






# **Nanomaterials: A Precautionary Approach based on the Chemical Agents Directive**

**5<sup>th</sup> Seminar on  
Workers' Protection & Chemicals  
ETUI-REHS, Helsinki, 28 – 29 January 2010**

**Henning Wriedt  
Beratungs- und Informationsstelle Arbeit & Gesundheit  
Hamburg, Germany  
wriedt@arbeitundgesundheit.de**

## Overview

-  **Motivation and goal**
-  **Limited knowledge – clear warnings:  
apply the precautionary principle**
-  **Necessity: Risk assessment**
-  **Content of risk assessment**
-  **Environmental issues at the workplace**
-  **Current regulatory initiatives**
-  **Resources: Websites and guidance  
documents**

# Motivation and goal

## Motivation for, and goal of, this presentation

- ▶ **overview both of possibilities of, and limitations in, dealing with nanomaterials within the framework of the CAD**
- ▶ **initialization of a debate** on the issues to be addressed in the **guidance on prevention and protection measures** to be drafted for the Advisory Committee on Safety and Health at Work by the Working Party on Chemicals
- ▶ **identification of deficits in existing legislation**
- ▶ **overview of regulatory initiatives with regard to OSH** at EU level and in certain Member States (and beyond)



# Application of the precautionary principle

## Health effects of nanomaterials

Still rather limited knowledge, yet clear **warnings**:

- ▶ **experience with ultra-fine dust exposure (humans)**  
environment: damage to respiratory system,  
circulatory system  
work environment: damage to respiratory system  
(welding fumes), inflammation of respiratory  
system (metal fume fever, polymer fever)
- ▶ **inhalation studies with selected nanomaterials (animals)**  
respiratory system (inflammation, fibrosis, tumors)  
inflammation reactions beyond the respiratory system  
penetration of tissue barriers (air-blood barrier,  
blood-brain barrier)  
storage in organ tissue, penetration of cell walls  
transportation into brain along the olfactory nerve



# Application of the precautionary principle

## Health effects of nanomaterials

### Current **status**:

- ▶ for repeated or permanent exposure with **stable** (i.e. insoluble or hardly soluble) **particulate nanomaterials** even significantly below the **OEL for inert dust** (currently 3 mg/m<sup>3</sup> in Germany) a health risk cannot be excluded.

**This situation justifies control measures based on the  
precautionary principle**



# Operationalization of the precautionary principle

**Challenge for occupational safety and health:  
operationalization of the **precautionary principle**  
without infringement of the **proportionality principle****

**solution**

**generic:**

- ▶ **risk assessment according to CAD (98/24/EC)**

**specific:**

- ▶ **performing the individual steps of risk assessment  
under the premise of “precaution”**

**questions to be answered:**

- ▶ **are nanomaterials within the scope of the CAD?**
- ▶ **does risk assessment have to be performed for  
nanomaterials?**
- ▶ **is that the case even if a nanomaterial is not to be  
classified as hazardous?**
- ▶ **what generic hazards have at least to be taken into  
account in risk assessment?**



## Necessity: Risk Assessment

**Risk assessment is also obligatory for nanomaterials which have not been classified as hazardous but, notwithstanding, have to be perceived as “hazardous chemical agents” according to the Chemical Agents Directive (cf. Dir. 98/24/EC, art. 2 (b) (iii))**

Such nanomaterials “without specific hazardous properties” have also taken into account when performing a risk assessment for uses of mixtures.

**In view of the above-mentioned warnings, insoluble (or hardly soluble) nanomaterials should generally be considered as hazardous chemical agents** unless their release from a matrix can be excluded.

Even without any substance-specific adverse health effects, for the exposure to insoluble nanomaterials the deleterious effects of “inert dust” always have to be assumed – without any certainty that below the OEL for inert dust adverse health effects will be avoided.



## Necessity: Risk Assessment

**Are there in fact any nanomaterials “without specific hazardous properties”?**

**The majority of the substances on the OECD list** (amongst them carbon black, titanium dioxide, silica) **have not been classified by the EU as “hazardous”**; recently, **carbon black** has been **registered** under REACH **without a classification as “hazardous”**

**How is the employer even to find out about his obligation to perform a risk assessment for uses of nanomaterials “without specific hazardous properties”?**

- ▶ **application of the CAD / its transposition in the respective Member State**
- ▶ **BAuA- / VCI-guidance** for handling and use of nanomaterials at the workplace
- ▶ trade union request: **manufacturer / formulator should include the respective information in the safety data sheet or in the information according to art. 32 REACH**



# Content of Risk Assessment

## ■ Provision of information

1<sup>st</sup> challenge: **Do SDS** or in future **extended SDS with exposure scenarios need to be provided at all** for nanomaterials “without specific hazardous properties”?

