Aspects & Needs Related to Emerging Risks within the Industrial Safety Area Including Dimensions of Safety – An EU-Policy Perspective Viewpoint

1st iNTeg-Risk Conference: Dealing with Risks of Tomorrow's Technologies – Stuttgart, DE

Dr. Achim Boenke*

Unit Chemicals – Industrial Pollution & Emission Control;

Enterprise and Industry Directorate-General; European Commission; Brussels



* The views expressed in this presentation are personal and may not necessarily reflect those of the European Commission.

Content

- Setting the Scene;
- Industrial Policy & Sustainable Development;
- The Seveso II Directive Review & the Integrisk Project;
- Nanomaterials & the Integrisk Project;
- Nanomaterials Exposure Measurements & Mitigation Aspects;
- Conclusions



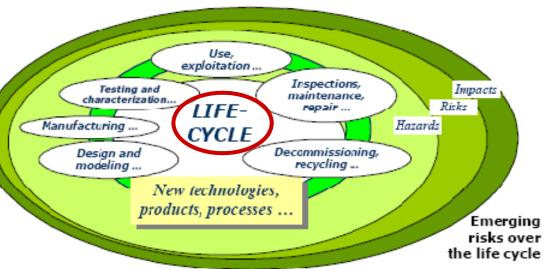
 Nano / Bio iNTeg-Risk Good Practice Guideline for Emerging risks iNTeg-Risk Safetypedia iNTeg-Risk Emerging Risk Early Warning & Monitoring System iNTeg-Risk Atlas of Emerging Risks Good Practice iNTeg-Risk Reference Library iNTeg-Risk Suite of Tools iNTeg-Risk Pre-Standardization iNTeg-Risk European Network of Industrial Systems and Common guidelines Facilities for exploration of iNTeg-Risk Emerging Risks Common iNTeg-Risk Education & methods and ... Qualification: The European Certified Risk Specialist ... tools for dealing with emerging risks

The iNTeg-Risk vision Risk – Benefit Analysis of Emerging Technologies?

CONCEPT: The new concept for integrated management of emerging risks in industry (the iNTeg-Risk paradigm)

SYSTEM (supported by INTEGRATED TOOLS!): This is a new system (the iNTegRisk framework) that enables the implementation of the paradigm consisting in a unified set of methods for risk management

LANGUAGE & METRICS: This is a new common language (the iNTegRisk Unified Model Language -UML) and metrics, based on KPIs, for management of emerging risks in industry.



KPIs – Measuring things difficult to

measure ...

iNTeg-Risk Box "KPIs"

In the business world, the Key Performance Indicators (KPI) are financial and non-financial metrics used to quantify objectives to reflect strategic performance of an organization. KPIs are frequently used to "value" difficult to measure activities such as the benefits of leadership development, engagement, service and satisfaction. KPIs are typically tied to an organization's strategy (as exemplified through techniques such as the Balanced Scorecard). They help an organization to measure progress towards their organizational goals, especially toward difficult to quantify knowledge-based processes. A KPI is a key part of a measurable objective.

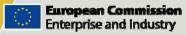
Cost Benefit Analysis

Research Needs:

- Work on a quick, practical, & accepted tool by networking with other parties & resolve fundamental scientific differences related to the various methodologies applied & using age-based lifestyle influences:
 - VSL (Value of Statistical Life);
 - VOLY (Value of Life Years Lost);
 - Application of premium of life insurances.

Reasons:

- VOLY & VSL was used in the CAFÉ (Clean Air for Europe)-Cost Benefit analysis.
- VOLY appears to be the right metric to apply as confirmed by EC, RTD-Projects (NewExt, NEEDS).
- **❖ VSL** provides an overestimation of health impacts & data is lacking.
- Uncertainties are large & differences in VSL (Median & Mean) & VOLY (Median & Mean) had a clear influence on selecting the final scenario for the Thematic Strategy on Air Pollution.
- Cost benefit analysis based on premium of life insurances not assessed in all details linked to the VSL & VOLY approaches.



Need for Quantitative Safety Cost Information

(Study on the effectiveness of the requirements imposed on operators ("F-Seveso"), results downloadable from: http://ec.europa.eu/environment/seveso/pdf/seveso_report.pdf & more on the study via http://www.f-seveso.eu-vri.eu/home.aspx?lan=230&tab=131&pag=134)

The F-Seveso Study concluded that:

- "Industry has generally stated that the costs related to the implementation of safety regulations are "on the margin" and that the requirements "have to be implemented by industry anyway".
- "Industry respondents were equally divided about the impact of safety requirements on the delocalisation of production towards third countries. The general trend is that the overall business costs in Europe compared to elsewhere is a more significant factor, with "safety costs" just one part of this wider picture."
- "On the other hand, industry recognises that safety costs are financial beneficial in the long run, because they reduce the chances of facing the huge cost of major accidents."
- "From the web-survey & the interviews, 4 particular comments have been made regarding requirements & costs being excessive for SMEs: "could be an important issue discouraging them from starting new activities & in this way reducing competition", "the cost benefit balance is unfavourable for SMEs" or "costs of the Safety Report acceptable for a multinational, but this situation may not be the same for a SME."

