iNTeg-Risk: Early Recognition, Monitoring and Integrated Management of Emerging, New Technology Related Risks

iNTeg-Risk Kick-off-Meeting

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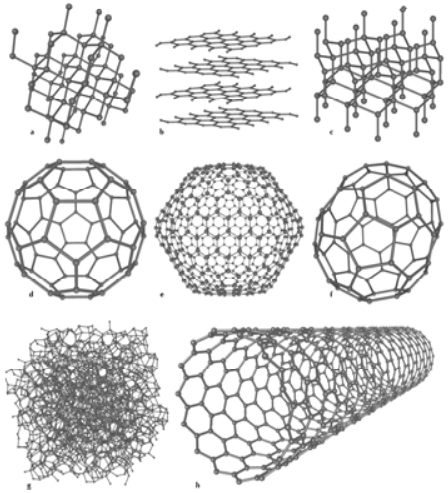
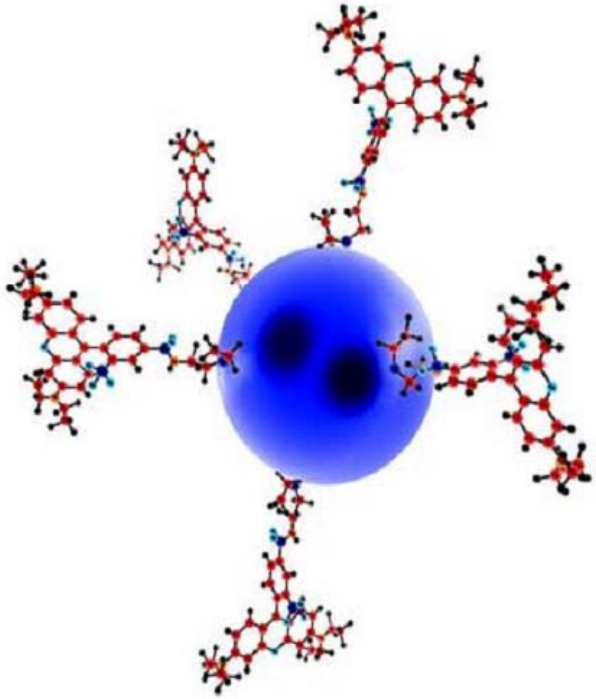
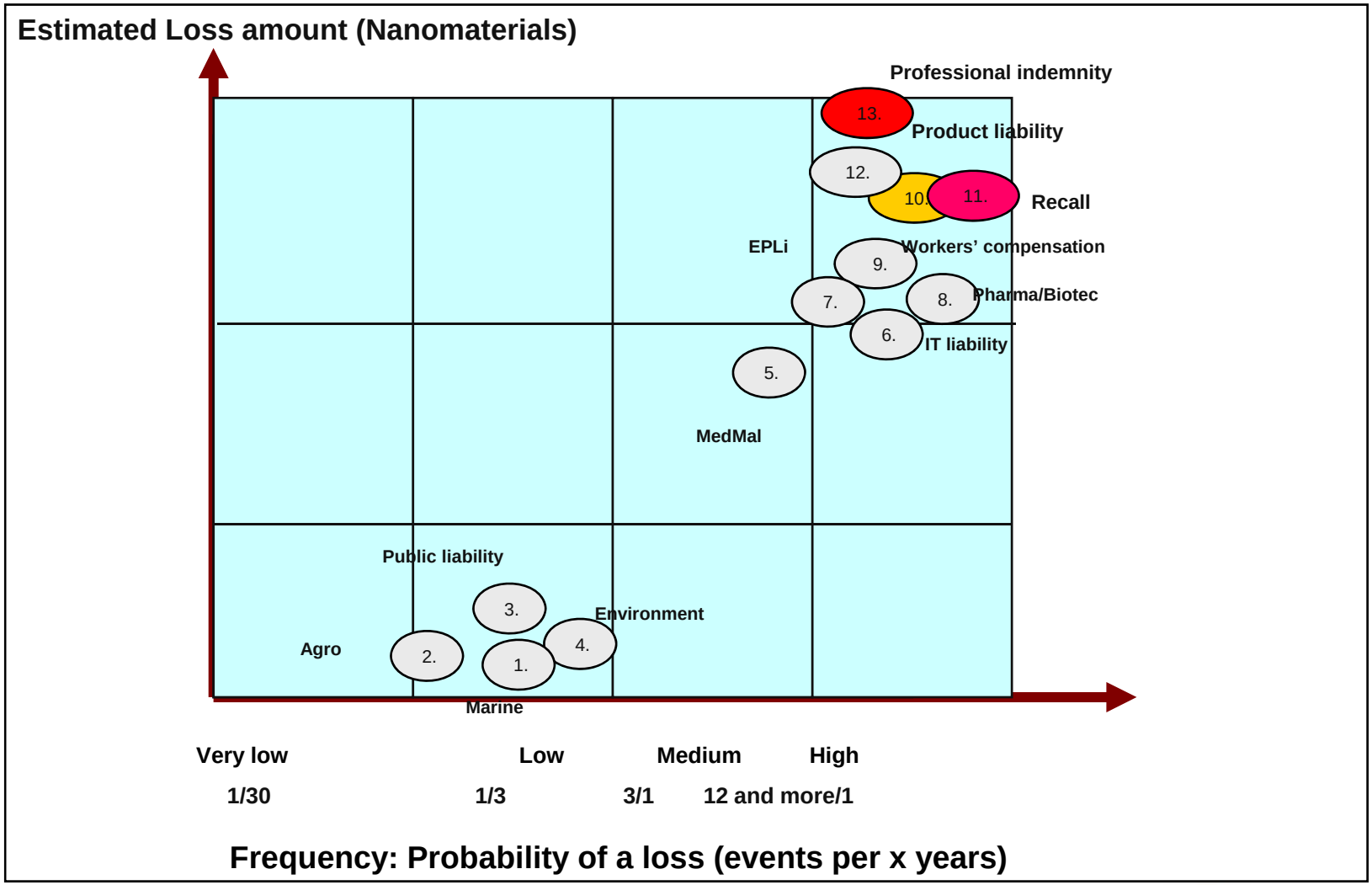
Specific Innovative Application
Storage & Transportation of Nano-Materials





