

# **How to ensure the safe use of nanomaterials under REACH – Part II:** Current best practices for human health and environmental hazard assessment for nanomaterials

## **Nanomaterials under REACH and ECHA activities on nanomaterials**

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# Nanomaterials under REACH



# Nanomaterials and REACH

- No explicit reference to nanomaterials in REACH
  - Considered as covered by the substance definition under REACH
  - Commission second regulatory review on nanomaterials  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0572:FIN:en:PDF>
- Nanomaterials can be either:
  - Substances on their own and thus registered as such substances
  - Nanoforms of a substance and included in the dossier of the corresponding bulk form of the substance

## Ensuring safety for nanomaterials

- Growing interest and need in understanding and regulating the possible adverse effects of nanomaterials
- Growing number of reliable references supporting regulatory action in order to ensure safety
- Registrants need to demonstrate the safe use of their substance, whatever the form

# Characterisation of nanomaterials

- The characterisation of nanoforms of a registered substance is a prerequisite to the proper determination of hazards and risks of the substance
- ECHA is thus concentrating on this characterisation:
  - when elements in a dossier indicate that the substance (may) fall under the definition of nanomaterial
  - when there is sufficient indication that the substance may be a nanomaterial in spite of the absence of reference in the dossier

## ECHA's observations

- ECHA & DG JRC screened REACH dossiers for nano-specific information (*NanoSupport project*)
- General trends and recommendations
  - Limited information provided on nano-specific properties, studies and risk assessments
  - Room for improvement → recommendations provided on <http://echa.europa.eu/chemicals-in-our-life/nanomaterials>
  - Nature of recommendations on dossier quality are in line with 'non-nano' specific recommendations (e.g. Art 54 report)
- Dossier submitted in 2010:
  - No agreed nano-definition; no nano-explicit reference to nano-materials in legal text; 'learning curve' effect

# **ECHA activities on nanomaterials**



## ECHA nanomaterial activities

- 1. Share experience** with and generate consensus among \*MSCAs, COM, MSC and RAC members on safety information of nanomaterials in REACH registration dossiers
- 2. Feedback and advice to registrants** that wish to register nanomaterials at the next registration deadline (2013)
- 3. Participate and contribute to ongoing international regulatory activities**

\***MSCA:** Member State competent authority; **COM:** Commission Services; **MSC:** Member States Committee; **RAC:** Risk Assessment Committee



# 1. Share experience and generate consensus

- **NANO SUPPORT** Project
- **GAARN** (Group Assessing Already Registered Nanomaterials)
- **Nanomaterial working group**

## NANO SUPPORT Project

- Joint JRC-ECHA project: Assessment of nanomaterials in REACH registration dossiers and adequacy of available information
- Part 1: Assess REACH dossiers containing nanoforms – public report available at:  
[http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc\\_report.pdf](http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf)
- Part 2: Assess the need for REACH adaptation, impact assessment. Report published and soon available at:  
<http://ec.europa.eu/environment/chemicals/nanotech/index.htm>
- Final report of the Nano-support project published and soon available at:  
<http://ec.europa.eu/environment/chemicals/nanotech/index.htm>

## **GAARN** (Group Assessing Already Registered Nanomaterials)

- 21-22 January 2013: Second meeting focusing on human health and environmental hazard assessment
- Third meeting (possibly September-October 2013): focus on exposure and risk assessment
- Best practice on **physicochemical and substance identity** information for nanomaterials (GAARN 1):  
[http://echa.europa.eu/documents/10162/5399565/best\\_practices\\_physicochem\\_subst\\_id\\_nano\\_en.pdf](http://echa.europa.eu/documents/10162/5399565/best_practices_physicochem_subst_id_nano_en.pdf)
- Assessing **human health and environmental hazards** of nanomaterials - Best practice for REACH Registrants (GAARN 2):  
[http://echa.europa.eu/documents/10162/5399565/best\\_practices\\_human\\_health\\_environment\\_nano\\_en.pdf](http://echa.europa.eu/documents/10162/5399565/best_practices_human_health_environment_nano_en.pdf)

# Nanomaterial working group

- MSCA, COM service and Accredited Stakeholder Observers
- Coordinated by ECHA
- First meeting: 23 January 2013
- Main topics discussed:
  - Requirements on measurements for the implementation of the European Commission definition of 'nanomaterial'.
  - Scientific and technical challenges on registering nanomaterials

## 2. Feedback and advice to registrants

### Guidance development for nanomaterials

- ✓ Six new appendices to chapters of the IR & CSA guidance on recommendations for nanomaterials were published (2012)
- ✓ Eight corrigenda to other parts of chapters of the IR & CSA guidance including minor amendments for nanomaterials
- ✓ Link to Guidance documents, including nano-specific guidances: <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

## Development of additional support documents for registration of nanomaterials

- IUCLID software updated (version 5.4, July 2012)
- IUCLID User Manual updated: **User Manual "Nanomaterials in IUCLID 5"**:
  - how to report when a nanoform was used in studies
  - prepare/update registration dossiers for substances that are nanomaterials or include nanoforms.
  - Link: <http://iuclid.eu/index.php?fuseaction=home.documentation>
- IUCLID 5.4 can be used to prepare REACH dossiers

## Development of additional support documents for NMs registration (2)

- IUCLID 5.5 released April 2013
- IUCLID 5.5 can also be used to prepare REACH dossiers
- Includes 13 Harmonised templates for nanomaterials
  - Templates prepared by DG JRC have been reviewed at the OECD level for harmonisation
  - Information related to the physical-chemical properties specific to nanomaterials can now be reported in IUCLID (not included in REACH dossiers yet)
  - Link: <http://iuclid.eu/index.php?fuseaction=home.documentation>
- Specific manuals are under development
- ECHA's website – specific nano section:  
<http://echa.europa.eu/chemicals-in-our-life/nanomaterials>

## **3. Participate and contribute to ongoing international regulatory activities**

- Improve understanding on assessment of hazard, exposure and risks of nanomaterials
- OECD WPMN (meetings and technical workshops)
- International nano-workshops



## Next steps

Back-to-back meetings (dates to be communicated):

- Third GAARN meeting
- Second ECHA-NMWG meeting

Link to **nanomaterials webpage** on ECHA website (current activities, meetings outcomes, webinars and latest guidance):

<http://echa.europa.eu/chemicals-in-our-life/nanomaterials>

**Thank you**

