Tour de Table Core aspects related to nanodatabases and labelling of the German Stakholders



- VCI supports creating more transparency for "nano products" by means of databases
- Substance level: Generate more transparency in the ECHA data bases
 - Make EU nanomaterial definition (incl. test method) binding for IUCLID 5.x
 - This allows adequate communication with downstream users on uses
 - Is the basis for nanomaterial-specific SDSs for communication in the value chain
- Transparency at the substance level is an indispensable prerequisite for transparency on products which contain nanomaterials
- Consumer products: use, and if needed improve, existing sectoral mechanisms and instruments
 - A lot has happened in regulation since 2009: cosmetics, biocidal products, polymers with food contact, printing of food packaging (DE, shortly to come)
- Labelling: In VCI's opinion in principle only for products with hazardous properties
 - New Biocides Regulation requires nano labelling for nano silver treated textiles;
 nano labelling also for food additives and for cosmetics

BUND demands for tracebility and transparency of nanomaterials' use

Create market transparency for authorities

Competent authorities need to know which nanomaterials are used in which products to be able to fulfil their job

- → mandatory notification (at first at national level if no European solution viable)
- → creation of a nano inventory
- → independent registration of nanomaterials under REACH

Rebuild the consumer's the right-to-choose

Consumers should have a right-to-know which products contain nanomaterials and if they want to buy them

- → mandatory labelling
- → provide additional information (e.g. through an inventory)
- → inform the public actively about the introduction of new technologies, and be transparent about potential risks



Responsible use of nanotechnology along the value chain

- IG BCE supports a greater transperancy for nano-products
- The due care principal for nano-products must be included in the safety data sheet along the value chain
- Works councils have to monitore carefully health and safety at work, therefore also the handling of the nano technologically relevant materials and processes. The responsibility lies in the enterprises.
- For IG BCE, scientific findings form the bases for a responsable use of nanotechnology. Safety research must be intensified.

Nanotechnologies – guarantee identification and tracebility!

- Manufacturers of nanotechnological products bear a big responsibility on the future perception and acceptance of this technology.
 - Safety of nano-products offered on the market must be guaranteed by manufacturers and needs to be validated by independent institutions.
 - Adjustment of advertised and actual benefits of nano-products.

Position of german consumer organisations

- Establishing an international consistent definition.
- Expansion of research on risk- and technology-assessment.
- Authorization and registration of nano-materials and –products.
- Declaration of products and raw-materials containing nano-materials.
- Special focus on saftey of children.
- Close gaps in legal framework.
- Active information and improved communication towards consumers.



No data – no surveillance

Ministerium für Umwelt, Gesundheit und Verbraucherschutz

Expectations

to translate precautionary principle in deeds

A nano-specific EU-wide product register (better than different national ones):

Sampling of data for consumer protection as well as for environmental purposes

(Decision of the Conference of the Ministries for Environment, May 2011)

Lessons learned

to avoid the usual faults

- no new agency for Epic Fail and Strange
- Assumptions or a new directorate for Curious
 Action
- no more bureaucracy instead of transparency
- no more reporting obligations than assistance

Projects

to reveal the sources in the traceability-chain

Establishing a system to detect and cover all facilities/plants handling or processing with nanomaterials in the Federal States

(Decision of the Conference of the Ministries for Environment, May 2011)

Hopes

to ensure a reasonable surveillance

- a common EU-register of products supporting national authorities for consumer and environmental protection
- specific national/regional registers of facilities and plants dealing with "nano"



Considerations on a register for nanoproducts

- Why? Knowledge gap on risks of NM
 - →Traceability for authorities
 - → Transparency for consumers / in the product chain
- How? Electronically; preferably European
- Legal framework? Separate regulation, but mainly omnibus regulation referring to REACH, other substance legislation (e.g. Biocides) and product legislation (e.g. Cosmetics)
 - → Avoid doubled obligations and inconsistencies
- Which products? Nanomaterials, mixtures with NM, articles with possible release of NM – necessary to group articles and mixtures
- Which data? Only basic data (e.g. characterisation, tonnage bands, uses / functionality) differentiation between open data and a confidential part
- Labelling? Only a non-discriminatory registration number which allows searchability
- Maintenance? Ensure updating (including deletion of old data)
- Effort? Impact study planned, but the database is expected to be manageable for notifiers and authorities – official controls (in particular regarding imported articles) necessary

BfR Risk Assessment (Chemicals/Food)

Hazard Identification for Humans Exposure Assessment Dose-Response-Relation Product/Article based (Individual Assessment) Substance based (Basic Assessment) - Dose-Response-Relation - Releasing of (Single) Substances - Toxicity of the relevant Substance(s) out of a marketed - Entry from Environment Formulation (Real Life Scenario!) - Identification of exposed Persons - Risik-specific Human Dose - Exposure in Relation to Path 1. Nanodatabase of Substances 2. Nanodatabase of (Real) Mixtures

Two Databases are needed

- 1) Database Substance orientated (REACH Format)
- **Downstreamusing!**
- 2) Database Mixtures orientated (BfR CLP- Art. 45 Format)



Real Risk Assessment

4 facts from the BAuA-questionnaire on NM

- 454 answers from approx. 1750 invitees asked to participate (26%)
 - 109 of 454 have NM production, use or emission from processes (24%)
 - Of 109: 57 vs. 52 answers industry vs. research institutes (52% vs. 48%)
- Personnel dealing with NM in total: 1-10: 63% -- 11-50: 30%
 - Industry: 1-10: 75% -- 11-50: 18%
 - Research: 1-10: 50% -- 11-50: 44%
- 1-5 NM handled by 69% of all answers (top answer: 300 NM)
 - Industry: 1-5 NM handled by 80%
 - Research: 1-5 NM handled by 54%
- Top 5 Materials: $SiO_{2 \text{ (am)}}$, TiO_{2} , MWCNT, Ag-NP, $SiO_{2 \text{ (cryst)}}$: $\Sigma = 44\%$
 - Industry: $SiO_{2 \text{ (am)}}$, TiO_{2} , Carbon Black, $SiO_{2 \text{ (cryst)}}$, Polymer ($\Sigma = 52\%$)
 - Research: MWCNT, TiO₂, Ag-NP, Ceramics/Glases, Au-NP ($\Sigma = 43\%$)

