Nanomaterials under REACH and ECHA activities on nanomaterials

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Nanomaterials under REACH

Challenges for registrants and authorities

- Relatively new and rapid development of nanomaterials as a class of chemicals
- No explicit reference to nanomaterials in the REACH Regulation
- Scientific discussion on-going in relation to their characterisation and assessment of their hazards, exposure and risks
- Limited experience of authorities and of many registrants

Necessity to ensure safety

- Growing interest/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 - 2009
  - Definition of nanomaterials, EU Recommendation – Oct 2011
  - Commission second regulatory review of nanomaterials – Oct 2012
  - Approaches for testing/assessing traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted (e.g. methods of sample preparation, dosimetry) to the specificities of nanomaterials.

Achievement of REACH aim and scope

- Article 1(3) of the REACH Regulation

  "*This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle*"

- Obligation to identify hazards and risks concerning all substances irrespective of their size or form and for all their identified uses
- Scientific uncertainty, if any, does not prevent proportionate actions to address non-hypothetical hazards and risks
- In other words, REACH applies to nanoforms
- Registrants need to demonstrate the safe use of their substance, whatever the form (also nanoform if substance falls under the definition of nanomaterials)

Characterisation of nanomaterials

- The characterisation of nanoforms of a registered substance is a prerequisite to the proper assessment 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
- It is the registrant's responsibility to determine whether their nanomaterial:
  - is a separate substance: the nanoform is then registered separately according to REACH rules, or
  - is a form of the bulk: the nanoform is included in the registration of the bulk form

ECHA activities on nanomaterials

ECHA nanomaterial activities

1. Share experience with and generate consensus among *MSCAs, 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

ECHA nanomaterials webpage:

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

*__MSCA:__ Member State Competent Authority; __MSC:__ Member States Committee; __RAC:__ Risk Assessment Committee

1. Share experience & generate consensus

- **NANO SUPPORT** Project (joint JRC-ECHA project): Assessment of nanomaterials in REACH registration dossiers and adequacy of available information
  - First part finalised: REACH dossiers on nanomaterials assessed – public report available
  - Follow-up: assess the need for REACH adaptation, impact assessment - ongoing
- **GAARN** (The Group Assessing Already Registered Nanomaterials)
  - Aim: Provide generic recommendations on the best practices on registration of nanomaterials
- Building up first experiences within REACH/Evaluation on registration dossiers: **workshop** organised 30-31 May 2012
  - Exchange views & discuss about first experiences on nanomaterial dossiers
- Starting up **nanomaterial working group** coordinated by ECHA
  - Role: provide scientific and technical support on evaluation of dossiers containing nanoforms

2. Feedback and advice to registrants

- Guidance development for nanomaterials
  - Guidance on information requirements were updated with nano specific appendices (Summer 2012)
- Development of additional support documents for registration of nanomaterials
  - Initiate regular webinars to interact with industry on nano specific issues
  - IUCLID database was updated in July 2012
  - IUCLID manual is being updated to align with guidance updates and RIP-oNs

3. Participate and contribute to ongoing international regulatory activities

- Improve understanding on assessment of hazard, exposure and risks of nanomaterials
- Fast pace of scientific development in the understanding of hazard, exposure and risk assessment of nanomaterials ➔ international involvement crucial
- Involvement/contributions to OECD WPMN, and other international regulatory events

GAARN

Group **A**ssessing **A**lready **R**egistered

Nanomaterials

Objectives of GAARN

- To build a consensus in an informal setting on best practices in assessing and managing the safety of nanomaterials under the REACH Regulation
- To increase confidence and mutual understanding among stakeholders so that nanomaterials can be sustainably developed
- Participants: ECHA, Commission, MSCAs, representative registrants
- Three meetings foreseen (First meeting - 29 May 2012)

First GAARN meeting - Scope

- Challenges faced on registering substances with nanoforms under REACH and on the information requirements
  - substance identification
  - physical chemical properties

- Provide generic recommendations on the best practices on registration of nanomaterials

