Engineered Nanomaterials

Considerations of the Working Group of the German Committee for Hazardous Substances

NanoValid Workshop, Berlin, 27/11/2012

source: BASF SE

In the Next Couple of Minutes …

- Challenges and Uncertainties
- National/European Situation
- Scope
- Categories of Nanomaterials
- Risk Assessment in the Workplace
- (Some) Conclusions

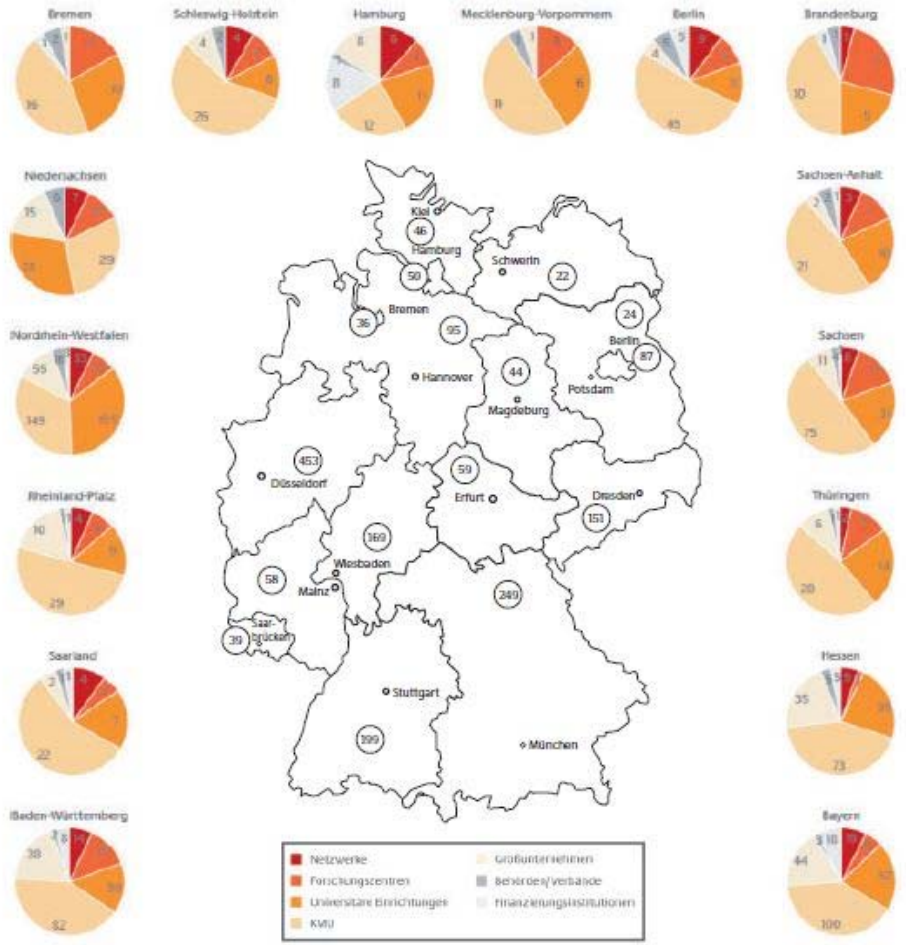
Challenges

- enabling technology
- cross-sectional
  - ➲ (very) diverse materials with heterogenous (toxicological) property profiles
- limited knowledge base
  - on labelling and classification
  - on exposure
  - on suitabilty of risk management measures
- highly dynamic technology field

