

Nanomaterials under REACH and ECHA activities on nanomaterials

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Frank Le Curieux
Evaluation Directorate
ECHA



Nanomaterials under REACH



Nanomaterials and REACH

- No explicit reference to nanomaterials in REACH
 - Considered as covered by the substance definition under REACH (Commission 2nd regulatory review on nanomaterials)
- Nanomaterials (NMs) can be either:
 - Substances on their own (and registered as such substances)
 - Nanoforms of a substance (and included in the dossier of the corresponding bulk form of the substance)
- Different forms can be included in a single registration of a substance
- Registrants need to demonstrate the safe use of their substances, 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 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 a reference in the dossier

ECHA's observations

Annual Evaluation report (Article 54) provides general recommendations to improve quality of REACH registration dossiers

Four key recommendations to registrants:

- Clearly identify your substance
- Demonstrate the relevance of the test material
- Provide clear information on use and exposure
- Make good use of available information and alternative approaches

These recommendations for 'standard' substances also apply to nanomaterials.

Compliance checks in 2013: in approximately two out of three cases, non-compliance was detected (ECHA sent draft decisions)

ECHA activities on nanomaterials



Activities - Strategic Aim 1

Improve dossier quality

(A)

- Continuation of ECHA NM working group, informal discussions with registrants and accredited stakeholders
- Guidance development, updates and communication on NMs

(B)

- Provide relevant support in context of regulatory impact assessment of changes in REACH Annexes, and scheduled review of the EU recommendation on definition of NMs

Activities - Strategic Aim 2

Intelligent use of dossier information

- Provide relevant support to MSCAs in context of the REACH risk management processes and Biocidal Products Regulation
- Participate and contribute to on-going international regulatory activities
 - OECD Activities
(ECHA, Chair of Steering group on Testing and Assessment)
 - CEN activities

Activities - Strategic Aim 3

Scientific hub

- Strengthening scientific capacity
 - Interaction with several FP7 projects
 - Participation in FP7 project NANOREG
- Scientific workshop on NMs in support of regulatory processes

ECHA Nanomaterials Working Group

- Dates of next meetings
 - Fourth NMWG: 24-25 June 2014
 - Fifth NMWG: 21-22 October 2014 (back-to-back with workshop)
- Topics:
 - Follow-up of Third NMWG meeting:
 - Characterisation of nanomaterials
 - Read-across/grouping of nanomaterials
 - Possibility for case specific discussion

ECHA Scientific Workshop on NMs (1)

23-24 October 2014 at ECHA premises

Aim: Create dialogue between academia and regulators to better address risk assessment of NMs within regulatory context.

Workshop format:

- plenary lectures by invited speakers
- panel discussions
- conclusions in the plenary
- poster session

Scientific committee

Experts with regulatory, business and academic backgrounds

ECHA Scientific Workshop on NMs (2)

Indicative content:

- 1. Challenges in regulatory risk assessment of NMs*
- 2. Measurement and characterisation of NMs*
- 3. Metrology and dose metrics for hazard and exposure assessment*
- 4. Environmental fate, persistence and bioaccumulation*
- 5. Read-across and categorisation*

- Participation based on expression of interests
- MSCAs are invited to participate with experts in the field
- Ensure fair representation of all interested bodies: academia, regulators, industry, NGOs
- Workshop organised back-to-back with Fifth NMWG meeting

ECHA's key messages on nanomaterials

- 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).

Thank you

ECHA Helpdesk

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