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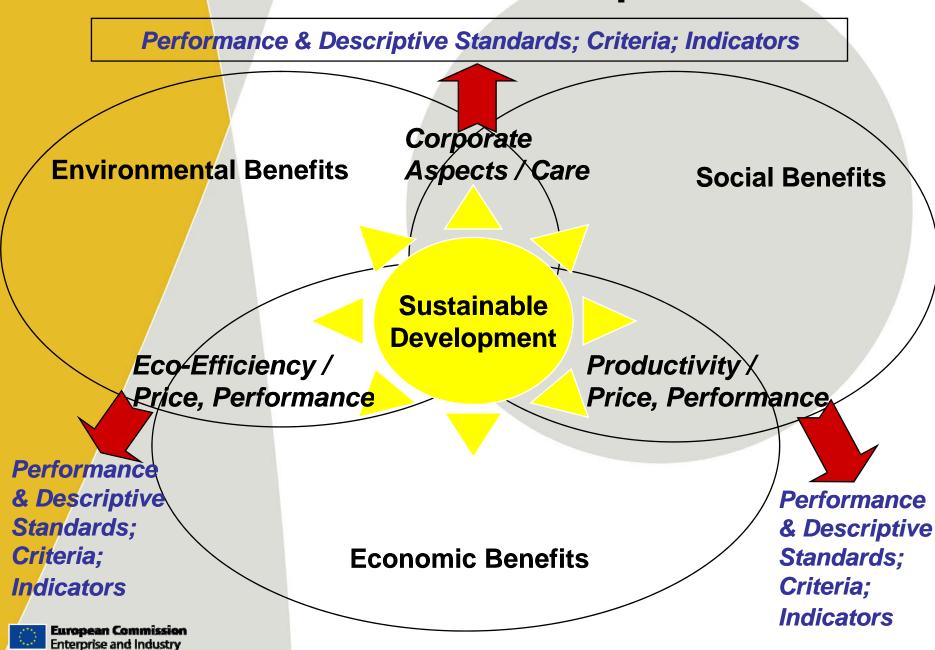


Industrial Policy

- A New Industrial Policy "Partnership for Growth & Jobs":
- Making Europe a more attractive place to invest & work;
- Putting knowledge and innovation at the heart of European Growth;
- Shaping policies to allow business to create safer & better jobs;
 - Fewer accidents & occupational diseases lead to:
 - Fewer outages of industrial installation;
 - Fewer absences from work;
 - Lower health care cost;
 - Higher capital efficiency.



Sustainable Development



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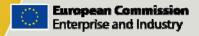


Seveso II Directive Review (1)

- Adaptation to the Global Harmonised System (GHS);
- Technical Working Group;
- Impact assessment;
- Results of Implementation Reports, Feedback Member States, Inspectors (Enforceability), seminars etc..

Study on the effectiveness of the requirements imposed on operators ("F-Seveso"), results downloadable from:

http://ec.europa.eu/environment/seveso/pdf/seveso_report.pdf



Seveso II Directive Review (2)

Studies:

- Study on requirements imposed on public authorities just started;
- EU Action Programme for reducing administrative burdens (Information Obligations);
- Other issues (security, emerging risks...);
- Prevention Strategy (Commission communication) see

http://ec.europa.eu/environment/civil/pdfdocs/com_2009_8 2en.pdf .

Overall Aim: Seveso II Directive Review Proposal Early 2010

Seveso II Directive (96/82/EC) – Responsibility EC-DG Environment

- The Seveso II Directive was last amended in 2003 & ~8000 establishments in Europe are subject to its safety requirements.
 - => Broadening scope & reinforcement of various requirements such as land-use planning.
- Transposition measures had to be in place by summer 2005.
- Most Member States communicated transposition measures & conformity checks are on-going.
 - Implementation checked by means of regular reports from Member States.
 - Last reporting period covered 2003-2005 forms basis for overall report to EP & Council in 2007.
 - The Commission will continue work closely with Member States on the number one priority, i.e. implementation.



Seveso II Directive (96/82/EC) – Responsibility EC-DG Environment

- Environment & Industry Aspects:
 - Investing in technologies for improved industrial safety will boost economic success & reputation in society.
 - Referring to the safe handling & storage of hazardous substances, the objective is to establish & maintain consistent & effective measures.
- For Seveso competent authorities (CAs) need to cooperate with industry & each other to prevent accidents:
 - Safety & health CAs;
 - Environment CAs;
 - Civil Protection CAs;
 - Land-use Planning CAs.

All need to speak the same "language".

⇒ training activities can help.



Integrisk – Further Harmonised Implementation of the Seveso II Directive (96/82/EC)

How could Integrisk contribute to the "EU Safety Network"?