- **prerequisite for the provision of an SDS**  
(cf. art. 31 (1) REACH): substance / mixture
  - meets criteria for **classification as hazardous** or
  - is PBT or vPvB or
  - has been included in the candidate list for authorisation
- **prerequisite for the development of an exposure scenario** as part of the chemical safety assessment  
(cf. annex I no. 0.6 REACH): substance
  - meets criteria for **classification as hazardous** or
  - is to be classified as PBT or vPvB

# Content of Risk Assessment

## ■ Provision of information

Approaches for overcoming the first challenge:

- **also for nanomaterials “without specific hazardous properties”, manufacturer / formulator should automatically provide an SDS**
  - ▶ trade union demand
  
- **also for nanomaterials “without specific hazardous properties”, manufacturer should develop exposure scenarios as part of the chemical safety assessment and should add them to the SDS**
  - ▶ **recommendation by RIVM** (Dutch National Institute for Public Health and the Environment) **in recent study “Nanomaterials under REACH”**
  - ▶ trade union demand



# Content of Risk Assessment

## Provision of information

2<sup>nd</sup> challenge: **Information in the SDS is not nano-specific** – parameters relevant for the assessment of nanomaterials are not part of the obligatory SDS information

approach for a solution:

- **for nanomaterials, manufacturers should provide information in the SDS generally on a number of relevant parameters**
  - ▶ **recommendation in the VCI "Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets"**
  - ▶ **detailed compilation of parameters in the VCI "Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials"**
  - ▶ **Swiss guidelines on the necessary information in the SDS for synthetic nanomaterials** – under preparation, draft to be published soon

# Content of Risk Assessment

## Assessment of health hazards

Challenge: In view of insufficient or missing data, an **assessment** of health hazards is **not feasible**

consequence:

- **health hazards should be assumed**
- **exposure to those substances should be minimised**
  - ▶ **recommendation in BAuA- / VCI-Guidance** for Handling and Use of Nanomaterials at the Workplace as well as in other guidance documents
  - ▶ **BASF-guidance** for safe production and for uses of nanoparticles at workplaces of BASF SE: **exposure should not exceed the background level** (i.e. without nanoparticles) **outside the workplace**



# Content of Risk Assessment

 Comment on exposure minimization:

**minimization according to which technical standards?**

- chemical industry?
- pharmaceutical industry?
- nuclear industry?

 **exposure determination**

challenges: measurement methods, background exposure with ultra-fine aerosols

guidance and support:

- ▶ **BAuA- / VCI-Guidance** for Handling and Use of Nanomaterials at the Workplace
- ▶ **IFA website**

# Content of Risk Assessment

## Control measures

### Guidance and support:

- ▶ **SDS** / in future: **eSDS, exposure scenario**
- ▶ **BAuA- / VCI-Guidance** for Handling and Use of Nanomaterials at the Workplace
- ▶ **guidance** in other countries (France, Switzerland)
- ▶ **IFA website**
- ▶ **Internet offers**, e.g. GoodNanoGuide

warning: quality of certain recommendations questionable

### example (from different German guidance documents):

- **Does the possibility of substitution have to be checked?**

### answers:

**yes** (two guidance documents)

**no** (one guidance document: "since the intended usage of specific nano-properties will exclude the possibility of substitution")



# Content of Risk Assessment

## Efficacy check of the control measures implemented

**Comparison** of residual exposure after implementation of control measures **with “benchmark levels”**

challenges:

- currently **no OEL derivable**
- **OEL for inert dust is not applicable**  
(scope of OEL for inert dust explicitly excludes ultra-fine particles)
- choice of **metric** (mass, surface, number of particles?)

consequence:

**interim solution** desirable to assess “minimization progress”

initial proposals for benchmark levels:

- ▶ **BSI** (British Standards, 2007)
- ▶ **NIOSH** (for TiO<sub>2</sub>, 2005)
- ▶ **IFA website** (2009)
- ▶ Swiss “reference values” announced for 2011
- ▶ requested in a motion by the Dutch parliament ( July 2009)

discussion seems to be getting broader



# Content of Risk Assessment

## Efficacy check of the control measures implemented

Main results of the current proposals for benchmark levels:

