

Breakout Session 1

Red group

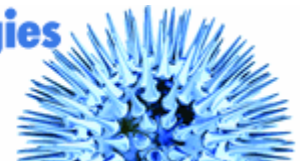
Facilitator: Harald Bosse



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1) Concentrating on EHS issues

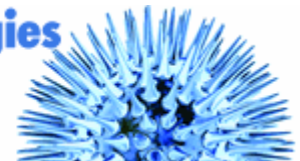
- Analyzing OECD Foundation Data set (see next slide)
- Data set resulted from Risk Assessment studies
- Terminology needs further clarification: mix of measurands, measurement method
- “Dustiness” specified as one critical parameter:
 - understood as product ability to release NP / NM
 - in emissive and/or abrasive processes during use
 - definition sufficiently clear?
 - measurement methods needed are available?



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OECD Foundation Data Set

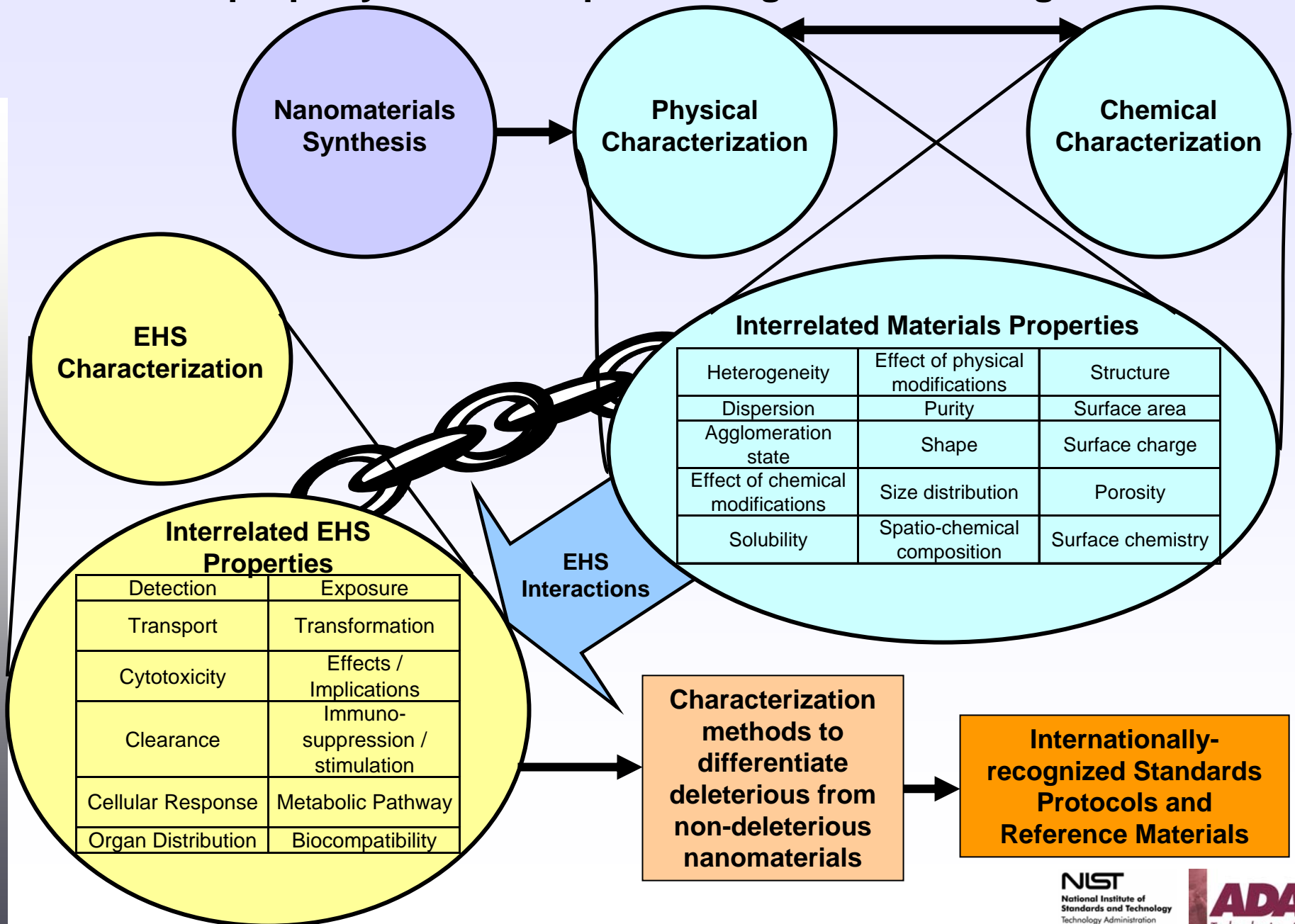
Physical-Chemical Properties and Material Characterization

