



REACH Information and Experience Exchange Forum (RIEF I)

**How should
dossiers cover
nanomaterials
more
specifically**

What to test and how?

- *SCENIHR 2009: "As there is not yet a generally applicable paradigm for nanomaterial hazard identification a case-by-case approach for the risk assessment of NM is still warranted"*
- *The OECD: "Recommends that Members in the testing of manufactured NM apply the OECD Test Guidelines, adapted as appropriate to take into account the specific properties of manufactured NM.."*

What to expect in a Dossier?

- *Which nanoforms are covered; accurate characterisation; Operational conditions and risk management measures available*
- *Information on which forms have been tested and test conditions*
- *CSA should cover all forms; Non-test data based on scientific justification only; Similarly regarding exposure scenarios and risk management measures*

Conclusion for REACH and Nano

- *The REACH registration and proof of safe use can work for nanomaterials provided*
 - **The case-by-case approach is respected**
 - **That each type of nanomaterial is described**
- *Data generation and testing for nanomaterials is possible based on current risk assessment requirements*
 - **Assuming that data for each 'case' is provided**
 - **Good description of test conditions and type of nanomaterial**

The Ex-post REACH assessment

- *As of February 2012:*
 - **Voluntary tick box 'Nanomaterial' ticked in 7 (9 as of today) registrations and 18 notifications;**
 - **Further registered substances are obvious nanomaterials or nanoforms**
- *Dossiers were generally unclear in whether and how they cover nanomaterials*
- *Therefore more specific requirements in REACH Annexes have proven necessary*

Next steps

- *Focus on Annexes – Committee Procedure*
- *Evidence base: JRC Nano support + new consultancy support*
- *CASG Nano for consultation*
- *Public consultation*
- *Impact Assessment Board*
- *Proposal by December 2013*

Thank you for your attention!