

“Nanomaterials in REACH”:
ECHA’s perspective on the implications for
Registration and Evaluation

Th. Jakl, Chair ECHA Management Board



Nanomaterials in REACH

- Competent Authorities for REACH have endorsed the (Commission) document ‘Nanomaterials in REACH’ (CA/59/2008 rev. 1)
 - **Nanomaterials (NMs) as substance, preparation or contained in an article fall under REACH**
 - **REACH requirements apply to nanomaterials, even though there are no specific provisions for nanomaterials**
 - **NMs registered either as a specific substance or as a form of the bulk**

Nanomaterials in REACH

- ‘Nanomaterials in REACH’ (CA/59/2008 rev. 1) (cont.)
- **Safety has to be ensured for the substance in whatever size or form and for manufacturing and all identified uses.**
 - **A registration dossier must include all relevant information on the nanomaterial.**
 - **Need to clearly identify the NM specific information in the IUCLID dossier**

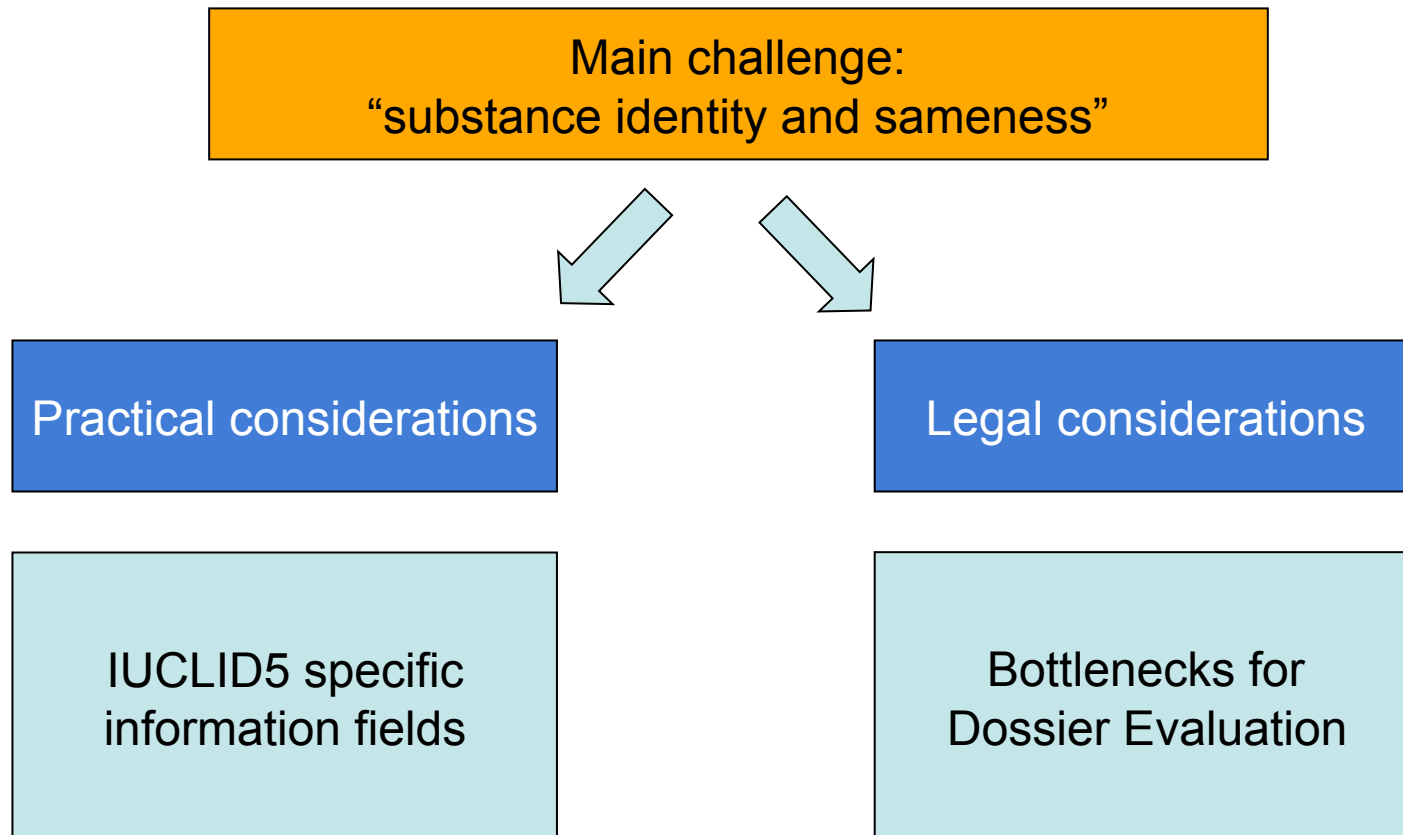


implementation: where and how?

