

Scientific Workshop Grouping of Nanomaterials

EU H2020 projects NanoReg2 and GRACIOUS
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Welcoming you today



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Scientific Workshop

Grouping of Nanomaterials

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Welcome and Introduction

The NanoReg² project

Development & implementation of Grouping strategies & Safe-by-Design approaches within regulatory frameworks

www.nanoreg2.eu

Duration: September 2015 – February 2019

Partners: 42 from EU academia, industry, regulators and policy makers

Funding: 10 million Euros

NanoReg2 key objectives:

- Identify, build and evaluate regulatory relevant grouping approaches, linked with intelligent testing and non-testing strategies
- Develop and promote supportive technical & organizational tools (SOPs) for Safe by Design implementation, based on regulatory orientated grouping approaches
- Develop candidates for industrial value chain demonstrators, including potential exposure & life cycle scenarios
- Evaluate the relative change in environmental and human health risk, following implementation of SbD processes
- Identify & overcome barriers to the application of SbD concepts,
- Develop approaches to adequately address such barriers, taking into consideration grouping approaches and Risk Management (RM) requirements

The GRACIOUS project

Grouping, Read-Across and Classification framework for regulatory risk assessment of manufactured nanomaterials and Safer design of nano-enabled products

www.h2020gracious.eu

Duration: January 2018 – June 2021

Partners: 23 from EU and US academia, industry, regulators and policy makers

Funding: 7.4 million Euros

GRACIOUS aims to develop a highly innovative science-based framework that supports the assessment of risk posed by the ever increasing array of nanomaterials on the market and under development.

Grouping will allow extrapolation between (read-across) nanomaterials, materials and substances, and reducing the need to assess exposure to and toxicity on a case by case basis.

Current status: September 2018 stakeholder consultation of draft framework. Version 2 due in December 2018.

Intended workshop impact

- To create international scientific critical mass to support Grouping & Read Across strategies
- Promoting a clear state of the art on Grouping & Read-Across, including understanding of limitations
- To support policy makers & regulatory bodies in development of robust and practical frameworks
- To support faster uptake of active use of Grouping & Read-Across in materials development

Workshop Thoughts

- Grouping should facilitate safety considerations during product development, facilitate risk assessment and support regulatory decision making
- However, a grouping framework should be sufficiently flexible to adapt to future scientific and regulatory developments

Workshop Aims

- To present the state-of-the-art on grouping and read-across.
- To facilitate stakeholders input into the design of a science-based framework to enable practical application of grouping, leading to read-across of NMs.
- To identify the most relevant outputs from previous projects
- To feed these outputs into new projects such as GRACIOUS to generate a grouping framework that builds on previous work.

The workshop builds on the common principles found across different projects and does not intend to endorse one or other framework in the long term.

It recognises that this is an evolutionary pathway to which all frameworks have contributed.

Achieving Workshop Aims

- Stakeholders include industry, policy makers, regulators and academia
- All are represented here today
- **Contributions from all these groups are critical**
- Give your direct input today and in post-workshop activities
- Keeping momentum and expertise

Legacy

- The primary goal for GRACIOUS is to improve the Grouping and Read-Across framework design to better ensure suitability and usefulness for stakeholders
- The primary goal for NanoReg2 is to ensure outputs have impact e.g. via PC WPMN and GRACIOUS
- The primary goal for OECD to ensure connectivity and impact of PC WPMN activities e.g. to populate the ‘what they are’ aspects of the GRACIOUS grouping framework
- The role of CEN and ISO will be to provide current and future technical guidelines

After the workshop

- GRACIOUS Grouping and Framework design improvements before embarking on construction
- NanoReg2 will improve Grouping strategy to present to OECD WPMN and GRACIOUS
- Peer reviewed publications for both projects
- Follow up workshops to test Grouping framework
- Direct integration into next generation projects across territories
- Follow up via international webinar(s) for stakeholders to share workshop results and roadmap
- Provide dissemination via news websites, conferences and EUON
- Ultimately allow Grouping and Read-Across to be integrated into commercial development of nanomaterials

The Organising Team



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The Workshop

- **Session 1 - Nanomaterial Grouping:** Principles, History and Context
- **Session 2 - Cutting Edge Grouping Frameworks**
- **Session 3 - Grouping in practice:** connecting to test methods and test strategies
- **Breakout session 1 – Grouping Frameworks**
- **Breakout session 2 – Identifying tests for development of Integrated Approaches to Testing and Assessment**
- **Reporting** from breakouts to plenary
- **Final Panel Discussion**
- **Concluding remarks**