- Provide additional knowledge & cost-effective tools to further improve the dissemination & uptake of relevant research project results to different stakeholders (here: Member States – Competent Authorities, industry operators, NGOs & the Commission).
- Provide cost-effective tools to further improve the EU Safety Network by making it more effective & increase the uptake of new knowledge linked to e.g. services; monitoring; inspections; management (linking with responsible care, etc.); planning, design & development of products & processes.

Integrisk – Further Developments in Risk Assessment & Industrial Safety

How could Integrisk contribute to an improved risk assessment & industrial safety?

- Provide additional knowledge & cost-effective tools to allow for greater convergence & dissemination of risk assessment practices between Member States by facilitating learning & the development of future harmonised prevention activities.
- Provide additional knowledge & cost-effective tools for improved training, inspection & risk communication approaches taking into account specialities.
- Provide additional knowledge & cost-effective tools based on the user perspective to further help in the analyses of the natural environment & surrounding activities to identify the hazards linked to a safe installation operation & the vulnerability of the area.
- Contribute to ETPIS activities for a forum to allow for an informal & open discussion of various safety aspects including any ideas by

 European Commission involving all stakeholders.

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Integrisk – Health, Safety & Environmental Aspects of Nanomaterials

Nanomaterials - Hazard

size, shape, composition, surface chemistry including surface charge & adsorbed species

Nanomaterials - Exposure

- urgent need for exposure data on humans (consumers & workers) & environmental species including micro-organisms leading to inherently safe processes
- but, need to be applicable for

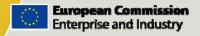
Enterprise and Industry

- routine sampling & measurement
- counting & measuring particles that are below the limit of detection by visible light
- => For Integrisk: Contribute to This Gap Closure

Integrisk – Health, Safety & Environmental Aspects of Nanomaterials

Nanomaterials – Risk Characterisation

- sources
- properties: high surface to volume ratio + quantum effects
- characterization is essential
- routine human exposure note background & history
- principal route: inhalation but changing
- environmental exposure: air, water, soil note background & history



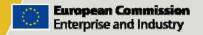
Integrisk - Health & Safety of Nanomaterials

Knowledge gaps

- mechanisms & kinetics of the release
- exposure levels to humans & environment
- possibility of extrapolation
- toxicokinetic data after exposure for target organs identification & doses for hazard assessment
- occupational exposure
- fate, distribution &, persistence & bioaccumulation
- effects

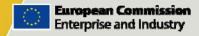
Actions

- boosting collaboration => CA&Industry; OECD, ISO&CEN
 - => For Integrisk: Contribute to This Gap Closure

