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Development and implementation of Grouping and Safe-by-Design approaches within regulatory frameworks (NANOREG II, RIA)

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The **NANOREG II project** is a **H2020: Research & Innovation Action (RIA)**, built around the challenge of coupling **Safe by Design (SbD)** and **Groupings principles** to the regulatory process dealing with rapidly development of novel manufactured nanomaterials (MNM).

The NANOREG II objectives are centered on:

- 1) To identify and define the regulatory requirements in order to apply and implement MNM grouping principles in a regulatory framework.
- 2) To identify and select materials as candidates for value chain demonstrators in collaboration with industry, then develop life cycle maps and identify existing and potential exposure scenarios
- 3) To evaluate relative changes in environmental and human health risk following implementation of the SbD process
- 4) Develop and adapt supportive technical and organizational tools for Safe by Design, based on regulatory orientated grouping approaches
- 5) Identify and overcome barriers to the application of SbD concepts, taking into consideration grouping approaches and Risk Management (RM) requirements
- 6) Disseminate Safe by Design tools and SOPs, promoting regulatory orientated guidelines

The “Ilie Murgulescu” Institute of Physical Chemistry of the Romanian Academy (IPC) is main partner contributing to the **Task 1.2 (co-leader of this Task) *Monitoring future regulatory needs*** and to the **Task 1.5 *Implementation of Technically Oriented instruments in a global ITS***.

The main activities accomplished under these tasks could be summarized as follows:

Task 1.2 *Monitoring future regulatory needs*

- Providing an overview on the regulation of chemicals under REACH and performing in-depth analysis of the currently available information.
- Evaluate acquired information based on an integrative approach bridging NM characterization and toxicity evaluation
- Identifying the possibilities how to implement SbD based on grouping approaches.

Task 1.5 *Implementation of Technically Oriented instruments in a global ITS*

- IPC supports this task by prospective research on new key parameters for MNM grouping by using methods of Applied Chemical Thermodynamics to characterize and investigate from the energetic point of view the micro and nanostructure materials, as well as to explore the interactions between biological and non-biological systems
- Searching for adequate metrics for MNM grouping.
- Performing fundamental physico-chemical research into the interaction of NPs with bio-molecules: assessing the thermodynamics of binding interactions, protein corona formation and the effect of the NPs on the protein stability.