

REACH-NanoHazEx (RIPoN3)

Specific advice on exposure assessment and hazard/risk characterisation for nanomaterials under REACH

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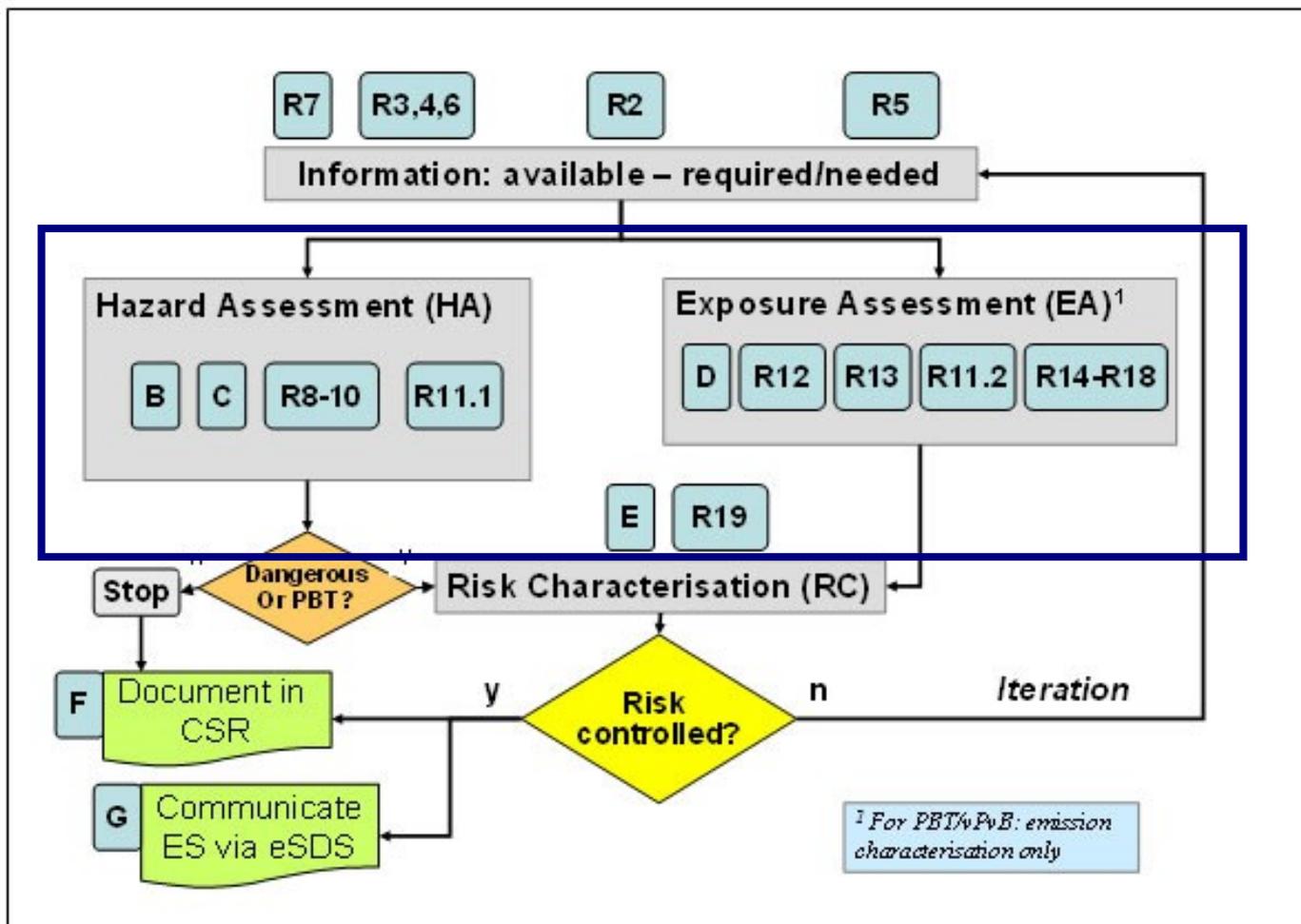


S A F E N A N O

Disclaimer

- This project is not complete. No recommendations have yet been agreed and the reports have not been finalised.
- The information provided here is the personal views of the authors and does not reflect an agreed position of the European Commission or ECHA

REACH framework and guidance



Overview of RIPoN 3

- Aim
 - Main aim is to develop recommendations for changes to the **REACH** guidance which take account of specific issues in relation to nanomaterials. This assessment is based on current generation NMs
- Objectives
 - Develop advice on how to do ***exposure assessment*** for nanomaterials within the REACH context
 - This is the main focus of the project and covers:
 - 1) development of Exposure Scenarios;
 - 2) evaluation of operational conditions and risk management/mitigation measures, and;
 - 3) exposure estimation
 - Develop ideas for how to conduct ***hazard and risk characterisation*** for nanomaterials
 - This will involve threshold/non-threshold considerations

Methods

- The project has been performed as an objective review of the existing guidance and available scientific evidence pertinent to the specified tasks.
- Develop an informed, objective and systematic gathering and consideration of evidence by experts who have used their knowledge and professional judgement when considering the impact and contribution of a source document to the task objective
- Based on the objective and informed assessment of published reports constituting the evidence-base available to call upon, a synthesis of findings, implications and/or issues distilled from the sources has been developed and integrated into the task reports.
- The review of source reports has identified and used the methods and materials used (as appropriate), key findings, and remaining gaps in establishing the technical basis facilitating the development of advice pertinent to the project.