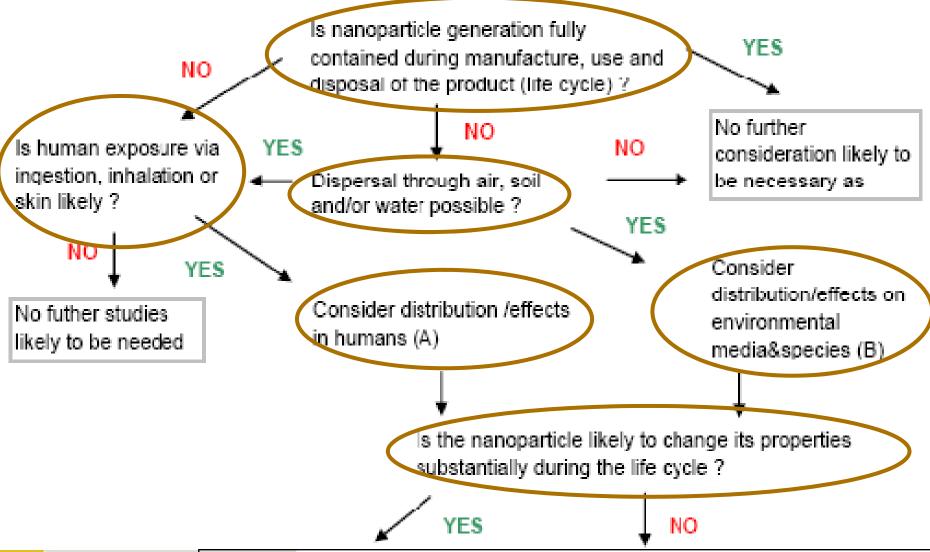


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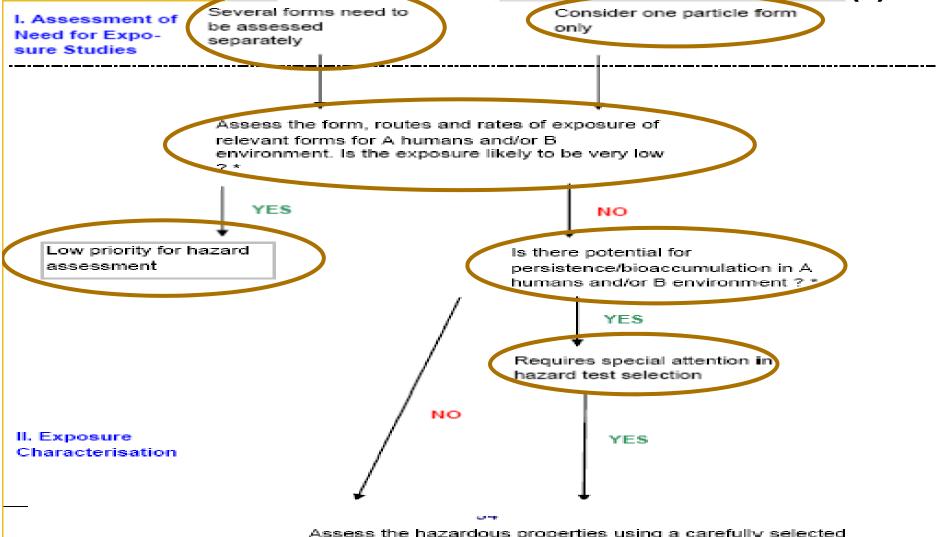
Outline of the staged approach to identifying the human & environmental risks from nanomaterials (1)



European Commission Enterprise and Industry SCENIHR (2007), Opinion on the Appropriateness of the Risk Assessment Methodology in Accordance with the Technical Guidance Documents for New and Existing Substances for Assessing the Risk of Nanomaterials, adopted after public consultation,

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_opinions_en.htm.

Outline of the staged approach to identifying the human & environmental risks from nanomaterials (2)



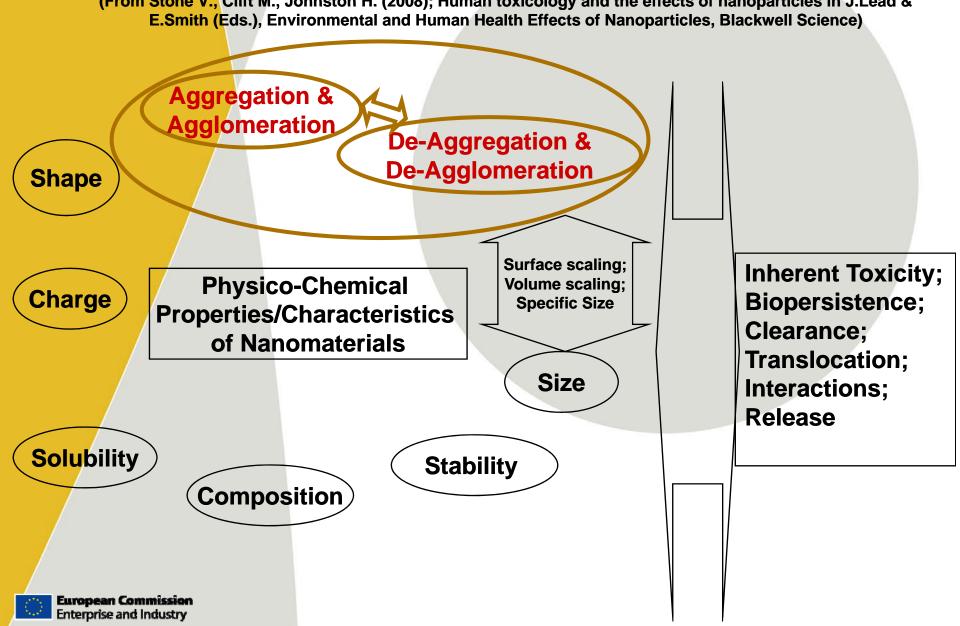
Assess the hazardous properties using a carefully selected battery of in silico, non-mammalian and/or mammalian in vitro

European Commission Enterprise and Industry SCENIHR (2007), Opinion on the Appropriateness of the Risk Assessment Methodology in Accordance with the Technical Guidance Documents for New and Existing Substances for Assessing the Risk of Nanomaterials, adopted after public consultation,

http://ec.europa.eu/health/ph risk/committees/04 scenihr/scenihr opinions en.htm.

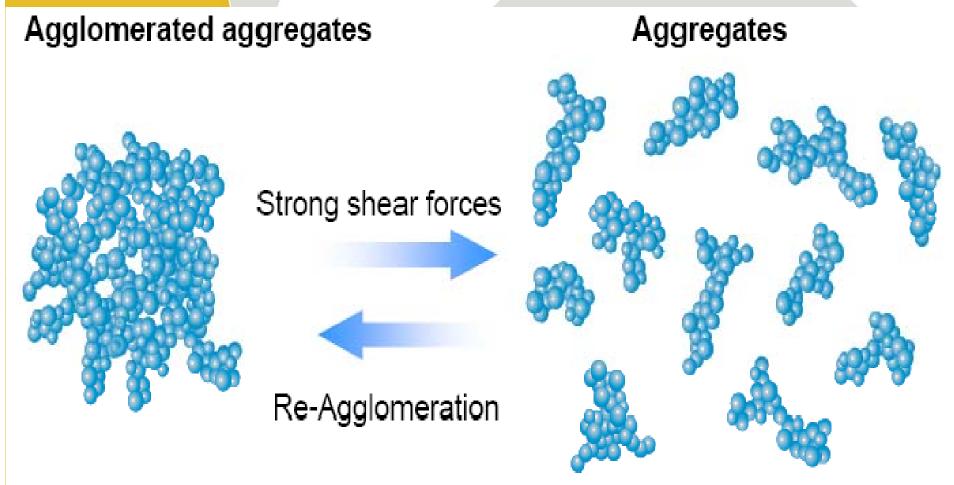
Nanomaterials – Physico-Chemical Properties & Likely **Effects on Biological Interaction**