- Agglomeration/aggregation
- **Water solubility**
- Crystalline phase
- Dustiness
- Crystallite size
- Representative TEM picture(s)
- Particle size distribution
- Specific surface area
- Zeta potential (surface charge)
- Surface chemistry
- Photocatalytic activity
- Pour density
- Porosity
- **Octanol-water partition coefficient, where relevant**
- Redox potential
- Radical formation potential
- Other relevant information (where available)

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Nano-EHS property relationships needing understanding



Interrelated Materials Properties

Heterogeneity	Effect of physical modifications	Structure
Dispersion	Purity	Surface area
Agglomeration state	Shape	Surface charge
Effect of chemical modifications	Size distribution	Porosity
Solubility	Spatio-chemical composition	Surface chemistry

Interrelated EHS Properties

Detection	Exposure
Transport	Transformation
Cytotoxicity	Effects / Implications
Clearance	Immuno-suppression / stimulation
Cellular Response	Metabolic Pathway
Organ Distribution	Biocompatibility

1a) EHS issues

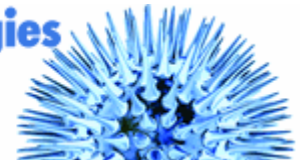
- Chicken & egg problem was addressed:
- EHS issues/questions can better be described or addressed e.g. by regulatory bodies if accurate measurement methods are clearly defined and/or standardized
- NMIs and other institutes in measurement traceability chain would need to know on which measurands and methods should be concentrated first
=> prioritization necessary!



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1b) EHS issues

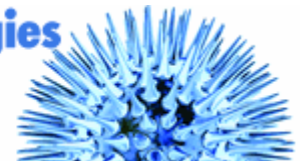
- Example: Toxicity testing => prioritization made:
- Discussion in U.S.: one needs to measure at least these parameters of NP / NM:
 - size and size distribution
 - surface area
 - surface charge
 - solubility
 - purity/composition
- but: uncertainty levels needed for traceability of above measurands can not be specified due to complexity of interactions in toxicity; no simple functional relation: e.g. toxicity = f (surface area)



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List of OECD Representative Nanomaterials

- Fullerenes (C60)
- SWCNTs
- MWCNTs
- Silver nanoparticles
- Iron nanoparticles
- Carbon black
- Titanium dioxide
- Aluminum dioxide
- Cerium oxide
- Zinc oxide
- Silicon dioxide
- Polystyrene
- Dendrimers
- Nanoclays

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1c) EHS issues

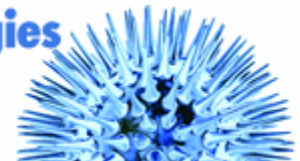
- OECD list of 14 NanoMaterials (NM):
- is indeed a list of different NM classes
- needs to be restricted to meaningful subsets
- this work still needs to be done
- support for this task is needed
- OECD workshop is planned to address this issue



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2) Industry demands

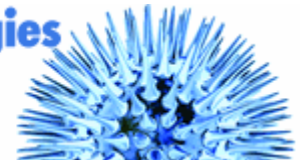
- In mixed production processes of NM enabled products, key control characteristics (KCC) of needed NM properties have to be identified and specified first
- If this has been worked out, a usual customer / vendor relationship can be established
- A product specification e.g. for CNT based NM can be done on basis of the IEC 113 draft blank detail specification standard for CNT properties



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3) Short-term, long-term needs

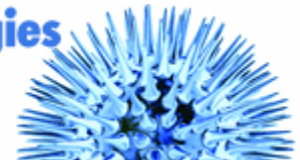
- On a short-term basis guidelines or peer-reviewed published review articles on different topics like e.g. toxicity testing methods are sufficient to help condensation of discussion
- Standards are needed in addition on a mid-term (> 2 y) and long-term basis
- A permanently updated discussion forum is needed to align information and development from the different standardization development organizations (SDOs)



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Existing documentary standards

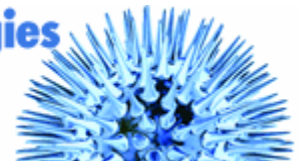
- See compilation of this workshop



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Documentary Standards Needs

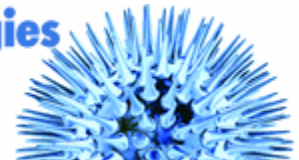
- Short term (less than 2 years)
- Medium term (2-5 years)
- Longer term (>5 years)



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Measurement Needs

(In prioritized order, if possible)

- Existing tools

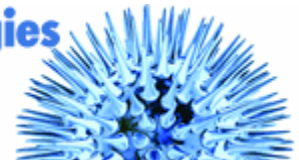
- New tools needed



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Barriers

- Need for PNR, CNR

