The GRACIOUS Project:



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

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GRACIOUS project

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About the project

About the project

GRACIOUS

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

Number	Organisation	Country
1 Coordinator	Heriot-Watt University (HWU)	UK
2	BASF SE (BASF SE)	DE
3	Green Decision (GD)	IT
4	Institute of Occupational Medicine (IOM)	UK
5	European Research Services (ERS)	DE
6	Yordas Group (Yordas)	UK
7	National Research Centre for the Working Environment (NRCWE)	DK
8	German Federal Institute for Risk Assessment (BfR)	DE
9	Natural Environment Research Council (NERC)	UK
10	University of Vienna (UNIVIE)	AT
11	Italian Institute of Technology (IIT)	IT
12	National Institute for Public Health and the Environment (RIVM)	NL
13	Eidgenoessische Technische Hochschule Zuerich (ETH Zurich)	СН
14	Leitat Technological Centre (LEITAT)	ES
15	Akzo Nobel Pulp and Performance Chemicals (AKZO)	SE
16	Ideaconsult (IDEA)	BG
17	JRC-Joint Research Centre-European Commission (JRC)	IT
18	Unilever (Unilever)	UK
19	ThinkWorks (ThinkWorks)	NL
20	Arizona State University (ASU)	US
21	Duke University (DUKE)	US
22	Athens Research and Innovation Center (ATHENA)	EL
23	Swiss Federal Laboratories for Materials Science and Technology (EMPA)	СН







Overview



- GRACIOUS aims to develop a highly innovative sciencebased framework that supports the assessment of risk posed by the ever increasing array of nanomaterials on the market and under development.
- The Framework will enable practical application of grouping, leading to read-across and classification of nanoforms (NFs)

To logically group nanoforms based on similarity

Extrapolation of NFs which leads to reducing the need to assess exposure to and toxicity on a case by case basis

Current status:

- Sept 2018: stakeholder consultation of draft Framework
- Dec 2018: advanced draft of the Framework produced





Overview of Stakeholder Consultation Activities



Stakeholder Engagement Methodology

Inform Stakeholders Informal Engagement

- Newsletter signup
- Website
- Press releases
- Emails
- Social media

Engage Stakeholders Formal Engagement

Strategy:

- Stakeholder database
- Stakeholder champions
- Advisory board

Activities/ Tools:

- Interviews/ face-to-face discussions
- Online open consultation
- Stakeholder events
- Webinars
- Online stakeholder engagement platform

Develop GRACIOUS stakeholder database

ca. 70 contacts from industry, NGOs, regulators, policy makers, standardisation bodies GRACIOUS Advisory Board members

- > 500 NSC academic contacts
- Formalise stakeholder champions
- Conduct interviews with key stakeholders e.g. ECHA, EFSA, NIA, NIOSH, Health Canada, FDA
- Run an online open consultation (June-Oct 2018)

ca. 30 complete results

30+ partial results

Spanning all stakeholder groups and numerous countries (e.g. UK, Germany, Poland, Sweden, Austria, US, Netherlands, Canada, Portugal, Finland, Norway, Spain, Japan, South Korea)



Results (2/2)

Stakeholder workshop

- ✓ ca. 120 participants
- ✓ All types of stakeholders
- ✓ 4 break out sessions:
 - Draft GRACIOUS Framework
 - What they are
 - Human Health
 - Environment
- ✓ Live discussions
- ✓ Generally positive feedback

Online stakeholder engagement platform

- <u>https://www.h2020gracious.eu/ab</u> <u>out/stakeholders</u>
- Collects all stakeholder engagement activities





Further Results (related to GRACIOUS dissemination activities)

- Press Release (https://www.h2020gracious.eu/news/nanotechnology-expertsfrom-across-the-globe-join-forces-to-advance-nanomaterials-safety-assessment
- **GRACIOUS** Newsletter
- Social Media communication

Horizon2020 GRACIOUS Newsletter - October 2018



Nanotechnology experts join forces to advance nanomaterials safety assessment

Advancing nanomaterials safety testing was the mission of two European Union funded Horizon2020 projects, NanoReg2 and GRACIOUS. They brought together 120 nanotechnology specialists from Europe, North America and Asia at the Organisation for Economic Co-operation and Development (OECD) in Paris on September 12-13, 2018.