- **differentiation** according to **classes of nanomaterials**
  - ▶ **soluble** nanomaterials
  - ▶ **insoluble** nanomaterials
  - ▶ nanomaterials with **CMR properties**
  - ▶ **fibrous** nanomaterials
- differentiation according to **size** of nanomaterials (where mass concentration is chosen as metric)
- consideration of **density** of nanomaterials

## Additional indication for possible size of benchmark levels:

- **EU environmental levels** for “**total fine dust**” (PM<sub>10</sub>):
  - ▶ more than 50 µg/m<sup>3</sup> per day for fewer than 35 days/year
  - ▶ less than 40 µg/m<sup>3</sup> per year

## Query to be encountered soon:

Will the new **DNELs** present any useful **support** for an assessment **or** will they rather contribute to **confusion**?



# Content of Risk Assessment

## Initial proposals for DNELs

(ENRHES review: <http://nmi.jrc.ec.europa.eu/project/ENRHES.htm>)

| substance                            | [ $\mu\text{g}/\text{m}^3$ ] | [ $\text{n}/\text{cm}^3$ ] |
|--------------------------------------|------------------------------|----------------------------|
| titanium dioxide, sc. 1              | 17                           |                            |
| titanium dioxide, sc. 2              | 70                           |                            |
| titanium dioxide (NIOSH, ref. value) | 100                          |                            |
| silver, sc. 1                        | 0.3                          | 4,000                      |
| silver, sc. 2                        | 0.1                          | 1,200                      |
| carbon fullerenes                    | 0.3                          |                            |
| MWCNT, sc. 1                         | 35                           |                            |
| MWCNT, sc. 2                         | 0.7                          |                            |
| MWCNT (Baytubes, company DNEL)       | 50                           |                            |
| MWCNT (Nanocyl, company DNEL)        | 2.5                          |                            |

# Content of Risk Assessment

## ■ Medical surveillance

Challenge: up to now **no specific indicators** have been identified; hence there are none to be utilized for medical surveillance

question:

**as an interim solution**, could medical surveillance methods focused on “adverse effects to the respiratory system” which neither include invasive methods nor cause additional health risks be developed and implemented?

note:

NIOSH published a proposal for an interim solution on this issue already in 2006, which was extended in early 2009:

- ▶ **NIOSH**: Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles

# Content of Risk Assessment

## Documentation of risk assessment

The obligations regarding the documentation of risk assessment are unambiguously defined (at least in Germany) **beyond those obligations** a worker-specific exposure register should be installed which could serve as basis for future epidemiological studies.

- ▶ **recommendation of the Socio-Economic Council (SER) of the Netherlands**
- ▶ **trade union demand**

## Documentation of medical surveillance

Results of medical surveillance should be documented in such a way that they can be combined with the exposure register and can enable epidemiological studies.



# Environmental Issues at the Workplace

## Treatment of waste, effluents, and atmospheric emissions

Outside the scope of the CAD ...

... but

in practice, management of both OSH and environmental issues at the workplace should be addressed by a **joint approach** – irrespective of it being covered by different parts of legislation

guidance and support

- ▶ **VCI-Guidance** for the Safe Recovery and Disposal of Wastes containing Nanomaterials
- ▶ **Swiss guidelines for the waste management of synthetic nanomaterials** – under preparation, preliminary version to be published soon



# Current Regulatory Initiatives

## Regulatory initiatives directly regarding OSH

### EU level

- Resolution of the **European Parliament** (April 2009):  
“review worker protection legislation”
- **ACSH mandate** to the WPC for 2010 / 2011:  
“consider the risks from exposure to nano-materials at the workplace and the need for concise guidance on prevention and protection measures”

### MS level

- **Germany:** nanomaterials part of the current working programme of the Hazardous Substance Committee (possible outcome: guidance)



# Current Regulatory Initiatives

## Regulatory initiatives relevant for OSH

### EU level

- preparation of **REACH revision** 2012 / activities of **CASG on Nanomaterials**
- considerations re. **product register** by DG ENV (cf. workshop “Nanomaterials on the Market - What Regulators Need to Know”, Brussels, 9 October 2009, and studies presented there)

### MS level

- **France**: register of nanomaterials (compulsory reporting) types, volumes, and uses (advanced stage in legislative process)
- **Germany**: register of nanomaterials and nano-products (initial discussions started by Federal Environment Ministry)
- **Netherlands**: notification obligation for the use of nanoparticles in products (motion passed by the Dutch parliament, July 2009)



