Risk Management of Industrial Nanomaterials

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Background

- Engineered nanomaterials (ENM) have unique properties that enable improving the quality of consumer and industrial products and processes.
- Some of these unique properties may also endanger human health
- These properties include a large surface area to mass ratio, high surface reactivity, aspect ratio of especially of fibers, and functional groups on the ENM; they may have interactions with important biomolecules cells, organs and organisms

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Diversity of different nanomaterials complicates the assessment of risks of the materials. **Schulte et al.** ***J. Occup. Environ. Med. 2009***

Fig. 1. Example of different types of airborne engineered nanoparticles (adapted from reference 20).

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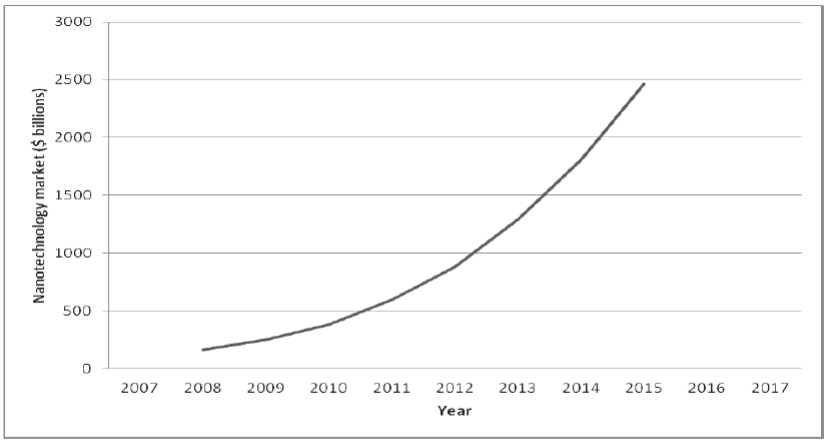

FIGURE 3-4 Projection of the size of the nanotechnology market. Source: Data from Lux 2009.

NRC 2012: A Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials

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Knowledge gaps of engineered nanomaterials, nanotechnologies

- Shortage on knowledge on associations between material characteristics and subsequent effects for most/all ENM in mammalian, environmental species
- Mechanisms of release and exposure not fully known in both human and environmental settings
- Bio-identities of materials (hazards) unknown for most ENM
- Risk prediction tools (above) and predictable risk assessment and management challenging

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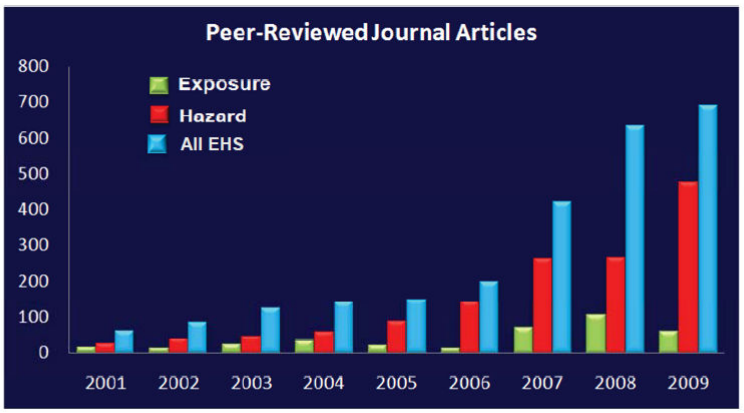

FIGURE 3-2 The number of peer-reviewed publications relating to exposure and hazard. Although the number of peer-reviewed publications on EHS effects of nanotechnology has grown substantially, far more publications address issues related to hazard than exposure. Adapted from ICON 2011.