(From Stone V., Clift M., Johnston H. (2008); Human toxicology and the effects of nanoparticles in J.Lead & E.Smith (Eds.), Environmental and Human Health Effects of Nanoparticles, Blackwell Science)



Nanomaterials – Aggregation / Agglomeration Aspects

(M. Pridöhl (2009), Definitions & Working Programmes, Presentation at the Workshop Nanomaterials, Rheinfelden, EVONIK, 5th February)



No disintegration without strong shear forces

Immediate re-agglomeration without stabilizing surfactants

Nanomaterials – OECD Sponsorship Programme - Selected Materials

OCDE	Lead sponsor(s)	Co-sponsor(s)	Contributors
Fullerenes(C60)	Japan, US		Denmark, China
SWCNTs	Japan, US		Canada, France, Germany, EC, China, BIAC
MWCNTs	Japan, US	Korea, BIAC	Canada , Germany, France, EC, China, BIAC
Silver nanoparticles	Korea, US	Canada, Germany, Nordic Council of Ministers	Australia, France, EC, China
Iron nanoparticles	China	BIAC	Canada, US, Nordic Council of Ministers
Carbon black			Denmark, Germany, US
Titanium dioxide	Germany	Canada, Korea, Spain, US, BIAC	Denmark, China
Aluminium oxide			Germany, US
Cerium oxide	US, UK/BIAC	The Netherlands	Australia, Germany, EC
Zinc oxide	UK/BIAC	US, BIAC	Australia, Canada
Silicon dioxide	EC	Korea, BIAC	Denmark, France
Polystyrene			Korea
Dendrimers		Spain	US
Nanoclays			Denmark, US

OECD-WP-MN - Nanomaterials Exposure Measurement & Mitigation

(OECD-WP-MN (2009); PRELIMINARY ANALYSIS OF EXPOSURE MEASUREMENT AND EXPOSURE MITIGATION IN OCCUPATIONAL SETTINGS: MANUFACTURED NANOMATERIALS; see http://www.oecd.org/dataoecd/36/36/42594202.pdf or via http://www.oecd.org/department/0,3355,en_2649_37015404_1_1_1_1_00.html)

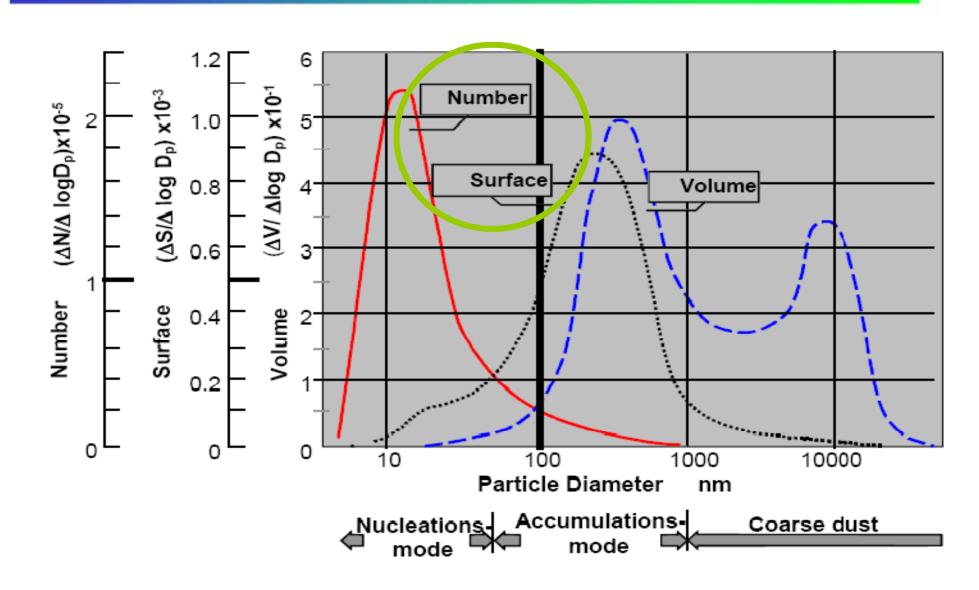
- The project on Exposure Measurement and Exposure Mitigation was established as a formal Steering Group of the OECD-WP-MN in Nov.2007.
- The operational plan outlines three phases of work:
 - 1) exposure in occupational settings;
 - 2) exposure to humans resulting from contact with consumer products & environmental releases of manufactured nanomaterials; &
 - 3) exposure to environmental species resulting from environmental releases of manufactured nanomaterials including releases from consumer products containing manufactured nanomaterials.
- The objectives of phase 1) are described as:
 - ✓ To identify & compile guidance information for exposure measurement & exposure mitigation for manufactured nanomaterials in occupational settings, including manufacture & use of products in industrial, institutional and commercial settings;
 - To analyse existing guidance information for their adequacy in addressing manufactured nanomaterials, identify issues that are unique to manufactured nanomaterials, & prepare recommendations for next steps to be undertaken by the WPMN.