Progress on the GRACIOUS Framework development

The GRACIOUS Framework aims to support practical application of grouping of nanomaterials and nanoforms for risk assessment and decision making. This includes the ability to read across from data rich substances to similar nanomaterials for which information is lacking.









Read more about our stakeholder engagement activiti

and read

Upcoming Events

GRACIOUS Consortium Meeting 26-28 November 2018, Barcelona, Spain

Cutting Edge Approaches for the Risk Assessment and Management of Nano-(bio)materials: From the Lab to the Market: H2020 BIORIMA-GRACIOUS & COST Action NANO2CLINIC Training School 25-29 March 2019, Venice, Italy

See full events schedule



PRESS RELEASE Paris, September 26 2018

Nanotechnology experts from across the globe join forces to advance nanomaterials safety assessment

Advancing nanomaterials safety testing was the mission of two European Union-funded Horizon2020 projects, NanoReg2 and GRACIOUS They brought together 120 nanotechnology specialists from Europe, North America and Asia at the Organisation for Economic Co-operation and Development (OECD) in Paris on September 12-13. Experts from research, industry, regulation and policy worked to improve how safety information can be more effectively obtained supporting faster growth in nanomaterials developmen



Many variations of a single solid substance can exist, with differences in size, morphology and surface characteristics. Depending on the size, some variations have to be reported and regulated as nanomaterials. Financial and ethical considerations mean that safety testing of each variation for their potential adverse effects is virtually impossible. For these reasons, improved ways to obtain safety information are needed for a successful and sustainable nanomaterials sector

Clustering nanomaterials with similar characteristics (Grouping) and predicting the behaviour of new nanomaterials within each group (Read Across) is the widely recognised solution. It would reduce testing within regulatory requirements without compromising safety standards. This allows efficient development of safe and novel nanomaterials, based on increased understanding of their behaviour and possible impact on humans and the environment.



The joint OECD/NanoReg2/GRACIOUS workshop was an effective platform for stakeholders to bring their expertise to the design of a science-based framework for effective Grouping and Read Across of nanomaterials. NanoReg2 and GRACIOUS will finalise concepts and practical roadmaps to support producers, governments, regulatory agencies and standardisation bodies for safe and innovative nanomaterials.

The GRACIOUS Project Coordinator, Professor Vicki Stone explains the expected impact of he workshop

"The combined contributions of representatives of industry, regulators, policy makers and academics provided a real opportunity to generate a grouping framework that can benefit all stakeholders.

The NanoReg2 Project Coordinator, Dr Emeric Frejafon added that

"This was an opportunity to create a alobal critical mass of opinion so we can support nanomaterial development and safety assessment worldwide."





Current status of GRACIOUS Framework

Introduction: GRACIOUS Framework





https://echa.europa.eu/documents/10162/23036412/appendix_r6_nanomaterials_en.pdf

Simple overview of the GRACIOUS Framework



* If the purpose is to fill data gaps in regulatory REACH dossiers, then the same terminology applies as in the REACH Annexes 2.4: "NF" stands for a single manufacturing output, or a "set of similar NFs", if defined.



...More detailed version of the GRACIOUS Framework is currently being written up for publication...

Next Steps and Expected Results

2019-2021

- ✓ Peer reviewed publications:
 - Modified draft Framework for grouping, read-across and classification
 - Hypothesis Generation Templates
 - The first IATA
- ✓ Ongoing stakeholder consultation activities (webinars/events)
- \checkmark Testing and refining the framework using case studies
- ✓ Outputs:

The Framework and its Integrated Approaches to Testing and Assessment (IATAs) will be delivered as:

- An E-tool fit-for-purpose for various key stakeholders (regulatory and industrial)
- A Guiding Background Document
- ✓ Impacts:

Both the E-tool and the guiding background document will be designed for practical application to:

- Help industries and regulators assess environmental and human health risks of existing NMs/NFs cost-effectively
- Facilitate business decisions concerned with developing new nano-enabled products (NEPs)
- To inform Safety-by-Design practices





Thank you!

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