NRC 2012: A Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials

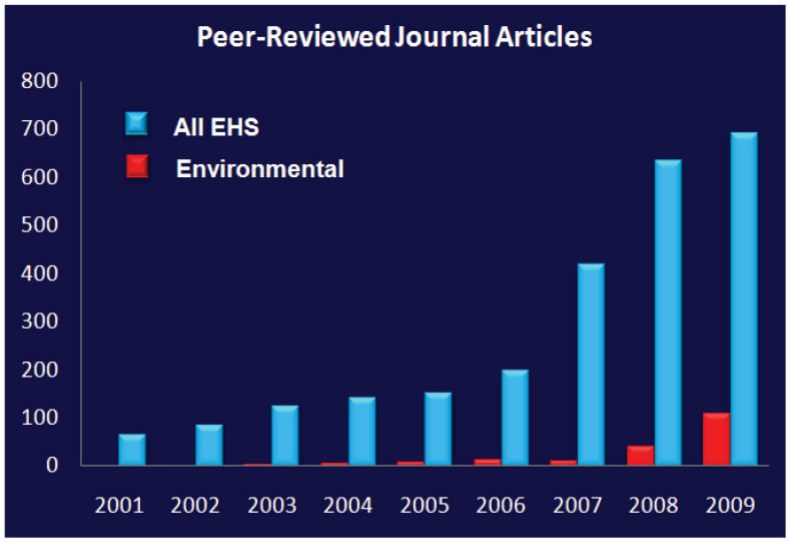

FIGURE 3-3 The number of peer-reviewed publications on environmental issues. Although the number of peer-reviewed publications on EHS effects of nanotechnology has grown substantially, only a small number of publications address environmental issues. Adapted from ICON 2011.

NRC 2012: A Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials

BOTH EXPOSURE AND HAZARD ARE REQUIRED TO POSE A RISK BY ENM

HAZARD X EXPOSURE = RISK

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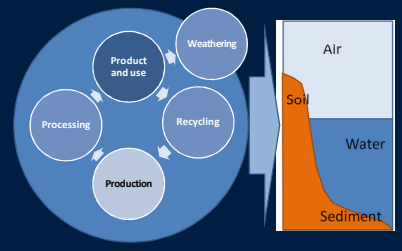
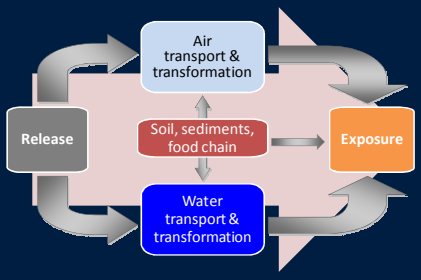
Exposure, Transformation and the Life Cycle of Engineered Nanomaterials

(courtesy of Thomas Kuhlbusch, 2012)



Nanomaterial life-cycle and release



Nanomaterials from release to exposure

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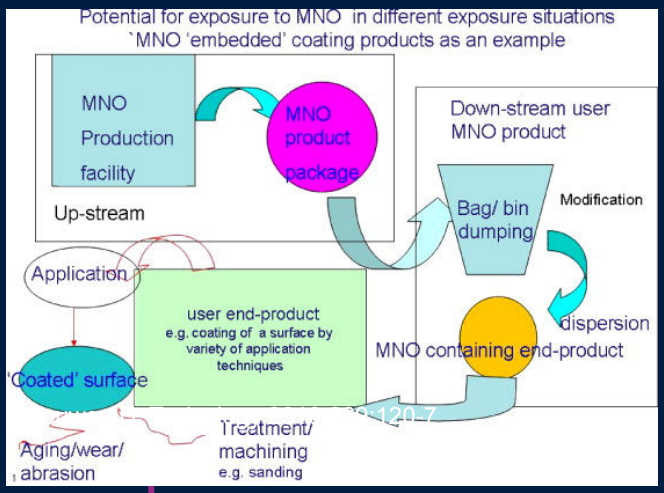
LCA-approach for identifying exposures to ENM



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Range of workplaces in which exposure to ENM can take place

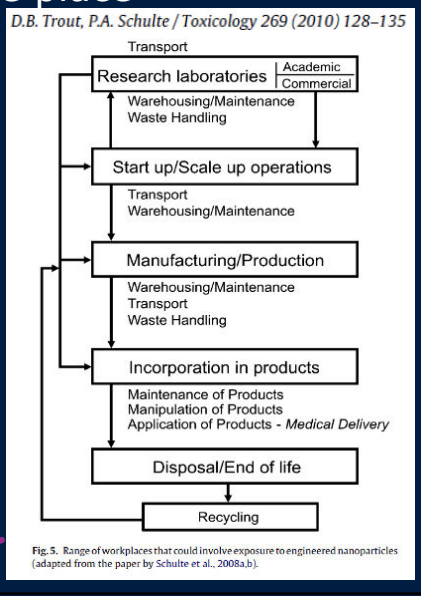

Fig. 5. Range of workplaces that could involve exposure to engineered nanoparticles (adapted from the paper by Schulte et al., 2008a,b).