Nanomaterials – Inhalation Aspects & Metrics

(Th. Kuhlbusch (2009), Nanoparticles & Exposure, Presentation at the Workshop Nanomaterials, Rheinfelden, EVONIK, 5th February)

Particle size distribution



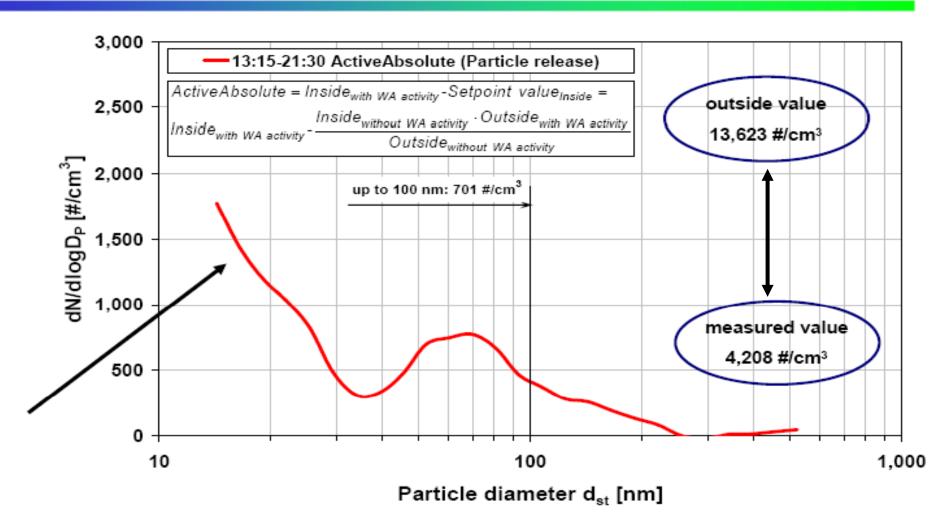


Nanomaterials – Exposure / Emission Aspects

(Th. Kuhlbusch (2009), Nanoparticles & Exposure, Presentation at the Workshop Nanomaterials, Rheinfelden, EVONIK, 5th February)

'Emission' size distribution





Particle emission (not significant) during "bagging" of TiO2, small bags (Plant 1)

OECD-WP-MN - Nanomaterials Exposure Measurement & Mitigation

(OECD-WP-MN (2009); PRELIMINARY ANALYSIS OF EXPOSURE MEASUREMENT AND EXPOSURE MITIGATION IN OCCUPATIONAL SETTINGS: MANUFACTURED NANOMATERIALS; see http://www.oecd.org/dataoecd/36/36/42594202.pdf or via http://www.oecd.org/department/0,3355,en-2649-37015404-1-1-1-1,00.html)

Preliminary recommendations for exposure measurements in occupational settings:

- (1) Provide guidance on appropriate metrics (e.g. nanoparticle number, surface area, mass) of exposure => work started Workshop 2008;
- (2) Provide recommendations on measurement techniques & sampling protocols for inhalational & dermal exposures in the workplace => document completed & for declassification in 2008/9;
- (3) Identify reference nanomaterials for quality control of exposure measurements => included in (2) & EC,JRC-IRMM published availability of 1st RM;
- (4) Compare available Workplace Industrial Hygiene Survey & Sampling protocols => partly included in (2);
- (5) Identify biomarkers of exposure to nanomaterials => not yet started; &
- (6) Compare available Health Surveillance guidance & protocols => work started Workshop 2009.

OECD-WP-MN - Nanomaterials Exposure Measurement & Mitigation

(OECD-WP-MN (2009); PRELIMINARY ANALYSIS OF EXPOSURE MEASUREMENT AND EXPOSURE MITIGATION IN OCCUPATIONAL SETTINGS: MANUFACTURED NANOMATERIALS; see http://www.oecd.org/dataoecd/36/36/42594202.pdf or via http://www.oecd.org/department/0,3355,en_2649_37015404_1_1_1_1_00.html)

Preliminary recommendations for exposure mitigation in occupational settings:

- (1) Compare guidance on personal protective clothing, gloves & respirators => document completed & for declassification in 2008/9 & Workshop 2008;
- (2) Compare guidance on engineering, work practice controls, worker training & education => partly included in (1);
- (3) Compare minimum exposure mitigation measures for nanomaterials required within government nanotechnology risk management programs (for example, as part of voluntary reporting programs for engineered nanomaterials) => a workshop activity started linked with other steering groups;
- (4) Compare exposure mitigation guidance for laboratories => work recently started with data/information collection;
- (5) Analyse Exposure Mitigation frameworks, such as Control Banding approach, for applicability to nanotechnology => work partly started Workshop 2008.

