

Scientific Workshop - Grouping of Nanomaterials
European H2020 projects NanoReg2 and GRACIOUS
12-13 September 2018, Paris

Background, aims and delegate role

This document presents workshop aims and the important role that all participants will have in contributing, plus supporting documents that you may wish to read.

Background: Nanomaterials (NMs) exist in varying physicochemical characteristics such as size, morphology and surface characteristics. Due to financial, time and ethical considerations, safety testing of every unique NM for their potential adverse effects is virtually impossible. For these reasons, more efficient ways to obtain safety information, such as grouping and read-across, are needed.

The scientific foundations for the application of grouping and read-across to NMs have been established in a number of conceptual schemes as developed in the EU-funded projects MARINA, NANoREG, ProSafe and ITS-NANO, and in the ECETOC Nano Task Force. In addition, ECHA has provided recommendations on how to apply grouping and read-across to NMs in the context of REACH (see supporting documents on page 2).

One of the major conclusions from all these activities is that nano-specific grouping and read-across strategies should be hypothesis-driven and must consider not only intrinsic (physico-chemical) properties and (eco)toxicological effects, but also extrinsic (system-dependent) descriptors of exposure, toxicokinetics, environmental fate and modes or mechanisms of action.

The Aim of the workshop is to present the state-of-the-art on grouping and read-across and for stakeholders to bring their expertise to the design of a science-based framework to enable **practical** application of grouping, leading to read-across of NMs. This includes identifying the most relevant outputs from previous projects (such as NanoReg2), allowing the new GRACIOUS grouping framework to build on previous work. The workshop builds on the common principles found across different projects and does not intend to endorse a specific framework in the long term. It recognises that this is an evolutionary pathway to which all frameworks have contributed.

A grouping framework should be useful to different stakeholders such as industry, policy makers and regulators. Contributions from all these groups are critical and the workshop facilitates this by its highly interactive setup. Grouping should facilitate safety considerations during product development, facilitate risk assessment and support regulatory decision making. However, a grouping framework also should be sufficiently flexible to adapt to future scientific and regulatory developments.

The workshop first provides an overview of grouping history as well as regulatory requirements to NM grouping (Session 1), then presents most recent grouping frameworks for NMs (Session 2) followed by recent examples on how to apply grouping in practice, which is closely linked to establishing appropriate testing strategies (Session 3). The physico-chemical properties which underpin grouping frameworks will benefit from the outcomes of the OECD workshop immediately preceding this workshop and which will report into our meeting.

During the breakout sessions we first discuss the design of a grouping framework for NMs (Breakout 1), followed by discussing specific tests/testing strategies (including the construction of Integrated Approaches for Testing and Assessment – IATAs) to support and justify grouping and read-across for NMs (Breakout 2). Outcomes from these sessions are intended to inform on:

- Key physico-chemical parameters required to inform about similarity and to justify a NM group
- Target Technology Readiness Levels (TRL) for practical application
- Priorities for development/improvement of OECD Guidance Documents or Test Guidelines
- Overcoming obstacles to the application of grouping
- Elements needed to build a reliable, relevant and practical testing strategy for the purpose of grouping and read-across

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Supporting documents

- [ProSafe Paper](#)
- [Gracious draft framework](#) (to be presented in detail at the workshop)
- [Ecetoc Decision making framework for the grouping and testing of nanomaterials \(DF4NANOGROUPING\)](#)
- [ECHA Guidance on information requirements and chemical safety assessment – Appendix R.6-1 for nanomaterials applicable to the Guidance on QSARs and Grouping of Chemicals](#)
- [ECHA Report: New Approach Methodologies in Regulatory Science Proceedings of a scientific workshop Helsinki, 19–20 April 2016](#)

Open access publications

- [Oomen et al. Grouping and read-across approaches for risk assessment of nanomaterials. International Journal of Environmental Research and Public Health 2015, 12:13415-13434.](#)
- [Dekkers et al. Towards a nanospecific approach for risk assessment. Regulatory Toxicology and Pharmacology 2016, 80:46-59.](#)
- [Park et al. Development of a systematic method to assess similarity between nanomaterials for human hazard evaluation purposes – lessons learnt. Nanotoxicology 2018:1-25.](#)
- [Stone et al. ITS Nano – Research prioritisation to deliver an intelligent testing strategy for the human and environmental safety of nanomaterials. pp. 128; 2013:128.](#)
- [Arts et al. A decision-making framework for the grouping and testing of nanomaterials \(DF4nanoGrouping\). Regulatory Toxicology and Pharmacology 2015, 71:S1–S27.](#)
- [ECHA: Assessing human health and environmental hazards of nanomaterials – Best practice for REACH Registrants. In 2nd GAARN meeting. Helsinki, Finland: European Chemicals Agency \(ECHA\); 2013.](#)
- [ECHA: How to prepare registration dossiers that cover nanoforms: best practices. In Guidance for the implementation of REACH. Helsinki, Finland: European Chemicals Agency \(ECHA\); 2017.](#)
- [ECHA, JRC, RIVM: Usage of \(eco\)toxicological data for bridging data gaps between and grouping of nanoforms of the same substance – Elements to consider. pp. 28. Helsinki, Finland: European Chemicals Agency \(ECHA\), Joint Research Centre \(JRC\), Dutch National Institute for Public Health and the Environment \(RIVM\); 2016:28](#)
- [Steinhaüser, K and P. Sayre. 2017. Reliability of methods and data for regulatory assessment of nanomaterial risks. NanoImpact 7 \(2017\) 66–74](#)