

# Nanomaterials and occupational safety and health in the EU

New OSH ERA Forum on new and emerging risks  
Workshop III

29-30 October 2009, Brussels

<http://osha.europa.eu>

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- What are nanomaterials?
- Health assessment of nanoparticles
- Workplace exposure to nanomaterials and measurement
- EU regulatory background
- Risk management in the workplace

# Categories of nano-sized materials

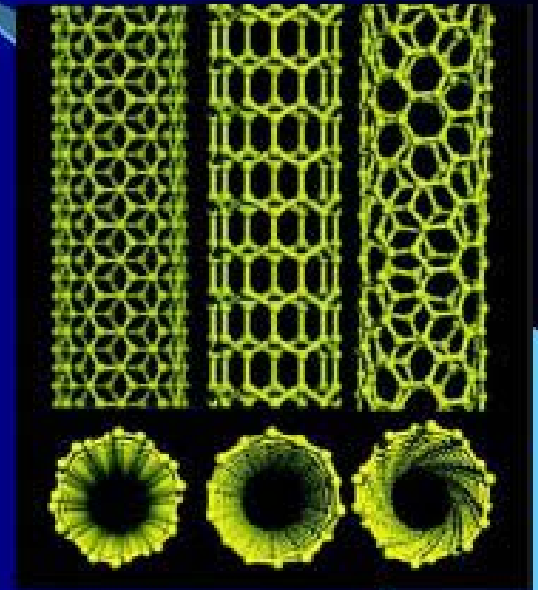
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**Natural**



**Man-Made**



**Engineered**

# Nanomaterials: at least 1 dimension < 100nm

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- Nanoparticle:  
3 dimensions < 100nm
- Nanorod:  
2 dimensions < 100nm
  - Nanotube: hollow nanorode
  - Nanowire: conductive nanorode
  - Nanofibre: flexible nanorode
- Nanoplate:  
1 dimension < 100nm

# Applications of nanomaterials (NMs)

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## ➤ Used in more than 1015 applications (08/2009)

- **consumer products:** sunscreen, cosmetics, textiles, sport & ICT equipments
- **health care:** medicines, oral vaccines, biocompatible materials
- **energy conversion:** economic lighting, batteries, solar & fuel cells
- **construction materials:** improved rigidity, insulating properties
- **automobile/aerospace industry:** reinforced materials, fuel additives, scratch-resistant, dirt-repellent coatings
- **ICT:** ultra fast compact computers, high-density memories



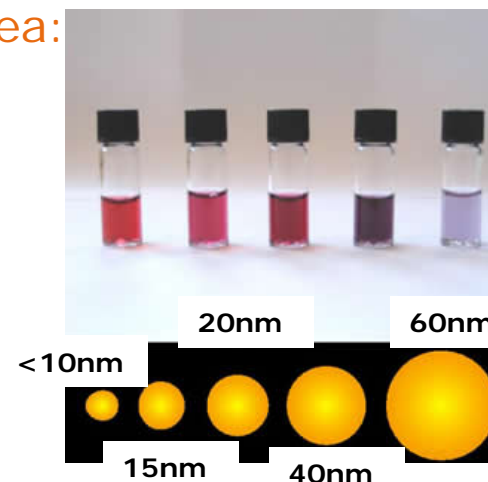
## ➤ By 2014: NMs in 15% of manufactured products and 10 million jobs worldwide involved in NM manufacturing



# New properties... new risks?

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- NPs have different properties than materials at the macro scale
- Due to their small particle size and increased surface area:
  - modified physical and chemical properties
    - e.g. gold NPs are not inert
    - electrically insulating particles are conductive at nanosize
  - behavioural properties similar to gas
    - the smaller the size, the faster they diffuse and can be found far away from their point of emission
  - their reactivity and hence toxicity increase
- There is no 'universal' NP to fit all cases
  - need to determine physico-chemical, behavioural and toxicological properties of each NP type
  - list of 17 characteristics possibly relevant for NPs toxicity (OECD)
    - particle size, particle distribution, specific surface area, shape, crystalline structure, surface reactivity, surface composition, solubility, dispersion capacity, Zeta potential (surface charge), pour density, etc.





