How to ensure the safe use of nanomaterials under REACH – Part III

Conclusions

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11:00 - 12:00 Helsinki Time (EET, GMT +2)

Key messages - general

- 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:
  - ECHA invites registrants to update dossier content proactively
  - Registrants are invited to interact or consult ECHA (best practice, guidance, advice)

Key messages – Occupational settings

- Use field measurement data to support the risk assessment
- Follow a multi-metric approach if possible in the risk assessment
- Use qualitative approaches to support measured or estimated exposure data
- Conventional control technologies for handling dusty materials are applicable to NMs and provide good control if implemented and maintained correctly

Key messages - Environment

- The applicability of conventional exposure assessment models is limited
- Use measured information on environmental release when possible
- Registration dossiers need to be updated with new nano-specific studies as scientific developments are progressing
- Lack of data does not automatically mean there is a lack of specific hazards or risks for a substance but it complicates the risk assessment

Reminder - Key messages from the previous webinars on nanomaterials

- Part I and Part II of the webinar series:
  Best practices from First and Second GAARN meetings

- Part I: Characterisation of nanoforms of substances in registration dossiers

- Part II: Current best practice for human health and environmental hazard assessment for nanomaterials

- Part III: Current best practice for human health and environmental exposure assessment and risk characterisation for nanomaterials

Part I: Characterisation of nanoforms of substances in registration dossiers

- Appropriate characterisation of nanomaterials is a starting point to understanding hazards
- Different nanomaterials require different characterisation techniques, registrants should tailor testing to their substance
- Information on particle size is multi-faceted (primary particle size, aggreggate/agglomerate). Registrants should provide information on these different aspects
- Information on particle size is method dependent – therefore registrants should provide a detailed description of applied method
- Information on surface area can be used to characterise nanomaterials and should be included

Part II: Best practice for human health and environmental hazard assessment for nanomaterials (1)

- The registration dossier should contain a comprehensive physicochemical characterisation of the registered nanoform(s)
  - Read-across approach or use of existing data (e.g. weight of evidence) possible only when well-characterised nanoforms are reported in the dossier
  - Toxicokinetics data might also be considered
- Most standard biological endpoints used in regulatory hazard assessment remain appropriate for nanomaterials
  - Adaptations on sample preparation and dosimetry are foreseen for most of the tests
  - Parameters such as particle solubility and stability in the test media are essential parameters

Part II: Best practice for human health and environmental hazard assessment for nanomaterials (2)

- Lack of short-term toxicity should encourage to investigate the potential sub-lethal and long-term effects
  - Might be of better relevance for appropriate hazard identification
  - Unknown specific mode of action of most nanomaterials
  - Widespread exposure considerations
  - Difficulties on sample preparation and dosimetry of high concentrated exposure suspensions

Information on the ECHA website

Nanomaterials webpage:

- http://echa.europa.eu/regulations/nanomaterials

Upcoming events

Ninth Stakeholders Day
21 May 2014

How to bring your registration dossier in compliance with REACH – Tips and Hints (part 6)
Q4 2014

Questions and Answers

- Questions will still be answered through the Q&A panel
  - You can continue to submit questions until 12:00 (end of this presentation)
  - Panelists will continue to answer your questions until 13:00 Helsinki time (EET, GMT +2) via the Q&A panel (first come, first served)
  - The event will close at 13:00 Helsinki time (EET, GMT +2)
  - If by then no answer is provided to your question, please send your question to the ECHA Helpdesk using the contact form: http://echa.europa.eu/en/web/guest/contact
- If you use the ECHA contact form:
  - You will receive an acknowledgement of receipt
  - Answer within 15 working days

Feedback questionnaire

- Once the event has ended, you will be automatically directed to a post-event questionnaire page

- Your feedback is important to us and helps us make the content of future webinars more relevant for your needs

- Please take the time to fill out the questionnaire

Thank you!

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