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Inhalation typical in workplaces: lack of both exposure and hazard data

- Workplace ENM do not correlate with job shifts
- **ENM metrics that associate with hazards?**
- **Lack of nanospecific exposure indicators & bioindicators**
- Distinction of ENM from nano-sized background not yet possible due to lack of technology - no OELs available

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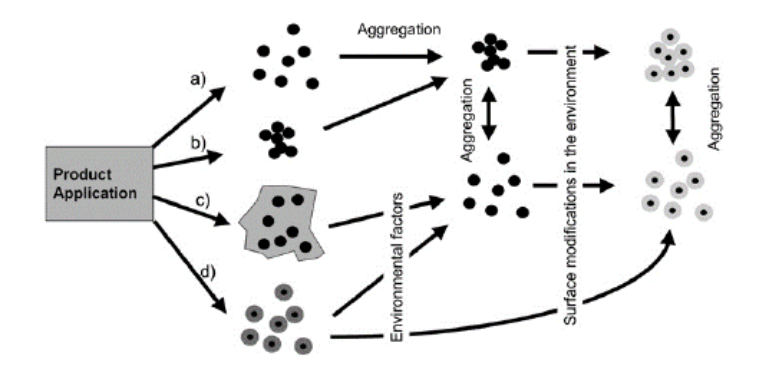
Exosure and behavior of ENM during the life-cycle and measurement



The figure shows the fate and release of ENM through their whole life-cycle (panel A on the left), and the exposure due to release of ENM at various stages of the life-cycle leading to exposure of humans and the environment (panel B on the right) adapted from Thomas Kuhlbush, with permission

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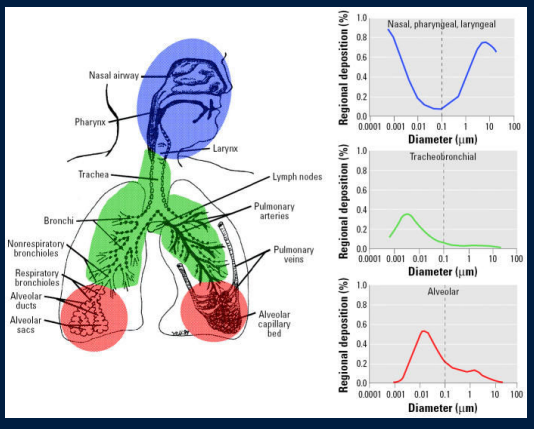
Understanding of biokinetics (ADME) of ENM



Predicted fractional deposition of inhaled particles in the naso-pharyngeal, tracheo-bronchial, and alveolar region of the human respiratory tract during nose breathing. Based on data from the IRCP.

Oberdörster G et al. *Environ Health Perspect* 2005;113:823-39

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Harmful health effects of ENM

- Several ENM cause pulmonary effects upon inhalational exposure
- Metal oxides (TiO2) induce inflammation and long, fibrous and rigid carbon nanotubes cause strong inflammation, granuloma formation, subpleural fibrosis, possibly potential to induce mesothelioma
- Mechanisms unknown, below example on mechanisms of CNT effects on the lungs

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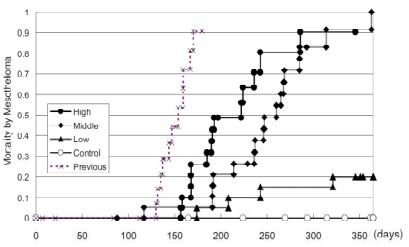
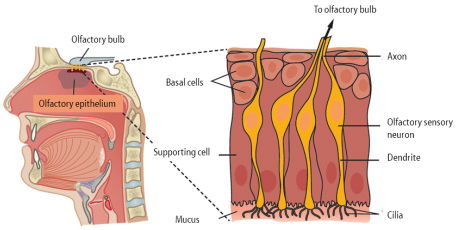
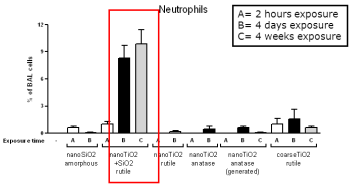
Harmful effects of engineered nanomaterials