European Risk Observatory - Nanomaterials

(European Agency for Safety and Health at Work (2009); European Risk Observatory Report – Expert forecast on emerging chemical safety and health; pp.8, 34-35, 45-52; Brussels, BE, see http://osha.europa.eu/en/publications/reports/TE3008390ENC_chemical_risks/view or directly at http://osha.europa.eu/en/publications/reports/TE3008390ENC_chemical_risks)

- Although quantitative data needed for satisfactory risk assessment are still required sufficient information is available to begin a preliminary assessment & to develop interim working practices to reduce possible workplace exposure.
- Manufacturing phase, maintenance & clean-up of equipment used to produce nanomaterials can be a source of exposure.
- Further research should concentrate on:
 - Complete LCA of nanomaterials to identify all sources of exposure situations & workplaces concerned.
 - In parallel, to perform environment, health & safety research to satisfy the responsible use of nanotechnologies.
 - Potential safety aspects involve catalytic effects, of fire & explosion hazards => perform small scale testing for fire & explosion prediction, studies on passivation of nanoparticles surfaces linked to oxide layers, agglomeration/de-agglomeration studies, use of new confined stainless steel & Hartman test tube & falling hammer equipment is recommended to boost safety & efficiency.

European Risk Observatory - Nanomaterials

(European Agency for Safety and health at Work (2009); European Risk Observatory Report – Expert forecast on emerging chemical safety and health; pp.8, 34-35, 45-52; Brussels, BE, see http://osha.europa.eu/en/publications/reports/TE3008390ENC_chemical_risks/view or directly at http://osha.europa.eu/en/publications/reports/TE3008390ENC_chemical_risks)

- Determine physico-chemical, toxicological and behavioural properties of each nanomaterial.
- Develop reliable methods for their detection & measurement in the environment & in humans.

Nanomaterials & Environment - Conclusions & Needs

(Report from the workshop workshop on "Nano and the Environment" organized by Nanoforum & the Institute for Environment & Sustainability, EC-JRC-Ispra, 30 & 31 March 2006, see:

http://www.nanoforum.org/nanoboard/comments.php?DiscussionID=10&page=1#Item_1

Life - Cycle - Analysis (LCA)

- Nanomaterials offer significant savings in raw material & energy requirements (e.g. more powerful & higher energy rechargeable batteries), however, materials used for new products should be ideally sourced from renewable or abundant sources:
- This is particularly important when rare materials are used in small amounts that are widely distributed in products, & which can consequently be widely dispersed in the environment (e.g. platinum in catalytic convertors through exhaust fumes, or indium in LCD screens and solar cells). Understanding these mobility issues is essential for the proper application of LCA.

⇒ Note available guide from European Platform on LCA – more information on/via: http://lca.jrc.it / LCA@JRC.it .

Enterprise and industry

Nanomaterials & Environment - Conclusions & Needs

(Report from the workshop workshop on "Nano and the Environment" organized by Nanoforum & the Institute for Environment & Sustainability, EC-JRC-Ispra, 30 & 31 March 2006, see:

http://www.nanoforum.org/nanoboard/comments.php?DiscussionID=10&page=1#Item_1

<u>Life – Cycle - Analysis (LCA)</u>

- to be subjected to a "full LCA":
 - A methodology that is adapted & applied to different scenarios & takes into account all of the raw materials and energy consumption of a product from manufacture (including waste materials and their disposal), through use, to disposal or recycling.
- The LCA must also take account of different usage scenarios which will be dependent on socio-economic impacts (e.g. will the introduction of a new product encourage people to purchase more of the same or similar item, or use it more extensively than an existing item on the market).
- ⇒ Note available guide from European Platform on LCA more information on/via: http://lca.jrc.it / LCA@JRC.it.

Enterprise and industry

Development of Safe Industrial Production Systems & Application

Several European Technology Platforms (ETPs) tackle specifically risk analysis issues that are important for the needed knowledge gap closure linked to the development of necessary guides, testing, measurement & sampling approaches for risk assessment methodologies.

⇒ Hence, it is essential to draw actively on all of their knowledge, activities & networks.

