

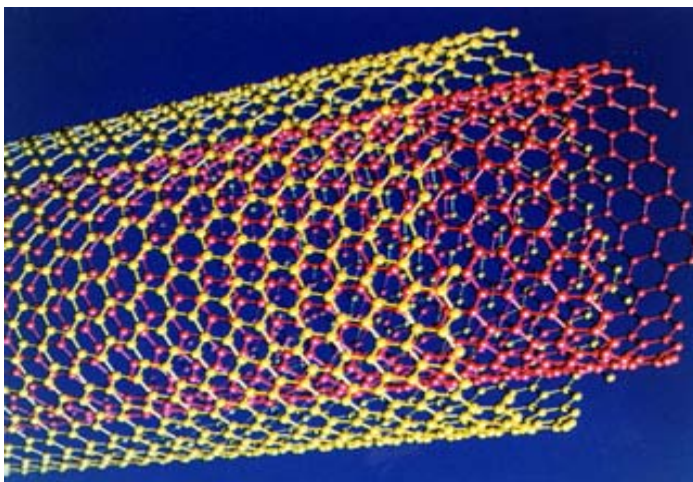
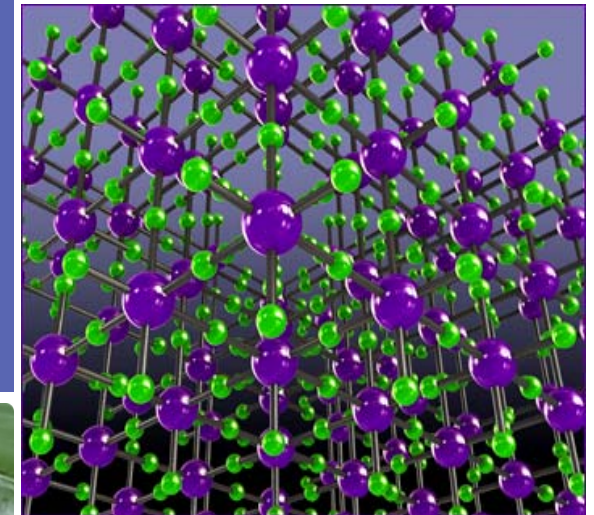
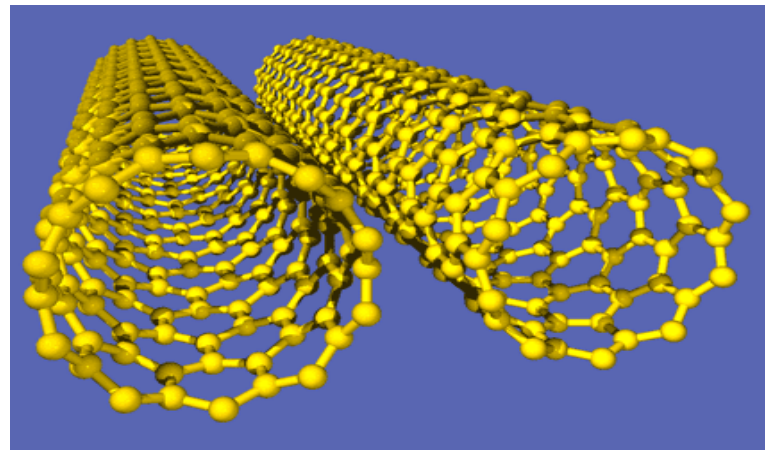
Management of Nanomaterials in Austria



lebensministerium.at

International Workshop on
Nanotechnologies – the present state of regulation

Renate Paumann
September 29th, 2008
Vienna



Content of presentation



lebensministerium.at

- Different nano-products / different responsibilities
- The Austrian “Nano-Plattform “
 - Who ?
 - Aim ?
- Review of Legislation in the field of Nano
- Management of Nanomaterials in REACH-Legislation



Different Legislations – Different Ministries

- Industrial chemicals (REACH)
- Other chemical products: **Cosmetics, Drugs,** Pesticides, Biocides
- **Workers protection**
- **Medical Devices**
- **Food additives and packages**
- Air, Water, Waste
- **Consumer Protection**
- **Innovation, Science**



Coordination needed



The Austrian „Nano-Plattform“

➤ Who ?

Academia, **BMGFJ**, NGOs,
BMWA, **BMLFUW**, Chamber of Commerce, **BMVIT**
BMWf, Agencies, **BMSK**

➤ Aim:

- Exchange of information
- Coordination of positions for international and EU Working Groups
- Discussion of possible national activities

➤ Organised by BMLFUW



Review of legislation

- One action in Nano-Action-Plan for Europe 2005-2009
- Review of existing EU-legislation
 - Suitable to cover nanos ?
 - Recommendations
- Published 17 June 2008
 - ➔ [Communication on regulatory aspects of nanomaterials](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF)
(<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF>)
- Covers legislation relevant for health, safety and environmental aspects of nanomaterials



Review of legislation – main conclusions

- Environmental and health risks of nanomaterials are in principle covered by EU regulatory frameworks
- Implementation of the legal frameworks remains a challenge:
 - ➔ **Knowledge gaps to be closed**
 - ➔ **More guidance needed**
- Current legislation may have to be modified as new information becomes available