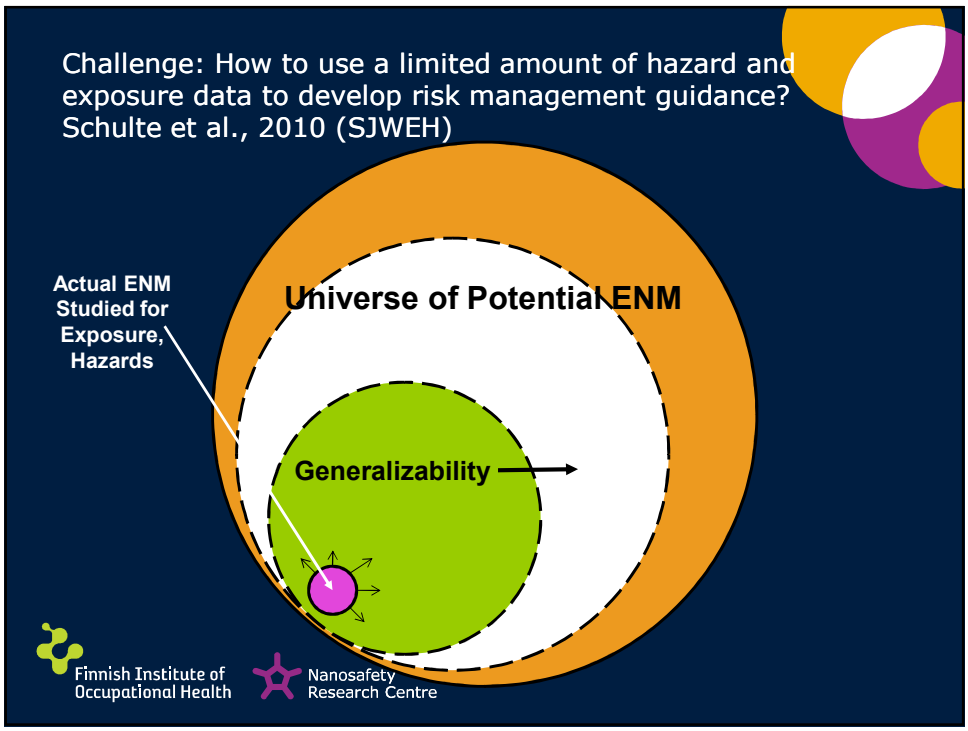
Dose-dependent mesothelioma induction by intraperitoneal administration of multi-wall carbon nanotubes in p53 heterozygous mice. Takagi A et al. Cancer Sci 108, 2012



Pulmonary inflammation in mouse lungs after TiO2 exposure



- None of the nanoTiO2 preparation tested, other than SiO2 coated TiO2, elicited pulmonary inflammation in mice !!!
- Exposure to nanoSiO2 did not induce any inflammatory effects !!!



Provisional Nano Reference Values (P-NRVs)

Class	Description	Density	P-NRV (8-hr TWA)	Examples
1	CNTs for which effects similar to those of asbestos are not excluded	-	0.01 fibres/cm³ (= 10,000 fibres/m³)	• SWCNT or MWCNT for which asbestos-like effects are not excluded
2	Biopersistent granular nanomaterial in the range of 1 and 100 nm	> 6,000 kg/m³	20,000 particles/cm³	• Ag, Au, CeO_2, CoO, Fe, Fe_xO_y, La, Pb, Sb_2O_5, SnO_2,
3	Biopersistent granular nanomaterial in the range of 1 and 100 nm	< 6,000 kg/m³	40,000 particles/cm³	• Al_2O_3, SiO_2, TiN, TiO_2, ZnO, nanoclay • Carbon Black, C_{60}, dendrimers, polystyrene • CNT for which asbestos-like effects are excluded
4	Non-biopersistent granular nanomaterial in the range of 1 and 100 nm	-	Applicable OEL	• e.g. fats, siloxanes, NaCl

