

Nanomaterials and REACH

Eighth Stakeholders' Day

26 March 2013
Wim De Coen
Head of Unit, Evaluation
European Chemicals Agency



Outline

- Nanomaterials and REACH
- ECHA's observations
- ECHA's initiatives
- Legal instruments
- Recommendations

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
- Nanomaterials (NM) 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, e.g.
 - SCENHIR opinions recognising non-hypothetical hazards and risks specific to some nanomaterials - 2010
 - Definition of nanomaterials, EU Recommendation – Oct 2011
 - Commission second regulatory review of nanomaterials – Oct 2012
 - Increasing body of scientific literature
- Registrants need to demonstrate the safe use of their substance, whatever the form (also nanoform if the form of the substance falls under the definition of nanomaterials)

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 & recommendations
 - Limited information provided on nano-specific properties, studies and risk assessments
 - Room for improvement → recommendations provided at <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's initiatives – guidance & advice

- Guidance development for nanomaterials
 - Six new appendices to chapters of the IR&CSA guidance on recommendations for nanomaterials NMs were published (2012)
 - Eight corrigenda to other parts of chapters of the IR & CSA guidance including minor amendments for nanomaterials
- Development of additional support documents for NMs registration
 - ECHA's website – specific nano section:
<http://echa.europa.eu/chemicals-in-our-life/nanomaterials>
 - Webinars to interact with industry on nano specific issues
 - IUCLID manual updated to align with guidance updates & RIP-oNs: (28 February 2013 - The IUCLID User Manual for nanomaterials - explicitly report nanoform used in (experimental) studies)

ECHA's initiatives – dialogue on NM

- Dialogue with registrants: Workshop & Events on Nanomaterials
- **GAARN** (The Group Assessing Already Registered Nanomaterials)
 - To build a consensus in an informal setting on best practices in assessing and managing the safety of nanomaterials under the REACH Regulation
 - ECHA, Commission, MSCAs, representative registrants
 - Challenges faced in registering substances with nanoforms under REACH and on the information requirements
 - substance identification, physical chemical properties,
 - hazard information (toxicology and ecotoxicology)

Example of GAARN best practices outcome

- Data already available on characterisation of nanoparticles
- Data on primary particles important to understand the hazard profile of the forms
- Characterisation of nanoform: instead of determining one single method, preference for a “matrix approach”
- Document as a minimum the following characteristics:

- Shape
- Particle size
 - (primary/constituent particle)
 - Number based
- Specific surface area

Select & justify the best available methods suitable for your specific NM

ECHA's initiatives – NM working group & international activities

- Nanomaterial working group:
 - Coordinated by ECHA – avoiding overlap with scope CASG-Nano
 - Composition: representatives from each MSCA, COM service and Accredited Stakeholder observer (three NGOs + three from Industry associations)
 - Primary focus of NMWG:
 - provide scientific and technical advice
 - support (not interfere with) ECHA formal processes (REACH & CLP)
- International activities
 - OECD WPMN
 - International nano-workshops

REACH legal instruments

- Art 36 decisions
- Dossier evaluation:
 - testing proposals
 - compliance checks
- Substance evaluation
- Beware: Ongoing impact assessment by Commission on possible review of REACH Annexes for Nanomaterials

Article 36 decisions

- Article 36 decision (In 2012, ECHA sent 166 decisions):
 - Request information that you as registrant may have available in order to carry out your duties under REACH
 - Does not require generation of new data
 - No information in the dossier showing the substance is nano
- Requires you as registrant to provide available information:
 - e.g. Information on all size grades placed on the market, surface treatment
 - Usually in the form of a questionnaire
- **What to do if you receive an Art 36 decision?**
- Respond to the request (legal duty)
- Update your dossier with the requested information

Compliance check

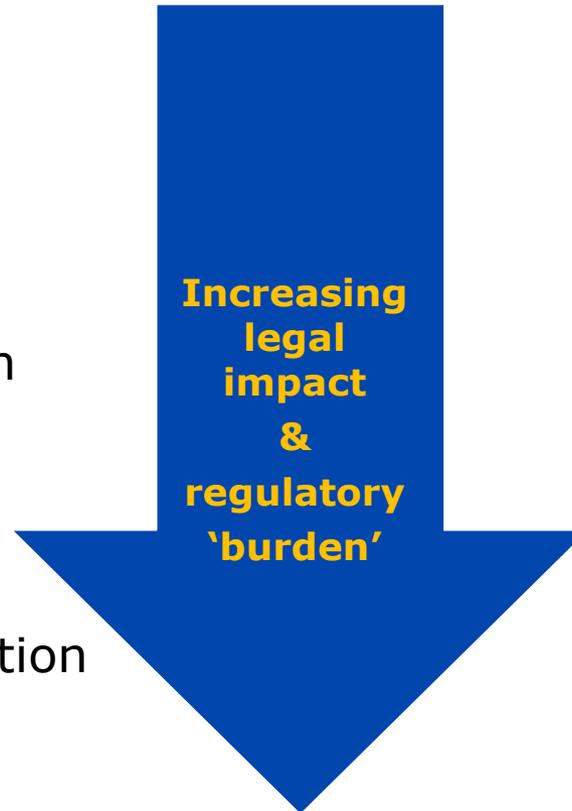
- Compliance check draft decision: request to generate or provide missing information
- May result in new (experimental) studies to be performed
 - Different from Art 36 decision
- Dossiers currently under targeted compliance check
 - Draft decisions on relevant nanomaterial characteristics
 - Illustrated the added value of the working group on nanomaterials
- Draft decisions (after amendment) sent to MSCAs for commenting
- After unanimous agreement by MSCAs and/or MSC → final decision with legal deadline to provide information

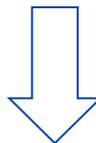
Substance evaluation

- Substances selected for CoRAP (Community rolling action plan) based on initial grounds of concern: evaluated by member states
- **Silicon dioxide (synthetic amorphous silica - SAS)**
- Evaluated during **2012** by the Netherlands
- ECHA performed consistency screening of Dutch draft decision
- The Netherlands submitted final version of their draft decision by the legal deadline (28 February 2013)
- Decision making process with SAS registrants ongoing
- Other substances:
 - **2014: Silver - evaluated by the Netherlands**
 - **2014: Titanium dioxide - evaluated by France**

REACH legal instruments

- Art 36 decisions
- Dossier evaluation
- Substance evaluation



- ECHA invites for your
 - Proactive
 - Constructive response
- 
- Update your dossier
 - Interact – consult ECHA
 - 'Nano-by-design' = your information matters
 - Transparency on the form-characteristics

Nanomaterials – key messages

- Nanomaterials are covered under REACH
- Nano definition (Commission recommendation) is ECHA's benchmark
- ECHA is addressing nanomaterial characteristics of substances through Article 36, dossier and substance evaluation
- Registrants need to demonstrate safe use of nanomaterials:
 - Update your dossier content proactively
 - Interact or consult ECHA (best practices, guidance, advice)

Questions?

Wim.decoen@echa.europa.eu

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

Thank you

