stick" Situation
  - Does an approach specified for Austria make sense?



13

Policy-related measures (3)

- Participation in international and EU Working Groups
  - EU Working Group „Nano and REACH"
    Start: mid 2008
    Measure of „EU-Action-Plan on Nanoscience and Nanotechnology 2005-2009"
  - Bilateral Exchange between European Countries
    Dialog D, Ö, Liechtenstein and Switzerland, Twinning with Slovenia
  - OECD Working-Group on manufactured nanomaterials

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Communication with the public

- „Risk-Dialogue"
  - Initiated by Umweltbundesamt GmbH, supported by stakeholders
  - Cooperation with Austrian Radio
  - www.risikodialog.at
- Other means of Communication
  - Nano-Broschure (inpublicration)
  - Publication of studies on Ministries websites
  - etc.

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Research

- Austrian „Nano-Initiative" and „Nano-Trust-Project"
  - National programme for supporting research and technological development in the field on Nanoscience and Nanotechnology, collection of risk data
  - Initiated by Ministry for innovation (BMVIT)
  - http://www.bmvit.gv.at/innovation/iktnano/nano.html
- Participation on EU-SKEP ERA-NET (Scientific Knowledge for Environmental Protection)
  - Network of 17 Ministries and agencies in 13 EU-MS
  - Current focus on emerging technologies
- Participation on public consultation for „Code of Conduct for responsible Nanoscience and Nanotechnologies Research
  - http://ec.europa.eu/research/consultations/list_en.html#closed

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Outlook for Austria

- Continuing and intensifying launched initiatives while taking into account international and EU developments
- Austrian Action Plan Nanotechnology
  - In discussion

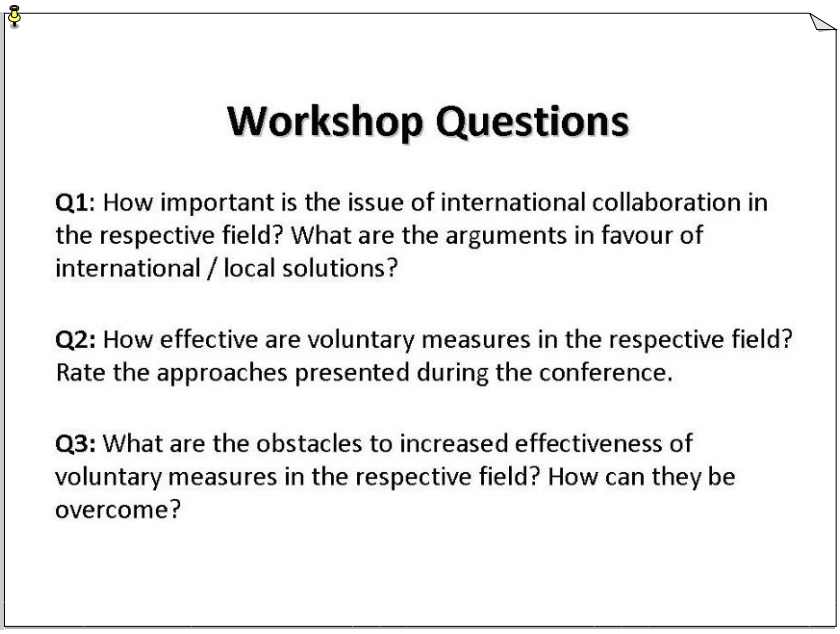
Workshops on voluntary measures

The workshop part of the conference intended to discuss in more detail some of the current issues surrounding voluntary measures touched upon by the speakers. The questions centered around three complexes of questions:

- international collaboration
- Suitability / Effectiveness of voluntary measures
- Barriers to overcome

In order to do justice to the broad field of voluntary measures in nano risk management, the workshops focused on the following three topics:

- Worker Protection (Occupational Safety and Health)
- Environment
- Consumers (Communication and Reputation)



Three broad questions were provided as a basis for discussion among the workshop participants. The concrete questions focused on issue in the respective fields of „Worker Protection, „Environment", and „Consumers".

The workshops were designed as parallel discussion rounds that discussed the same broad questions from different viewpoints. The results of the discussions were recorded on flipcharts and presented in a subsequent plenary session. Major differences in the findings of

different groups served as a starting point for a short discussion of the results by the workshop hosts and all participants .

The importance of international cross-border voluntary actions was perceived very differently by the groups. While in the area of „Environment“, an international focus seems to be a promising approach, the participants of the „Consumers“ workshop stressed the embeddedness of communication measures in the local cultural backgrounds of consumers. The findings of the „Workers“ group were also rather in favour of national approaches with a certain degree of overarching international coordination.

In terms of the effectiveness of different voluntary measures, the results were also rather diverse, making the choice of the „right“ voluntary measures in the concrete case quite difficult.

Furthermore, there was little overlap in the different groups‘ perception of the obstacles for improved effectiveness of voluntary measures. Keeping in mind that only a consensus on the obstacles allows for effective joint actions, this outcome clearly highlights the need for further discussion of the proposed voluntary measures.