- NPs can enter the human body and translocate to organs/tissues
  - Some NPs enter the blood circulation and reach other organs
  - Inhaled silver NPs detected in lung, liver and brain
  - Nanosized carbon can reach the brain via olfactory nerve
- The degree of damage is unknown, very specific to each NP type
- Airborne NPs tend to agglomerate quickly – what happens to this agglomerates in the body?
- *In-vivo* (animal) test are in principle appropriate although need to be further developed (SCENIHR)
- Need for validated *in-vitro* tests

- Most important effects found in the lungs
  - evidence of inflammation, chronic toxicity, tissue damage, fibrosis, tumours and risk of carcinogenicity in the lungs
  - the mechanism of tumour formation are not fully understood
- Specific modifications of carbon nanotubes (CNTs) show effects similar to asbestos
- No clear evidence of toxic effects on other organs than lungs
  - need for more research on effects on brain, liver, heart, kidneys
- Special attention to be given to the cardiovascular system
  - evidence of cardiovascular effects of environmental UPs
  - UPs and NPs show similarities (e.g. poor solubility, lung persistence)
  - not certain to what extent the same effects can be assumed for NPs



# Dermal exposure

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- Less research material available than for inhalation
- On healthy skin: no evidence of skin penetration, no effect observed except from sensitisation
- BUT need to consider that the barrier function of the skin can be breached – mechanical strain, lesions
- A case of erythema multiforme-like contact dermatitis found in a lab worker involved in synthesising dendrimers
  - started on the hand and progressed to other body parts
  - required 3 weeks hospitalisation

# Safety hazards

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- Acknowledged insufficient volume of research
- NPs have a large surface area, get easily electrostatically charged
  - Some NP metals (Al, Fe, Ti) minimum ignition energy so low that can be ignited by static electricity
- Fire and explosion: main risks described for nanopowders
  - Possible catalytic activity may result in unexpected violent or explosive reactions
- Presence of flammable materials would increase risk level

- No official data on the number of workers exposed to NPs
  - in 2004, 24,400 workers in companies working only with nanotechnology
  - France: ca. 7,000 lab workers and over 3,200 workers in the industry potentially exposed. The implementation and type of protection measures vary considerably (Afsset)
- Exposure studies available for NPs already used for some years
  - titanium dioxide (TiO<sub>2</sub>), carbon black, welding fumes, diesel exhaust
- Very limited number of studies on newer NPs
- Exposure during production normally controlled except if a leak occurs
- More likely when handling NM products, maintenance and cleaning

# Exposure measurement

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- Conventional aerosol sampling techniques not appropriate:
  - based on mass concentration – but the smaller the NP, the more toxic
- Some instruments exist for measurement of NPs' relevant indicators (size, number, surface area) but:
  - require specialist skills
  - provide information on 1 parameter only
  - size measurement can not reveal aggregates/agglomerates of NPs – to be considered as could break e.g. in lung fluid
  - interferences with background level of NPs to be considered
- EU Project NanoDevice (FP7):
  - developing an easy-to-use, portable instrument to measure and characterise airborne engineered NPs in workplaces
- OECD compilation of guidance on emission assessment for the identification of sources and release of airborne manufactured nanomaterials in the workplace

# EU legislative background relevant to nanoparticles

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- Communication from the EU Commission on the regulatory aspects of nanomaterials (COM(2008)366 final of 17.6.2008)
- Framework Directive 89/391/EC on the introduction of measures to encourage improvements in the safety and health of workers at work
- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work
- Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
- Regulation on the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH)
  - « Nanomaterials in REACH » - 1st document published 12/2008
  - SDS should contain nanoform information - has to be clearly visible
- Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixture (GHS), replacing Directive 67/548/EEC

# Occupational Exposure Limits (OELs)

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- No EU OELs
- Few national initiatives
  - Germany: OEL for amorphous silicon dioxide NPs
  - UK “benchmark levels”: pragmatic guidance
    - Insoluble NPs: 0.066xOEL of the corresponding micro-sized bulk material
    - Highly soluble material: 0.5xOEL
    - Carcinogenic, Mutagenic, Asthmagenic, Reprotoxic material (CMAR): 0.1xOEL
    - Fibrous material: 0.01 fibres/ml
  - US – draft OEL for  $\text{TiO}_2$  NPs:  $0.1\text{mg/m}^3$



- Classic principles of risk assessment and 'hierarchy of control' apply
  - Elimination > Substitution > Control
  - at source>technical>organisational>individual measures
- Precautionary principle recommended – minimise the exposure as much as possible
- “Control-banding” approaches for NPs available – reliable?
- Given the emerging state of knowledge, it is crucial that:
  - the risk assessment is reviewed regularly
  - those involved in the process take steps to ensure that their knowledge is kept up-to-date
- Workers' training on how to safely produce, handle, process and dispose NMs

# Control measures

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- Usual recommendation: same control methods as for aerosols from fine dust
- Engineering measures: enclosure, local & general exhaust ventilation
  - (little number of) studies confirm they work if well designed, installed and maintained (filters)
- Personal respiratory protection
  - half-mask's fit to the face has to be considered along with filter efficiency
- Protective clothing tested for Pt and TiO<sub>2</sub> NPs (Nanos:
  - air-tight non-woven textile better than cotton, polypropylene or paper
  - nitrile, latex and neoprene gloves seem efficient