NIOSH [TiO_2 as an example]

Ultrafine (Nanoscale) TiO_2

- Recommended Exposure Limit
  - 300 µg/m³ (TWA for full day for a working lifetime) – cancer as the basis of the value
  - recommendation based on mathematic modeling not used in the EU
  - RELs based on mass

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How to manage exposure to and hazards of ENM?

CURRENTLY TWO MAIN APPROACHES:

- P-NRV - policy-driven, no associated hazard data, number concentrations (The Netherlands, Germany – EU?)
- Health-based provisional in-house RELs (mass-based) (US NIOSH)
- Science does not yet provide an answer on how to assess or regulate exposure and risks of ENM
- Not yet associations between materials/exposure & hazards to judge ENM risks

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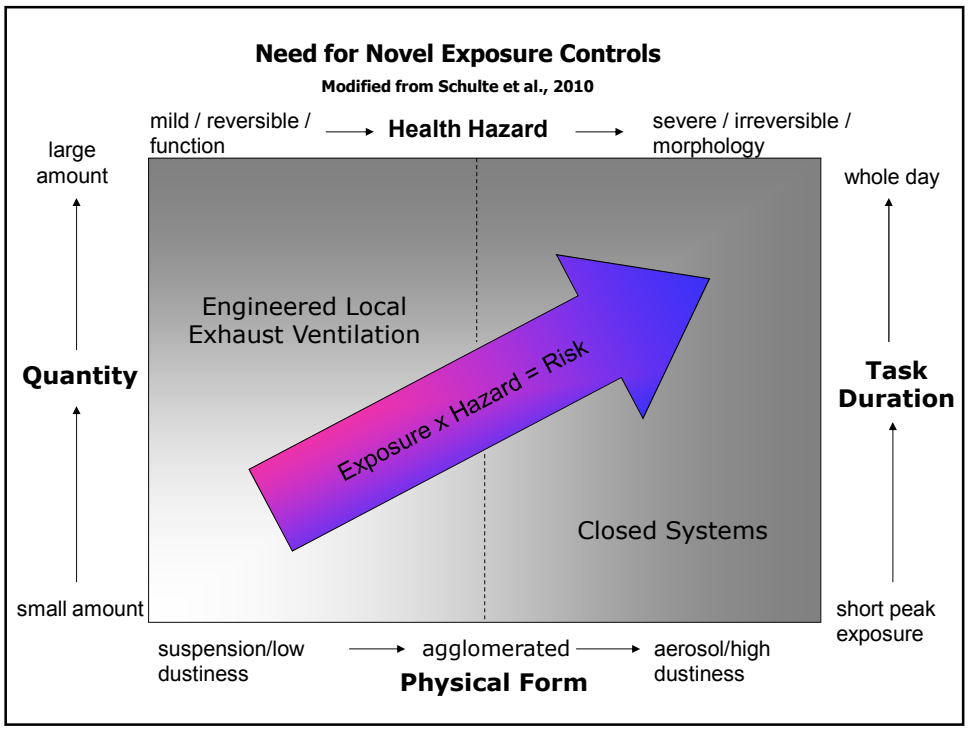

A snapshot on innovatio and regulatory challenges

- Even if material characteristics are poorly understood, there is a need to regulate
- Exposure assessment – what are the right metrics (need to regulate in the lack of data); exposure data should be able to predict risks
- Progress is, however, being made all the time, marked progress during last 5 years – there is a need for a new risk assessment concept

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Responsible management and innovations enable use of ENM

- SAFETY BY DESIGN promotion
- Safety = trust = acceptance of new technologies
- Safety assurance requires resources and commitment of all stakeholders (academia, regulators, industry)
  - new affordable, reliable, validated and quick risk assessment concept to be developed
  - international collaboration for such validated risk assessment concept required due to the lack of national resources

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THANK YOU

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