Summaries of the group discussions are provided over the next pages.

Discussion

Workshop 1: Occupational Health and Safety

This workshop was hosted by Dr. Martin Gschwind, head of the Chemistry section of the Swiss National Accident Insurance (SUVA).

Major findings of the group were:

Q1: The role of international collaboration in the context of worker protection was discussed controversially. On the one hand, it was agreed that international collaboration works in favour of standardisation and harmonisation and helps to pool available

knowledge. On the other hand, international solutions need to be adapted and simplified to suit local requirements. Furthermore, local solutions can usually be established much faster and more effectively.

Q2: As depicted in above illustration, the risk management system was rated as the most promising measure. This is mainly due to the fact that participation in reporting schemes or similar actions is usually limited to companies that already have a high level of risk awareness and responsibility. Furthermore, in the area of worker protection there already are many mandatory duties in place, limiting the additional effect of voluntary measures. An important factor determining the effectiveness is the level of internal and

external control of the measures taken. Finally, the participants concluded that the selection of which tool to use should be voluntary, but the need to do some form of risk management clearly is mandatory already under the existing legal frameworks.

Q3: In terms of the obstacles towards the implementation of voluntary measures in workers protections , “lack of knowledge”, “waiting for external input” and “fear that voluntary measures will become mandatory legal regulations”. Many companies are currently not able to find information on how to handle new substances and on how to treat them in the MSDS. Therefore, the development of practical guidelines was identified to be an important step to overcome these obstacles. In addition, the lack of knowledge should be faced by making relevant information available in particular to small companies via suitable platforms (e.g. lectures in professional formation, industry-specific information events) and by promoting research on the risks of nanomaterials.

Workshop 2: Environment

The participants of this workshop under the leadership of Prof. Klaus Günter Steinhäuser discussed the three questions under the viewpoint of environmental issues.

The conclusions of the groups were:

Q1: The starting point of the discussion was the general consent that environmental issues are by definition international and require an internationally coordinated approach. Although the relevant substances are produced on the national level, the distribution takes place on a global scale. Potential damages to the environment are also unlikely to be restricted to the national level.

However, the group members also concluded that it is important not to lose sight of national or regional solutions. The rapid implementation of the planned measures is only possible on the national level. This is especially true for voluntary measures that are higly dependent on specific economic, political and technological conditions on the national level.

Q2: All participants agreed that the most effective measures is an elaborate risk management system, since it is clearly and directly minimising the possible risks emanating from nanomaterials. However, its actual effectiveness depends on transparency and independent supervision. Other measures like Codes of Conduct or reporting schemes were judged as medium to low efficient. They are not directly protecting the environment against nanotechnology risks.

Q3: Among the many obstacles discussed, the most important ones were „Participation leads to legal requirements“, „lacking incentives“ and „confidential business information“. In order to overcome these obstacles, an increase in the number of participants for certain voluntary measures is necessary in order to make legal requirements dispensable. The lack of incentives could be solved with some kind of financial reward or subsidy for companies trying to implement voluntary measures. The obstacle of confidential business information could probably be overcome by certain agreements or contracts.

Workshop 3: Communication and Reputation

The questions surrounding the issue of consumer and public acceptance of nanotechnology were in the focus of the group hosted by Sergio Bellucci, Head of the Swiss Centre for Technology Assessment (TA-Swiss).

The group came to the following results:

Q1: There was a basic understanding inside the group that consumers and the public in the major markets for nanomaterials are increasingly international and influenced by issue in other countries. Internationally active companies therefore have to choose a transnational approach in their communication activities. However, this approach needs to be balanced with a sense of the local backgrounds of the people. Additionally, the awareness for the importance of communication and reputation issues is well established at the national level, while being neglected by the international bodies and structures. This leads the workshop participants to set an emphasis on national or regional initiatives without losing sight of the importance of an over-arching international framework that can serve as a basis for national actions.

Q2: It was agreed that voluntary reporting schemes, disclosure agreements and the prevalent risk management systems are not effective under the viewpoint of communication. The Code of Conduct, if applied as a communication instrument towards the consumers as well as the customers, can serve as an important first step in the direction of increased consumer acceptance. An even more effective solution was seen in a general voluntary labelling of products containing nanomaterials. However, labelling is connected with a variety of significant and complex challenges and therefore was seen as rather unrealistic in the near future.

Q3: The major challenges in the area of voluntary measures in the area of communication of nanotechnology risks were seen in a lack of a common understanding. There is not yet a consensus on the way in which to communicate and even on the actual toxicity of nanomaterials. There is only limited information or scientific evidence on which to base sound public communication. This situation favours isolated solutions that rather create confusion than trust.

Speakers and Participants of the 4th NanoRegulation Conference

Speakers

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Meili	Christoph	The Innovation Society Ltd, St.Gallen; Conference Chair	Switzerland

Workshop Moderation

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Gschwind	Martin	SUVA	Switzerland
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Impressions