# "CB Nanotool": Risk Level matrix as a function of severity & probability

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		Probability			
Severity		Extremely Unlikely (0-25)	Less Likely (26-50)	Likely (51-75)	Probable (76-100)
	Very High (76-100)	RL 3	RL 3	RL 4	RL 4
	High (51-75)	RL 2	RL 2	RL 3	RL 4
	Medium (26-50)	RL 1	RL 1	RL 2	RL 3
	Low (0-25)	RL 1	RL 1	RL 1	RL 2

Control bands:

RL 1: General Ventilation

RL 2: Fume hoods or local exhaust ventilation

RL 3: Containment

RL 4: Seek specialist advice

**The Annals of  
Occupational Hygiene**

Paik, S. Y. et al. Ann Occup Hyg 2008  
52:419-428;  
doi:10.1093/annhyg/men041

Table 1. Severity and probability factors and maximum points per factor (NM, nanomaterial; PM, parent material)

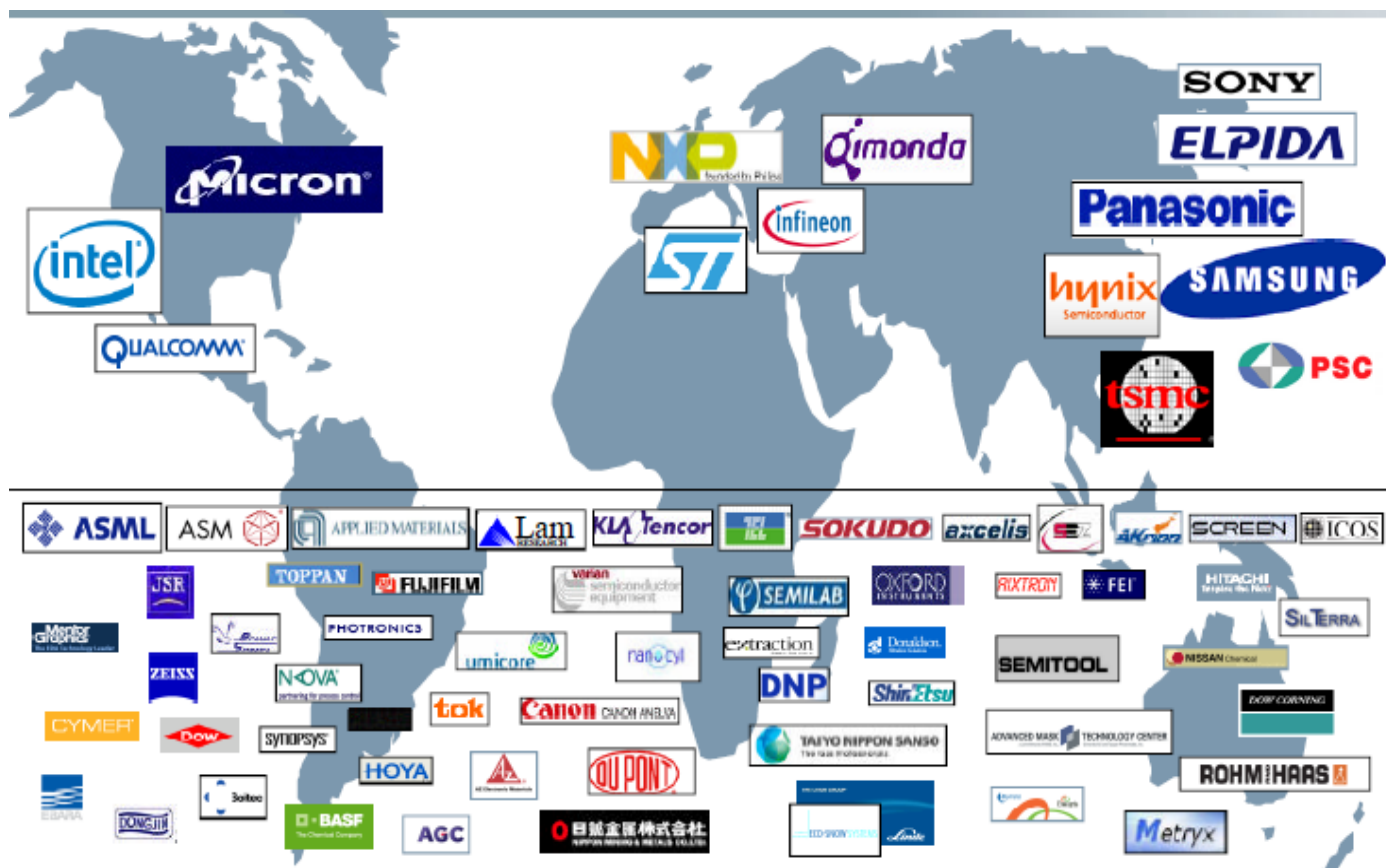
Severity factor	Maximum points	Maximum severity score
Surface Chemistry (NM)	10	100
Particle shape (NM)	10	
Particle diameter (NM)	10	
Solubility (NM)	10	
Carcinogenicity (NM)	7.5	
Reproductive toxicity (NM)	7.5	
Mutagenicity (NM)	7.5	
Dermal toxicity (NM)	7.5	
Toxicity (PM)	10	
Carcinogenicity (PM)	5	
Reproductive toxicity (PM)	5	
Mutagenicity (PM)	5	
Dermal hazard potential (PM)	5	
Probability factor	Maximum points	Maximum probability score
Estimated amount of nanomaterial	25	100
Dustiness/mistiness	30	
Number of employees with similar exposure	15	
Frequency of operation	15	
Duration of operation	15	