REACH – scope



lebensministerium.at

➤ REACH covers

- Substances (e.g. silver, titanium-dioxide, aluminium-oxide)
- Preparations/mixtures (such as paints, cleaning sprays, ..
Note: cosmetics, drugs, etc. have separate legislation)
- Articles (such as textiles, electronic equipment, tyres, etc.)
- Nanos fall under the scope of REACH

Note: Criteria for classification & labelling (C&L) of REACH-chemicals are laid down in “EU-Regulation on classification, labelling and packaging of substances and mixtures”

➔ input to REACH



REACH – main principles

- **“No Data - No Market”**
- Focus on Substances with high volumes and those of greatest concern
- Burden of Proof on Industry
- Registration of substances (General Info, CSA and CSR) – M/I/DU *
- Increased information and communication throughout the supply chain (Safety Data Sheet – SDS is important tool) – M/I/DU
- Evaluation of registration-dossiers for selected substances - Authorities
- Authorisation only for substances of very high concern - Authorities (application for authorisation from M/I/DU)
- Restrictions - the safety net (Community wide action) - Authorities

* Manufacturer / Importer / Down-Stream-User



REACH – Registration Dossier

A Registration Dossier consists of

- Technical Dossier (for ≥ 1 tonne)
 - A general part, which applies to all substances (e.g. Identity of manufacturer, substance identity, classification and labelling, Information about uses/exposures, confidentiality claims (where appropriate), All physicochemical, toxicological and ecotoxicological information relevant and available)
 - A tonnage-dependant part, in which progressively more information is required for quantities reaching 10, 100 and 1000 tonnes (deadlines for “phase-in-substances” till 2018)
- Chemical Safety Report (CSR) (for ≥ 10 tonnes)



REACH – Chemical Safety Report

Chemical Safety Report (CSR) consists of

- Assessment of physicochemical, human health and environmental hazards (e.g. inhalation toxicity, skin absorption, aquatic effects, etc.)
- PBT and vPvB assessment
- Exposure assessment and risk characterisation
 - only for substances meeting the criteria as dangerous and substances considered to be PBT and vPvB substances
 - addressing all the registrant's identified uses

Duty to identify appropriate **measures to adequately control the risks & recommend them down the supply chain (Safety Data Sheets - SDS) !**

Duty to communicate **uses/exposures up the supply chain !**

REACH – Safety Data Sheet



lebensministerium.at

Safety Data Sheet (SDS) needed for substances/mixtures

- Meet the C&L criteria
- are substance of very high concern (SVHC) incl. PBTs, vPvBs
- SDS may be provided for other substances as well
- No tonnage trigger !



REACH – Challenges for Nanos

- How to deal with the nano-form of substances where bulk-form is exempted from REACH (e.g. carbon, graphite)?
 - Need to include additional information for nano-form (risk management measures, C&L, etc.) in registration dossier
 - Need to update existing registration dossiers in order to include specific properties on nano-form of substance
 - Additional testing or information may be required
 - Communication of risk management measures (incl. operational conditions) in the supply chain
 - Evaluation of registrations (prioritise? Request additional info on nano?)
 - Restriction / Authorisation
- ➔ **Need for closing knowledge gaps**
- ➔ **Need for more guidance**

REACH and Nano



lebensministerium.at

- EU-Working-Group on „REACH and Nano“
 - Mandate and Working Plan for 2008-2012
 - Lebensministerium co-ordinates Austrian input

- OECD Working-Group on manufactured nanomaterials
 - Deals – among other issues – with review of test guidelines for Nanos

- ➔ input to REACH

EU-REACH-Nano – Work-Plan 2008-2012



lebensministerium.at

CASG Nano Advices	Indic.timing	Deadline
1. Carbon and graphite in Annex IV and V 2. Substance Identification 3. Registration of NM 4. Advice on C&L of NM	Dec 2008	Jan 2009 Jan 2009 Dec 2010 Dec 2010
5. Communication in the supply chain 6. Testing – Physico-chemical properties	June 2009	Dec 2010
7. CSA of NM 8. Testing – Human health toxicity 9. ? <i>Annex XIV - Authorisation of NM-SVHC</i>	Dec 2009	Dec 2010
10. Testing – Ecotoxicity Environment 11. Testing – Fate, Degradation, Aq. Env.	June 2010	Dec 2010
12. Risk management measures 13. Alternative testing methods for NM	Dec 2010	Dec 2010
14. Finalisation of REACH guidance 15. Finalisation of testing strategies for NM 16. Recommendations for further research	June 2011	REACH rev. June 2012

Links



lebensministerium.at



Austrian REACH-Helpdesk

Frequently asked questions for instance: „*How to register Nanos under REACH ?*“

REACH-Guidelines

www.reachhelpdesk.at

Tel: (+43 1) 31 00 472 (Mo-Fr. 9-15 h)



Main Nano-Website of European Commission

http://ec.europa.eu/nanotechnology/index_en.html



lebensministerium.at

Contact:

Renate Paumann

*Austrian Federal Ministry for Agriculture,
Forestry, Environment and Water*

Tel: +43-1-51522-1730

renate.paumann@lebensministerium.at

Thank you!

© Original Artist
Reproduction rights obtainable from
www.CartoonStock.com