Addressing Uncertainties

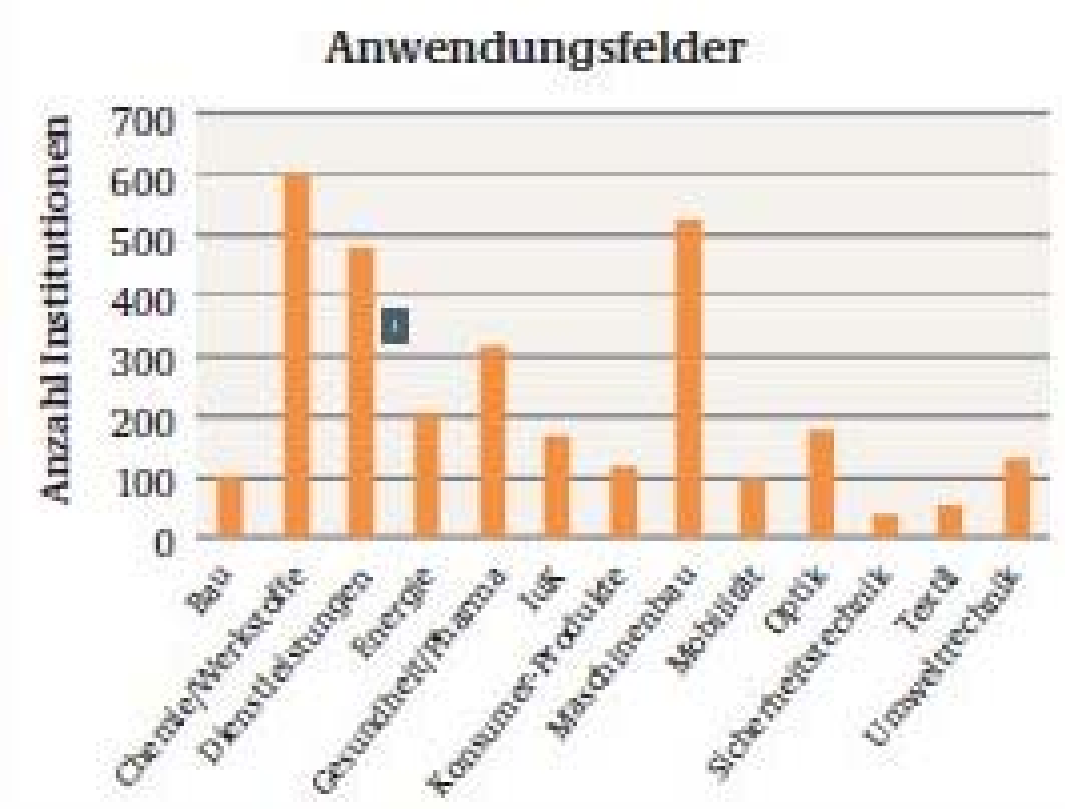
- several ongoing national/European R&D projects, e.g.
  - NanoGem
  - NanoSafe
  - NANODEVICE
  - NanoValid
- highly dynamic, "regulatory" environment, e.g.
  - publications by OECD, e.g. *Compilation of Nanomaterial Exposure Mitigation Guideline Relating to Laboratories*, 2010
  - publication on Control Banding by ANSES, 2010
  - guideline on CNTs published by Safe Work Australia, 2011
  - technical guidance by IVAM/RPA comissioned by EC, in progress

Nanotechnology Players in Germany



source: nano.DE Report, 2011

Nanotechnology Applications in Germany



source: nano.DE Report, 2011

Nanomaterials in the Market
Survey in Germany

- more than 450 responses from R&D and industry
- SMEs mostly concerned (63% companies/institutes with 1-10 employees)
- 45% companies produce/process 1 or 2 nanomaterials only
  - industry reports 85 different nanomaterials
- R&D typically handle several nanomaterials
  - R&D reports 109 different nanomaterials (100 g – 1 kg/year)
- but only few nanomaterials seem to have market relevance today
  - silica, titania, carbon black, CNTs, silver, gold

source: Federal Institute of Occupational Safety and Health, 2012

AGS Working Group Nanomaterials

- Dr. Au, Hessisches Ministerium für Arbeit, Familie und Gesundheit (➲ member AGS UAII)
- Dr. Baron, BAuA
- Dr. Berges, IFA
- Dr. Csomor, RP Kassel
- Dr. Engel, BASF SE (chair)
- Dr. Felten, Berufsgenossenschaft für Transport und Verkehrswirtschaft (➲ member AGS UAII)
- Herr Hackmann, University Bremen (➲ member AGS UAIII)
- Dr. Lange, BASF SE
- Dr. Rühl, Berufsgenossenschaft der Bauwirtschaft
- Dr. Ronge, Volkswagen AG (➲ member AGS UAI)
- Dr. Sövegjarto-Wigbers, University Bremen (➲ member AGS UAI)
- Dr. Wriedt, Beratungs- und Informationsstelle Arbeit & Gesundheit (➲ member WPC)

Liaisons with Experts on Specific Topics

- hazard assessment supported by Prof. Gebel, BAuA
  (➲ Chair of the AGS WG Fibres and Dust)
- Fire and explosion supporetd hazards by Dr. Dyrba, BG RCI and Dr. Scheid, BAM