# Good practice example: IMEC (BE)

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- Independent research organisation of over 1,700 workers
- NMs in IMEC:

- Single/  
Multiple  
Carbon  
nanotubes  
nanowires
- Fullerenes/  
bucky balls
- Cleaving of  
Si or  
Gallium  
arsenide  
NPs on  
wafers



# IMEC: Safety measures

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- If possible, NMs will be handled in a matrix/liquids
- Engineering controls (collective protection):
  - Conduct manipulations as much as possible in **glove boxes**
  - Fibrous HEPA filters efficient for nano particles
  - Local ventilation with same specifications as used for gases
- Personal protective equipment (PPE):
  - FFP3 – half face masks yield protection factor 20
  - Full face protection masks yield protection factor 40
  - Proven high efficiency unless for particles <2 nm
  - Disposable gloves (Always)
- Identification of NMs
- Specific annual medical checkup for staff handling NMs





# IMEC: Precautionary principle for transport

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- Shipped as dangerous goods (ADR/IATA) in UN rated package  
CNT's UN-Classification 2811 (Solid Toxic Organic)

**UN 2811**

**Nano-Materials  
Not for Office Delivery**




# Agency's activities in 2010

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- Literature review on risk perception and risk communication with regards to nanotechnologies in the workplace
  - recommendations on how to communicate efficiently to promote the safe and healthy production, handling and use of nanomaterials in workplaces and protect workers' health
  - cooperation with ECHA
  
- Case studies of GP examples
  - guidance and tools for the risk assessment
  - risk management at company level


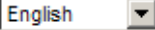
# Download our free report: <http://osha.europa.eu>

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 European Network  International Network  English 

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**Upcoming Events**

- Obstructive Airway Diseases in the Workplace: Asthma and COPD (4913) Saltsjöbaden, Sweden, 28.09.2009
- Quality at university through health and safety

## Workplace exposure to nanoparticles



Nanomaterials possess various new properties and their industrial use creates new opportunities, but they also present new risks and uncertainties. Growing production and use of nanomaterials result in an increasing number of workers and consumers exposed to nanomaterials. This leads to a greater need for information on possible health and environmental effects of nanomaterials.

**Author:** European Agency for Safety and Health at Work  
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Estimated Download Time:  Dial-up (56K) 27.0 sec

Available in: [\[English\]](#)

### Related Publications



#### Report - Labour inspectorates' strategic planning on safety and health at work

Labour inspectorates play a central role in promoting safety and health at work and are increasingly focusing their attention on the anticipation, definition and prevention of emerging risks. Through the work of labour inspectors, the inspectorates have access to a unique source of data that helps inform their strategic planning in three main areas: research, inspection and awareness-raising. This report presents an overview of the principal OSH-related priorities established by national labour inspectorates and provides information on how these priorities are set. The information contained in this report was provided by EU-OSHA's network of national Focal Points during 2008 in response to a questionnaire survey.

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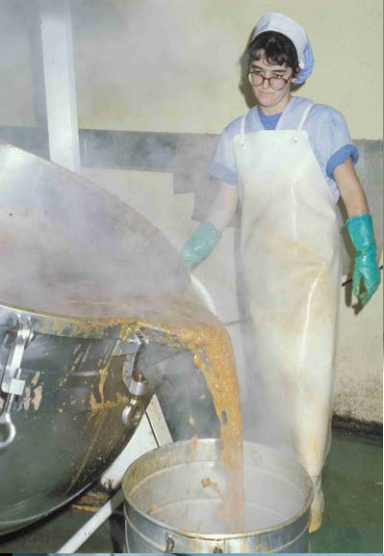
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**News**

- OSH in the school curriculum: requirements and activities in the EU Member States 28.09.2009
- Engineering Judgement: Core Competence 28.09.2009
- EU-OSHA: Call for tender for a foresight of new and emerging risks to occupational safety and health (OSH) associated with new technologies in "green" jobs. 28.09.2009
- EU-OSHA: Call for tender for a foresight of new and emerging risks to occupational safety and health (OSH) associated with new technologies in "green" jobs. 28.09.2009



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