NM included with the bulk

- One registration may cover all forms of a substance
 - nanoforms of a nominally identical bulk substance
- **Brings** legal and practical issues for REACH processes
 - **Impact on Registration and Evaluation processes**
 - **Impact on C&L**
 - **Impact on Restriction and Authorisation**

Impact on REACH processes



Substance Identification and sameness

How to identify the nanoform in practice

- Under discussion
 - naming convention
 - internationally agreed (working) definition for nanomaterials
 - OECD, ISO, RIP-oNs work in progress
 - criteria when a nanomaterial can be considered as a ‘nanoform of a nominally identical bulk substance’
 - criteria for the sameness of different nanomaterials under REACH

REACH - Registration

What it involves in practice

- Gathering and generating information:
- All available information (Annex VI)
- Information Annexes VII – X depending on volume
- Registrant may generate further information, such as specific properties of nanomaterials, not addressed in REACH Annexes, in order to demonstrate that risks are controlled
- Classification and labelling
- CSA and CSR hazard assessment
- PBT / vPvB assessment
- Exposure assessment
- Risk characterisation and risk management

CSA - Nanomaterials

Chemicals Safety Assessment (CSA/CSR):

Practical considerations

Are there any nano specific:

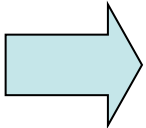
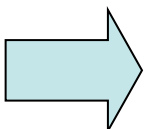
- properties
- hazards
- exposure scenarios
- risks
- risk management

– Communicate in Safety Data Sheets

Legal considerations

- A registration dossier covering **a bulk substance and its nominally identical nanoform(s)**
 - could be considered as physical forms of the same substance
 - in line with “one dossier – one substance” principle
- **Clarify what ECHA can request in practice**
 - further information on the identity of nanomaterial forms if they are considered the same?
 - more specific hazard information for the nanomaterial?

Legal considerations

- If legally ECHA cannot request both types of information 
- Effectiveness of industry voluntarily contributing additional data on nanoforms
- If ECHA can legally request information for different nanomaterial forms of the same substance in one registration dossier 
- **secondary (scientific/technical) hurdles** for Dossier Evaluation

Dossier Evaluation hurdles

- Request nano specific information relevant to
 - Substance identity
 - Hazard and exposure
 - Formal information requirements in REACH annexes
 - Testing proposals

But there are some knowledge gaps..

Secondary hurdles (1/3)

Substance identification

- The progress in COM's work on definition for nanomaterials
 - RIP-oN Substance Identification
 - Draft report by August 2010
 - Case studies chosen
 - OECD and ISO programmes
- To enable ECHA identifying nanomaterials consistently

Secondary hurdles (2/3)

Dossier Evaluation: Compliance check

Request for further information related to (HH and ENV)

- **Hazard**
 - Testing for nanomaterials
 - Sample preparation and dosimetry
- **Exposure**
 - Harmonised exposure assessment
- **Can adaptation of information requirements be applied to nanomaterials**
 - **Annex VII-X column 2**
 - **Annex XI waiving arguments**

Secondary hurdles (3/3)

Dossier Evaluation: Testing proposal evaluation

- ECHA has the right to change the testing conditions in case a proposed test will not provide the requested information.
- **What test(s) ECHA can propose for nanomaterial(s)?**
 - The applicability of the present test methods
 - Lack of standardized nano specific testing methodologies
 - Quantification (dosing, route)

ECHA workplan

Practical steps for NMs

- **IUCLID development**
- **Guidance development based on**
 - **RIP-oNs:**
 - Substance Identification
 - Information Requirements
 - Exposure and Risk Management
- **Practical guidance to industry on registration of nanomaterials**
- **International activities on the safety of nanomaterials**
 - OECD WPMN programmes progress
 - ISO programmes progress
 - SCENIHR opinions on Nano-RA methodology

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Thank you!