

# **Nano in REACH**

## **implementation and guidance**

**Safety for Success dialogue**  
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**Peter van der Zandt, European Commission**  
**Marita Luotamo, ECHA**

# What is REACH?

- Regulation on the Registration, Evaluation, Authorisation and Restrictions of Chemicals
- REACH aims at:
  - Ensuring a high level of protection of human health
  - Ensuring a high level of protection of environment
  - Promotion of alternative test methods
  - Free circulation of substances on internal market
  - Enhancing competitiveness and innovation

# REACH principle

- REACH is based on the principle that M/I and DUs have to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment.
- NMs as substance, preparation or contained in an article fall under REACH.
- REACH requirements apply to nanomaterials, even though there are no specific provisions for nanomaterials.

# REACH - key elements

- Registration of substances  $\geq 1$  tonne/yr
- Increased information and communication throughout the supply chain
- Evaluation of some substances
- Authorisation only for substances of very high concern
- Restrictions - the safety net (Community wide action)
- Agency to efficiently manage system
- Public access to key information

# Registration

- Registration of substances manufactured/ imported in volumes of 1 tonne or more per year
- Chemicals Safety Report required at volumes of 10 tonne or more per year
- Tonnage triggers apply to the total volume
- Safety has to be ensured for the substance in whatever size or form and for manufacturing and all identified uses.
- A registration must include all relevant information on the nanomaterial.

# Registration

- **Gathering and generating information:**
  - All available information (Annex VI)
  - Information Annexes VII – X depending on volume
  - Registrant may generate further information, such as specific properties of nanomaterials, not addressed in REACH Annexes, in order to demonstrate that risks are controlled.
- **Classification and labelling**
- **CSA and CSR**
  - hazard assessment
  - PBT / vPvB assessment
  - exposure assessment
  - risk characterisation and risk management

# Classification and labelling

- Information shall also relate to forms or physical states in which the substance is placed on market / used.
- Substances with different sizes or forms can have different classification  
e.g. nickel and nickel powder (< 1 mm)
- Same goes for substances at nanoscale/nanoform.

# Chemicals Safety Assessment

- **Chemicals Safety Assessment:**
  - specific properties of the nanomaterial
  - specific hazards (incl. classification and labelling)
  - specific risks
  - specific risk management (exposure scenarios)
- **Communicate in Safety Data Sheets**



# Chemicals Safety Assessment

- SCENIHR opinion on appropriateness of previous TGD:
  - insufficient knowledge
  - likely identify hazards associated to nanomaterials
  - appropriate dosimetrics needed
  - exposure assessment methods need review
  - no clear view on environmental effects
  - case-by-case assessment
- Guidance on Information requirements and Chemical Safety Assessment (IR-CSA TGD) is available from ECHA
- The guidance addresses nanomaterials marginally as yet
- The same assessment principles apply, but guidance needs further work for use on nanomaterials.

# REACH CA group on Nano

Addresses all issues related to nanomaterials under REACH

- REACH applicability to nanomaterials
- REACH implementation issues:
  - Substance identification
  - Registration of nanomaterials
  - Chemicals Safety Assessment and Risk Management
  - Communication in supply chain
- Information on nanomaterials
- Cooperation within the EU and internationally
- Ambitious work programme 2008 -2012

# Conclusions

- REACH requirements apply to nanomaterials. REACH does not contain specific provisions for nanomaterials.
- On the basis of knowledge development:
  - Guidance for implementation, eg. on safety assessment, may need to incorporate specific elements related to nanomaterials
  - Review REACH at a later stage as appropriate with regard to adequacy to address and manage the safety of nanomaterials (incl. information requirements, assessments and management by industries)

find REACH guidance at  
*[http://echa.europa.eu/reach\\_en.asp](http://echa.europa.eu/reach_en.asp)*

**We need to work together**  
EU Commission, ECHA,  
Member States and stakeholders  
OECD, International

**Thank you !**

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