# Resources: Websites and Guidance Documents

German language **websites** with guidance on **measurement methods, control measures, guidance documents** and **additional sources**:

- ▶ **BAuA** website „Nanotechnologie“: [http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/Nanotechnologie.html?\\_\\_nnn=true&\\_\\_nnn=true](http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Nanotechnologie/Nanotechnologie.html?__nnn=true&__nnn=true)  
in particular sections „Literatur“ and „Links“
- ▶ **IFA** website „Ultrafeine Aerosole und Nanopartikel am Arbeitsplatz“: <http://www.dguv.de/ifa/de/fac/nanopartikel/index.jsp>
- ▶ Informationsplattform **Nano-Sicherheit.de**:  
<http://www.nano-sicherheit.de/>  
in particular sections „Risikobewertung“ and „Risikomanagement“
- ▶ **SUVA** website „Nanopartikel an Arbeitsplätzen“: <http://www.suva.ch/nanopartikel>



# Resources: Websites and Guidance Documents

**Guidance** focussed on **occupational safety & health**,  
**environmental issues**, and **provision of information**

## occupational health & safety

- ▶ **BAuA- / VCI-**“Guidance for Handling and Use of Nanomaterials at the Workplace”: <http://www.vci.de/default2~rub~809~tma~0~cmd~shd~docnr~121306~nd~~ond~nano.htm>

## environmental issues

- ▶ **VCI-**“Guidance for the Safe Recovery and Disposal of Wastes containing Nanomaterials”: [http://www.vci.de/Default2~cmd~get\\_dwnld~docnr~126414~file~Handling%5FNanomaterials%5Fbeing+Wastes%5F7%5Fhtm](http://www.vci.de/Default2~cmd~get_dwnld~docnr~126414~file~Handling%5FNanomaterials%5Fbeing+Wastes%5F7%5Fhtm)



# Resources: Websites and Guidance Documents

## ■ **Guidance** focussed on **occupational safety & health, environmental issues, and provision of information** **provision of information**

- ▶ **VCI**-“Guidance for the Passing on of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets”:  
<http://www.vci.de/default2~rub~809~tma~0~cmd~shd~docnr~1223>
- ▶ **VCI**-“Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials”:  
<http://www.vci.de/default2~rub~809~tma~0~cmd~shd~docnr~1223>



# Resources: Websites and Guidance Documents

## Additional sources in German, English, and French

- ▶ Swiss Bundesamt für Gesundheit (BAG): "Vorsorgeraster synthetische Nanomaterialien": <http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=de>
- ▶ Sociaal-Economische Raad (SER), Netherlands: „Nanoparticles in the Workplace: Health and Safety Precautions“: [http://www.ser.nl/en/publications/publications/2009/2009\\_01.aspx](http://www.ser.nl/en/publications/publications/2009/2009_01.aspx)
- ▶ INRS, France: „Les nanomatériaux“: [http://www.inrs.fr/inrs-pub/inrs01.nsf/IntranetObject-accesParReference/Dossier%20Nano/\\$File/Visu.html](http://www.inrs.fr/inrs-pub/inrs01.nsf/IntranetObject-accesParReference/Dossier%20Nano/$File/Visu.html)
- ▶ OECD: „Preliminary Analysis of Exposure Measurement and Exposure Mitigation in Occupational Settings: Manufactured Nanomaterials“: <http://www.oecd.org/dataoecd/36/36/42594202.pdf>



# Resources: Websites and Guidance Documents

## Additional sources in German, English, and French (cont.)

- ▶ IRSST, Quebec, Canada: "Best Practices Guide to Synthetic Nanoparticle Risk Management": [http://www.irsst.qc.ca/en/\\_publicationirsst\\_100432.html](http://www.irsst.qc.ca/en/_publicationirsst_100432.html)
- ▶ safe work australia: „Engineered Nanomaterials – Evidence on the Effectiveness of Workplace Controls to Prevent Exposure“: <http://www.safeworkaustralia.gov.au/swa/AboutUs/Publications/EngineeredNanomaterials-EvidenceontheEffectivenessofWorkplaceControlstoPreventExposure.htm>
- ▶ NIOSH, USA: „Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles“: <http://www.cdc.gov/niosh/review/public/115/PDFs/DRAFTCIBExpEngNano.pdf>