Risks posed by nanomaterials



(MunichRe 2005)

Questions to be tackled by regulators

- Can nano-sized particles be treated the same as “ordinary” chemical substances by regulators?
- Which specific regulations are needed? (esp. product liability, workplace and consumer safety)
- Is “Nano-labeling” on products and prescription on chemicals needed to avoid lawsuits ?
- Do we need specific thresholds of NP in terms of occupational health & safety?
- How can regulation pace up with the technological development?
- How can (self-) responsibility of industry be strengthened?

Challenges to regulators

Needed

- Definitions of nanomaterials
- Standardized test methods / test strategies / risk assessment and risk evaluation tools for nanomaterials
- Evaluation of existing test requirements for nanomaterials (requirements for applications)

Important

Existing Assessment tools do not take into account that dimension of a substance is relevant in terms of environmental impact and toxicity.

Nano Regulation on international level

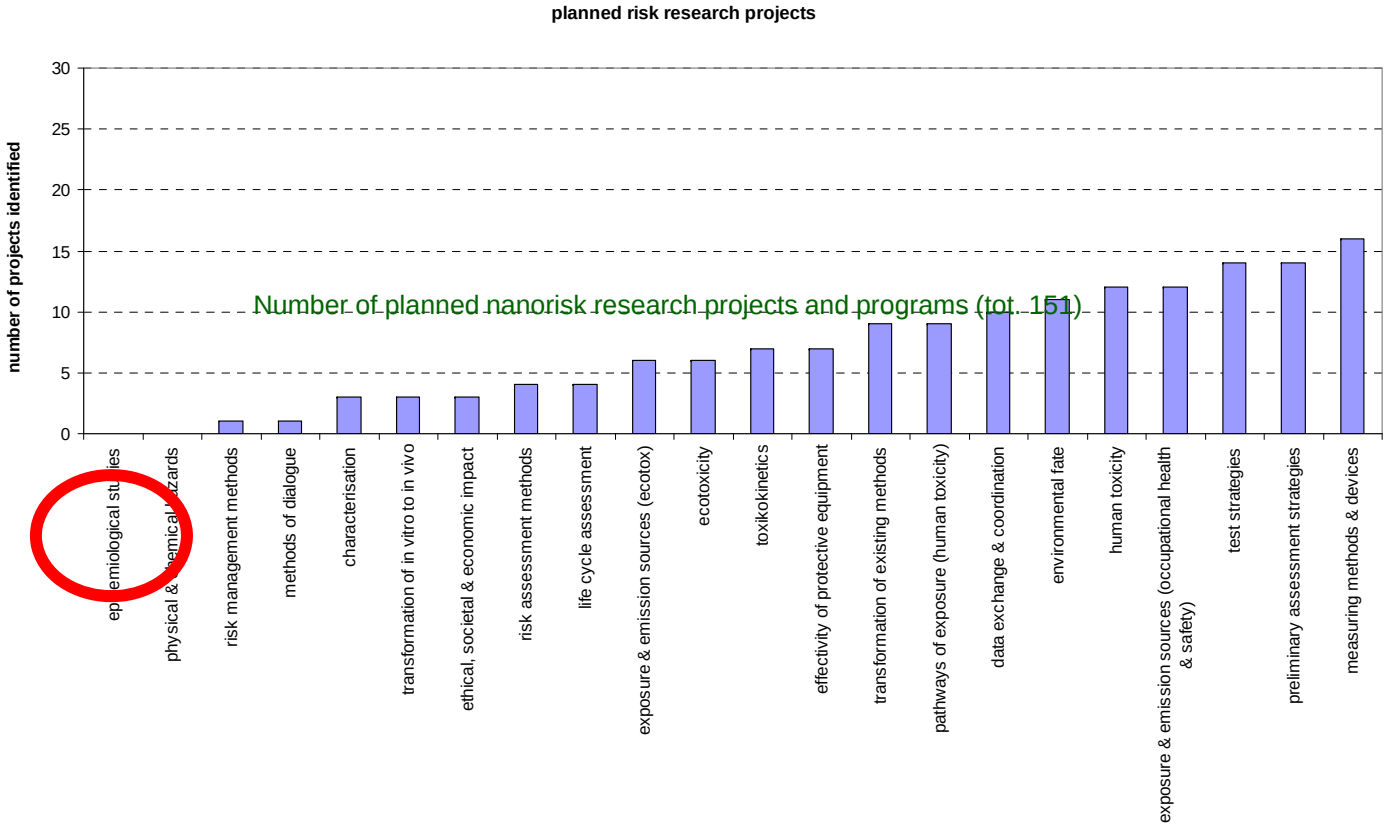
Supranational Level

- OECD Working Party on Manufactured Nanomaterials
- EU-Actionplan 2005-2009 (KOM(2005) 243, 7.6.2005)

National level (Action plan)

- UK, Germany
- Swiss Action Plan („Risk-Management of synthetic nanoparticles“)

Number of planned nanorisk research projects and programs (tot. 151)

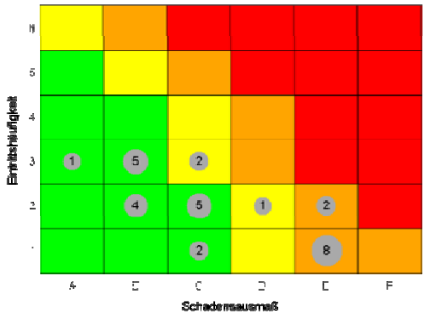


Risk Management for nanotech industry is a challenge

Background

- Few risk data available
- No nanospecific regulatory frameworks
- High volatility (society, media, Key-players)
- High awareness of insurance industry (nanospecific pricing of premiums)
- Small number of hazarders („fullerene cosmetic producers“