Project tasks

A. Identification & Review of Information Sources

B1. Exposure scenario case studies

B2. Operational conditions & RMMs - harvesting results from on-going activities

B3. Exposure estimation - harvesting results from on-going activities

B4. Advisory report on OC, RMM, ES and Exposure estimation with the purpose of conducting Exposure assessment of NM for REACH

C1. Case studies on how no effect levels could be established

C2. Hazard / risk characterisation – harvesting results from on-going activities

C3. Advisory report on hazard and risk characterisation for NM

D. Metrics to compare in risk characterisation

Final Report

Approach taken

- The initial activity was the collection and review of information from a wide range of sources. This comprised the main activity in Task A.
- This was followed by an evaluation of the evidence base to identify the key scientific issues arising which had the possibility of implications for the REACH guidance. This included, in relation to exposure and exposure scenarios Tasks B1, B2 and B3, in relation to hazard and to risk characterisation the Tasks C1 and C2 and in relation to metrics, the Task D.
- The next stage was the identification, from the perspective of the scientific evidence, where within the guidance changes should be made. This comprised Tasks B4 (in relation to exposure issues) and C3 (in relation to hazard and risk issues).
- The Final stage of the project was a section by section analysis of the existing REACH guidance specifically, for the B tasks, Part D (Exposure Scenario building), Part F (Chemical Safety Report, incl. CSR format), Part G (Extending the SDS), Chapter R.12 (Use descriptor system), Chapter R.13 (Risk management measures and operational conditions), including the RMM library and Chapters R.14, R.15, R.16 and R.17 (on exposure estimation in relation to different types of scenario). It also considers the RMM library. For the C tasks, the focus was on Chapters R8 and R10.
- The assessment considered in detail the optimum set of changes which could be made to the guidance. Based on this analysis, detailed guidance changes were developed along with recommendations for research where this was indicated. This activity forms the main aspect of this project final report.

Oversight

- All Task Reports were subject to review by JRC/COM/ECHA and an EC-appointed Stakeholder Consultation Group (SCG) drawing on representatives of the REACH Competent Authorities Sub-Group on Nanomaterials (CASG-Nano) and additional experts.
- The draft Task Reports were opened for written comments, discussed at meetings of the SCG, revised by the Project Consortium. Response to comments were provided to written comments. Some of the reports were re-opened for comments before being finalised.

Key issues – ES case studies

- Applicability of SUs, PROCs and ERCs
- Complexity of measurement programmes and data
- Discrimination from background particles
- Maximum particle size
- Metrics
- Use of instruments
- Data handling -Uncertainty of measurement
- Use of exposure models

Key issues- RMM

- Hierarchy of control
- Existing methods (in general)
- Modification and substitution
- Enclosure
- Ventilation, LEV, including fume hood, cabinets
- Filtration
- Administrative controls
- Respiratory protective equipment - RPE
- Other PPE, gloves suits etc
- Control banding
- Development of OELs
- Medical surveillance
- Safety Data Sheets
- Consumer RMM
- Environmental RMM
- Operational Conditions

Key issues - exposure

- Discrimination from background nanoparticles
- Measurement of size distribution
- Maximum relevant size
- Effect of high spatial and temporal variability
- Choice of metrics and instruments
- Emerging measurement strategy
- Assessment of high aspect ratio nanomaterials
- Exposure modelling
- Utility of exposure simulation studies

Derivation of no effect levels

- We considered 3-4 very different nanomaterials with potentially very different routes of toxicity as exemplars
 - Nano-TiO₂
 - Carbon nanotubes
 - Nano-silver
 - Nano-Zinc oxide (environmental)
- Using the REACH approach for generating no effect levels for human exposure (generation of DNEL/ DMEL) and for environmental exposure (PNEC) we:
 - Investigated the available data available for suitability
 - Performed example derivations of exposure limits to evaluate the process for nanomaterials
 - Evaluated the processes suggested by others including identified issues and comments

Rationale for guidance recommendations

- The content of a recommendation for a specific update to guidance is consistent with the focus of current REACH Guidance document, its level, and language, such that:
 - where the need is for 'strategic-level' guidance applicable to nanomaterials (i.e. high-level or overarching principles), succinct contextual information and reference(s) to primary sources of information are provided;
 - where the need is for updated detailed pragmatic information on, for example methods, a synopsis of specific guidance with appropriate reference(s) are provided;
 - where there is simply a need identified to acknowledge an important relevance or limitation in existing guidance to nanomaterials, a simple wording clarification may be proposed.
 - Superfluous and wide-scale acknowledgement confirming the general applicability of Guidance to nanomaterials has not been made.

Concluding Remarks: Recommendations for Guidance Updates and R&D

As the RIP-oN3 project has not yet concluded, an overview of the pre-finalised recommendations from the project will be highlighted in the remainder of the presentation.