Scope

- based on the categorization of the EC recommendation on the *Definition of Engineered Nanomaterials*, 2011
  - focus: liquid and solid substances in spray applications and which are dispersed/redispersed into workplace air
  - out of scope: natural and incidental nanomaterials
- specific guidance supplementing TGD 400 and TGD 402
  - focus: inhalation exposure

Required Information for the Risk Assessment in the Workplace

- specific information on the substance
  - classification of the nanoscale material
  - particle number distribution
  - specific surface area
  - morphological information
  - surface modification
  - information on dustiness behaviour
  - information on flammability
- information of the concerned operations

Proposed Categories of Nanomaterials

❶ soluble nanomaterials

❷ nanoscale, spherical, respirable inert dust

❸ biopersistent nanomaterials with specific toxicological properties

❹ biopersistent, rigid, fibrous nanomaterials (complying with WHO criteria)

Consequences in Practice

1. soluble nanomaterials
   - ➲ no particulate effects
2. nanoscale, spherical, respirable dust
   - ➲ safety factor 2 to be applied on the OEL for respirable, inert dust

   (TRGS 900: currently 3 mg/m^3 for a dust density 2,5
   MAK: 0,3 mg/m^3 for a dust density 1)
3. biopersistent nanomaterials with specific toxicological properties
   - ➲ individual hazard assessment,

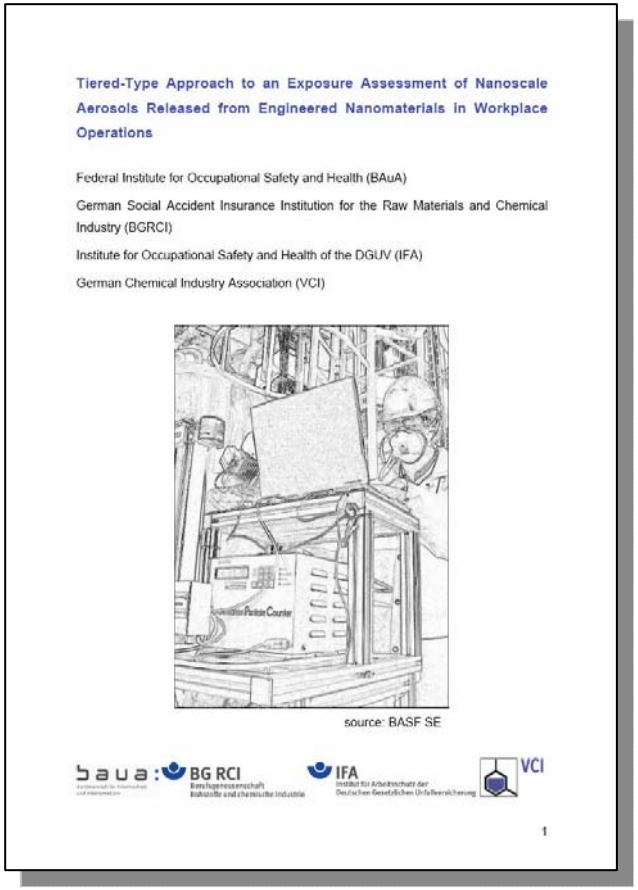
   but (draft) OELs for many microscale bulk materials < 0,1 mg/m^3
4. biopersistent, rigid, fibrous nanomaterials (complying with WHO criteria)
   - ➲ prevention, < 10.000 fibres/m^3

Risk Assessment in the Workplace
Additional Disburdening Criteria Supplementing the Standard Risk Assessment

- solubility
- embedded in a solid matrix
- no/low-release formulations and operations/process steps
- exposure data
  - respirable dust fraction
    - ➲ for nanoscale, spherical, respirable inert dust
  - total particle number concentration
    - ➲ biopersistent nanomaterials without specific toxicological properties

Role of Exposure Assessment
Tiered Approach to Exposure Assessment of Nanoscale Aerosols

- combines
  - principles of exposure assessment of nanoscale aerosols with
  - established industrial hygiene practices
- step-by-step approach:
  - Tier 1: Information Gathering
  - Tier 2: Basic Exposure Assessment
    - ➲ focus: particle number concentration
    - ➲ limited set of easy-to-use equipment (counting devices)
  - Tier 3: Extended Exposure Assessment
    - ➲ latest state-of-the-art technologies (counting and sampling devices including off-line analyses)