→ High uncertainty is hampering the business



Needs: Nanospecific Risk Management system

Risk-Assessment and risk evaluation tool (products)

Risk-Foresight Monitoring System (science, society, technology, market)

„Risk assessment must extend to all stages of the technology life-cycle, starting at the point of conception and including R & D, manufacturing, distribution, use, and disposal or recycling. Appropriate evaluations will need to be carried out and risk management procedures elaborated before

commencing with the large-scale production and application of engineered nanomaterials.

Particular attention will have to be paid to existing products and those that are close to commercial launch, including household products, cosmetics, pesticides, food contact materials, and medical products and devices."

Exploring the nano-world: Leading EU research in nanosciences and nanotechnologies (S. 9)

Office for official publications of the European Communities - CORDIS focus, issue No. 22, March 2006

For Nanotechnology, a common understanding of an appropriate RM-System should be developed including R & D, manufacturing, distribution, use, and disposal or recycling of Nano*products*.

➔ I. e. an *exclusive focus* on the production site is not sufficient, the product itself must be included (strong correlation to NMP-2007-1.3-4)

➔ To investigate just another module of *production* is not sufficient

„The question was raised whether substances in the nanoscale form should be regarded as new or existing substances. It was agreed that the decisive criterion whether a nanomaterial is a new or existing substances is the same as for other substances, i.e. whether or not the substance is on EINECS.

Thus, substances in nanoform which are in EINECS (e.g. titaniumdioxide) shall be regarded as existing substances. Substances in nanoform which are not in EINECS (e.g. carbon allotropes other than those listed in EINECS) shall be regarded as new substances.

New information on existing substances, including those with nanoforms, shall be submitted in accordance with Art.7 of Regulation (EEC) No 793/93.

New information on new substances already notified, including those with nanoforms, shall be submitted in accordance with Art.14 of Directive 67/548/EEC."

Manual of Decisions for implementation of the sixth and seventh amendments to Directive 67/548/EEC on dangerous substances (Directives 79/831/EEC and 92/32/EEC), updated Version of July 2006

Institute for Health and Consumer Protection - European Chemicals Bureau Report EUR 22311 EN

The effects of REACH on Nanoproducts must be analyzed to establish a certain legal certainty.

➔ What effects will REACH have on Nanotechnology?

Summary

- There is still a lack of risk related data related to nanomaterials
- Lack of risk data puts pressure on industry
- Voluntary programs and self responsibility of industry are key
- New approach towards Risk-Assessment of nanomaterials is needed
- Cooperation with industry partners is indispensable because the regulators need the professional risk management experience of industry and the data.

→ The biggest risk for nanotechnology is NOT overregulation but underregulation and hazardous technology management

Summary

The innovation:

- Monitor and define the state of the art (best practices) for monitoring and judging risks on the basis of little knowledge

  ➔ *"iNTeg-Risk Emerging Risk Monitoring System"*

- Define suitable risk assessment methods and data bases required for this case

  ➔ *"iNTeg-Risk Innovative Integration Methods"*

- Doing so, we support the industry in reducing liability risks and in increasing legal compliance, at the same time helping it to demonstrate responsible care and help the industry and the authorities by imbedding Nano in existing regulations

  ➔ *"iNTeg-Risk Reference Library"*

- Start an open-minded discussion with the public by transparent risk communication

  ➔ *"iNTeg-Risk Emerging Safetypedia"*

Subtitle

- Regular text
  - Text

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Consulting Testing Certification Training

for industry, retail, governments and private individual clients



TÜV SÜD market position

TÜV SÜD is world Nr. 4 of the technical safety companies