First GAARN meeting - Outcome

- Nano-definition
  - Acknowledged that the current definition is not perfect
  - However, it is the current benchmark
  - It aims to cover different regulatory frameworks
  - Although challenging: definition refers to “number based” approach
- Under REACH, registrants are responsible to ensure the safe use of the substance regardless of the form

First GAARN meeting - Best practices (1)

- 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 best available methods suitable for your specific nanomaterial

First GAARN meeting - Best practices (2)

- Surface treatment – recognised as a characteriser of the nanoform
- Surface treatment important to assess the hazard properties (influencing reactivity and interaction with biological systems)
- Provide documentation in the REACH registration dossier
  - Allowing transparent & independent assessment by ECHA and MSCAs
  - Similarities with other REACH requirements (SID)
  - Similarities with the approach that needs to be taken with regard to registration of some types of UVCBs (e.g. information on manufacturing process)
- Characterisation crucial for data sharing and safety assessment

Best practices from GAARN first meeting (phys-chem and SID):
http://echa.europa.eu/documents/10162/5399565/best_practices_physiochem_subst_id_nano_en.pdf

GAARN - Next steps

- Next GAARN meeting (21-22 January 2013)
  - Focus on human health and environmental hazard data in relation to safety of the nanoforms
  - Address the surface treatment in relation to safety and hazards
  - Feedback from ongoing projects (e.g. JRC standardisation project) on the methods to characterise nanomaterials
- Setting: back-to-back with the first meeting of the Nanomaterials Working Group

Workshop on Nanomaterials

From 30 to 31 May 2012

Workshop on nanomaterials - Topics

- Scientific challenges in evaluating nanomaterials
- Nanomaterials under REACH – activities at EU level
- Regulatory status of dossiers concerning nanoforms
- Nanomaterials Working group

- Break-out groups: Discussions on the approaches taken for evaluating the dossiers containing nanomaterials

- Participants: ECHA, Commission, MSCAs, Accredited Stakeholders Organisations (open sessions)

Workshop on nanomaterials - Conclusion (1)

- Current status in the context of Commission recommendation for nanomaterial definition (ECHA's benchmark for the way forward).
- There is significant room for improvement of registered dossiers regarding NM characterisation and properties
- Clear support for ECHA to continue assessment of nanomaterials in dossier evaluation
- Based on break out groups discussion outcome, ECHA's approaches on how to address nanomaterial registration was supported (tiered approach-characterisation first, considering case-by-case basis)

Workshop on nanomaterials - Conclusion (2)

- The first priority is to have a proper characterisation of the material (sample preparation and dosimetry).
- Various phases of material characterisation were discussed (e.g. as placed in the market, as tested).
- In a later stage, priority will move to hazard and risk characterisation.
- Registrant should be proactive and provide all available nano specific information.
- Proceedings of Nanomaterial Workshop available on ECHA website

Link to documents of Nanomaterial Workshop, May 2012:

http://echa.europa.eu/web/guest/view-article/-/journal_content/c299bea5-ccd1-495b-ba2b-c596fd8c0bed

Nanomaterials Working Group
(ECHA-NMWG)

Nanomaterials Working Group (ECHA-NMWG)

- Clear support from Commission and Member States.
- Avoid overlap with scope of CASG-Nano.
- Composition: need to balance Continuity and Expertise
  - One nominated representative from each MSCA, COM service and ASO observer (Three NGOs + Three IND).
  - Possible invitation of additional scientific experts, depending on the issues discussed
- Primary focus of NMWG:
  - Provide scientific and technical advice
  - Support (not interfere with) ECHA formal processes (REACH & CLP).
- Mandate published on 12 October 2012 (available on ECHA website)

Next steps

Back-to-back meetings:

- Second GAARN meeting (21-22 January 2013)
- First ECHA-NMWG meeting (23 January 2013)

Now available on the ECHA website:

- a dedicated webpage on nanomaterials (current activities, meetings outcomes, webinars and latest guidance)

Thank you

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http://echa.europa.eu/en/web/guest/echa-information-desk