Tiered-Type Approach to an Exposure Assessment of Nanoscale Aerosols Released from Engineered Nanomaterials in Workplace Operations

Federal Institute for Occupational Safety and Health (BAuA)

German Social Accident Insurance Institution for the Raw Materials and Chemical Industry (BGRCI)

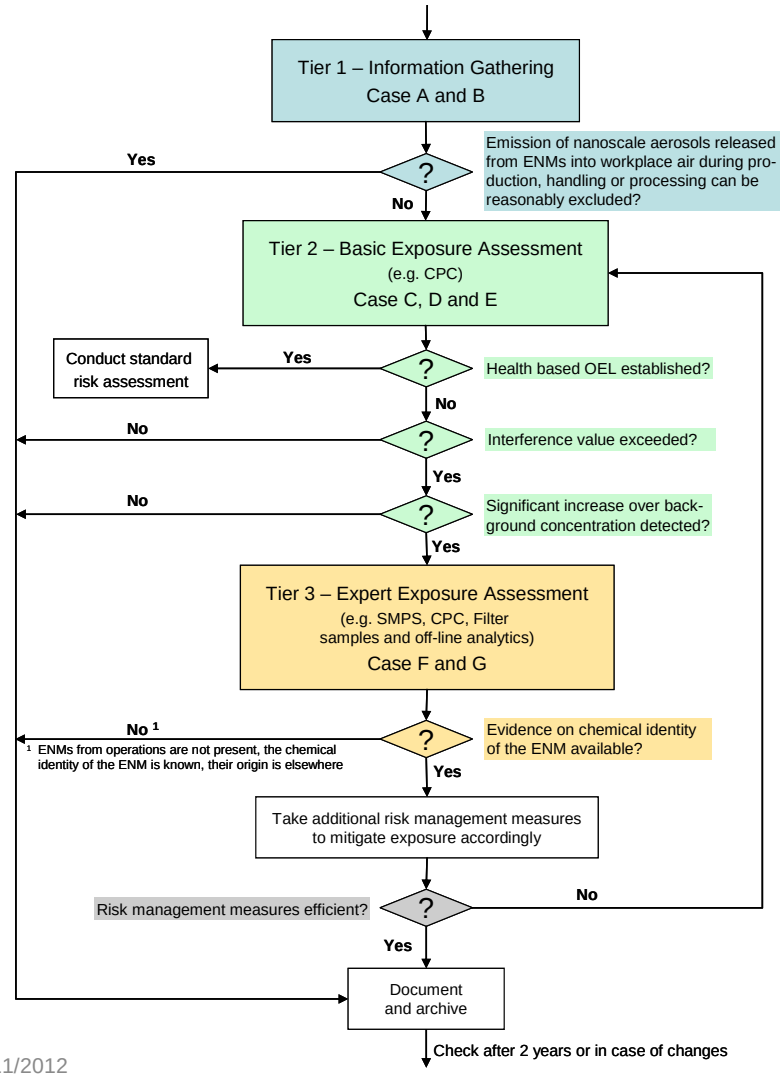
Institute for Occupational Safety and Health of the DGUV (IFA)

German Chemical Industry Association (VCI)

source: BASF SE

BAuA, BG RCI, IFA, IUTA, VCI, TUD, Germany 2011

Role of Exposure Assessment
Tiered Approach to Exposure Assessment of Nanoscale Aerosols



Consequences for Risk Management
Low/Very Low Air Concentrations Acceptable

BASF
The Chemical Company

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Consequences for Risk Management
Examples

- hierarchy of controls
- closed process steps
- efficient local exhaust ventilation (for open process steps)
- restricted access
- prevent dust deposition (high quality housekeeping)
- chemical protective gloves and suit, type 5
- respiratory protection, class P2 or P3

source: BASF SE

(Some) Conclusions

- established risk assessment concepts applicable
- principles for the evaluation of suitable controls not applicable due to limited data/knowledge
  - ➲ precautionary approach/preventive risk management measures
- additional, valid data/knowledge especially required on the
  - categorization of nanoplatelets and flexible nanofibres
  - efficiency of (technical controls and) PPE
  - suitable concepts to guarantee air concentrations < 0,1 mg/m^3
  - ➲ based on structured and harmonized R&D approaches

Hazardous Chemicals –
Safe and Professional Use in the Workplace

source: BASF SE