Fibres synthesis

Nanofactory pilot line 2 « Bulk »



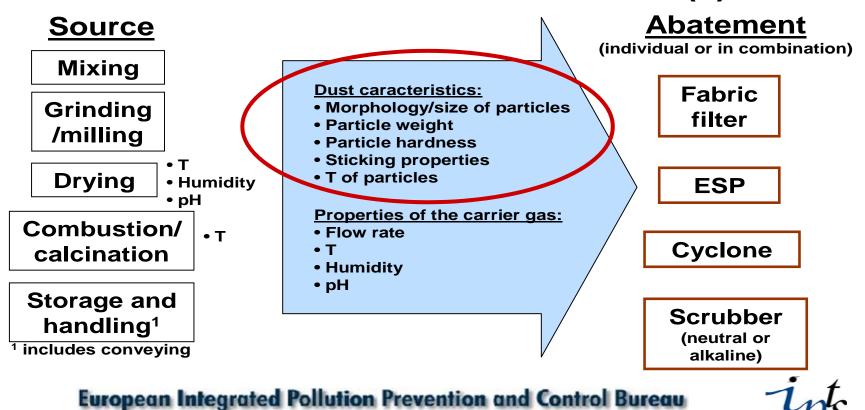
Joint Research Centre

<u>Dust Related BATs – IPPC-Directive - Reference Document on BAT</u> for the production of Speciality Inorganic Chemicals (SIC)

(The "Speciality Inorganic Chemicals Best Available Techniques Reference Document (SIC-BREF)" is downloadable from: http://eippcb.jrc.es/pages/FActivities.htm)



Some BAT conclusions reached Total dust abatement – whole SIC (1)



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<u>Dust Related BATs – IPPC-Directive - Reference Document on BAT</u> <u>for the production of Speciality Inorganic Chemicals (SIC)</u>

(The "Speciality Inorganic Chemicals Best Available Techniques Reference Document (SIC-BREF)" is downloadable from: http://eippcb.jrc.es/pages/FActivities.htm)



Some BAT conclusions reached Total dust abatement – whole SIC (2)

BAT is to:

- 5.6 minimise emissions of total dust in off-gases and achieve emission levels of 1 10 mg/Nm³ by one or more of the following techniques:
 - a. cyclone (see Section 4.4.2.1.2)
 - b. fabric or ceramic filter (see Section 4.4.2.1.5)
 - c. wet dust scrubber (see Section 4.4.2.1.3)
 - d. ESP (see Section 4.4.2.1.4).

The lower end of the range may be achieved by using fabric filters in combination with other abatement techniques. However, the range may be higher, depending on the carrier gas and particle characteristics (see Section 4.4.2.1). Using fabric filters is not always possible, e.g. when other pollutants have to be abated (e.g. SO_x) or when the off-gases present humid conditions (e.g. presence of liquid acid).

European Integrated Pollution Prevention and Control Bureau

Dust Related BATs – IPPC-Directive - Reference Document on BAT BAT in the Ceramic Manufacturing Industry

(The "Ceramic Manufacturing Industry Best Available Techniques Reference Document (SIC-BREF)" is downloadable from: http://eippcb.jrc.es/pages/FActivities.htm)





Sector specific BAT – Channelled dust emissions

Wall and floor tiles, household ceramics, sanitaryware, technical ceramics, vitrified clay pipes:

• Reduce channelled dust emissions <u>from spray glazing processes</u> to 1 – 10 mg/m³, as the half hourly average value, by applying bag filters or sintered lamellar filters.

Wall and floor tiles, household ceramics, technical ceramics:

• Reduce channelled dust emissions from spray drying processes to $1 - 30 \text{ mg/m}^3$, as the half hourly average value, by applying bag filters, or to $1 - 50 \text{ mg/m}^3$ by applying cyclones in combination with wet dust separators for existing installations, if the rinsing water can be re-used.

Expanded clay aggregates:

 Reduce channelled dust emissions <u>from hot off-gases</u> to 5 – 50 mg/m³, as the daily average value, by applying electrostatic precipitators or wet dust separators.

European Integrated Pollution Prevention and Control Bureau



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Conclusions – General Safety Aspects

- Effective training & education approaches including courses & tools are needed.
- Cost effective & efficient technology, tools & information for harmonised, cost-effective & efficient prevention approaches & guidance documents would be very helpful.
- Data for the economic viability test(s) of technology, tools & prevention approaches are needed.
- Further detailed data & studies for the economic assessment of safety approaches are needed F-Seveso Study's Indicative Results.
- Use the different mechanisms & networks (e.g. ETPs,ISO,CEN & OECD) to ensure detailed collaboration between all stakeholders, develop possible representative approaches, contribution to relevant testing aspects & continuation of an informed & targeted dialogue.





Conclusions – Prioritisation - Nanomaterials

- Work on sampling, measurements, test & reference materials for exposure assessment especially based on number concentration, surface & shape choice of suitable metrics.
- Ensure enough trained personnel, boost education & training.
- Ensure suitable, easy to access &/or sharing infrastructure.
- Harmonise & validate sampling, measurement & systems for exposure assessment intelligent work sharing.
- Build actively on existing activities & finding answers to questions to further develop existing & new exposure assessment tools, ensure a further implementation of current regulations & a thorough gap analysis.
- Use the different mechanisms & networks (e.g. ETPs,ISO,CEN & OECD) to ensure detailed collaboration between all stakeholders, develop possible representative approaches, contribution to relevant testing aspects & continuation of an informed & targeted dialogue.







Thanks very much for your kind attention



