Selection of tools for their integration in a novel risk governance framework

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1. Introduction

The aim of the Nanorigo project is the development of a **Nano Risk Governance Framework (NRGF)**: a comprehensive and integrative approach to help understand, analyse and manage important risk issues arising for nanomaterials for which there can be deficits in current risk management structures and processes.

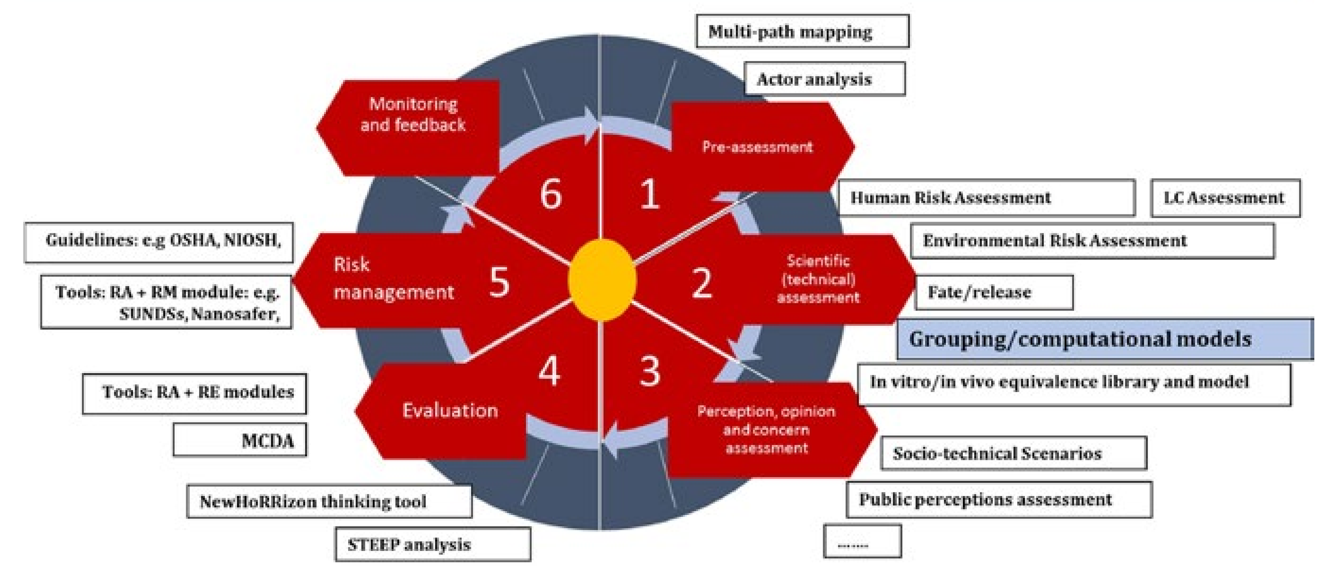


Fig. 1. Example of integration of evidence-based tolos in the RGF

Considering the number of **tools and approaches** developed in the last years for the different aspects of risk governance, a selection of the most suitable evidence-based ones for the different sections of the RGF is needed.

2. Selection of tools and approaches

Grouping tools. The following steps have been used for selection of the grouping tools:

- Development and Prioritisation of criteria
- Scientific soundness
- Completeness and usability
- Evaluation
- Description
- Identification of gaps
- Recommendations for refinement

Computational tools. The current landscape was evaluated related to applicability and affinity to the purposes of the regulatory framework, mainly REACH. Priority was given to Quantitative structure-activity relationship model and to a variety of compartment –based mathematical models (4 classes of compartment-based mathematical models: toxicokinetic, toxicodynamic, in vitro and in vivo dosimetry models, and environmental fate models).

3. Evaluation of tools and approaches

3.1 Grouping Tools/Approaches.

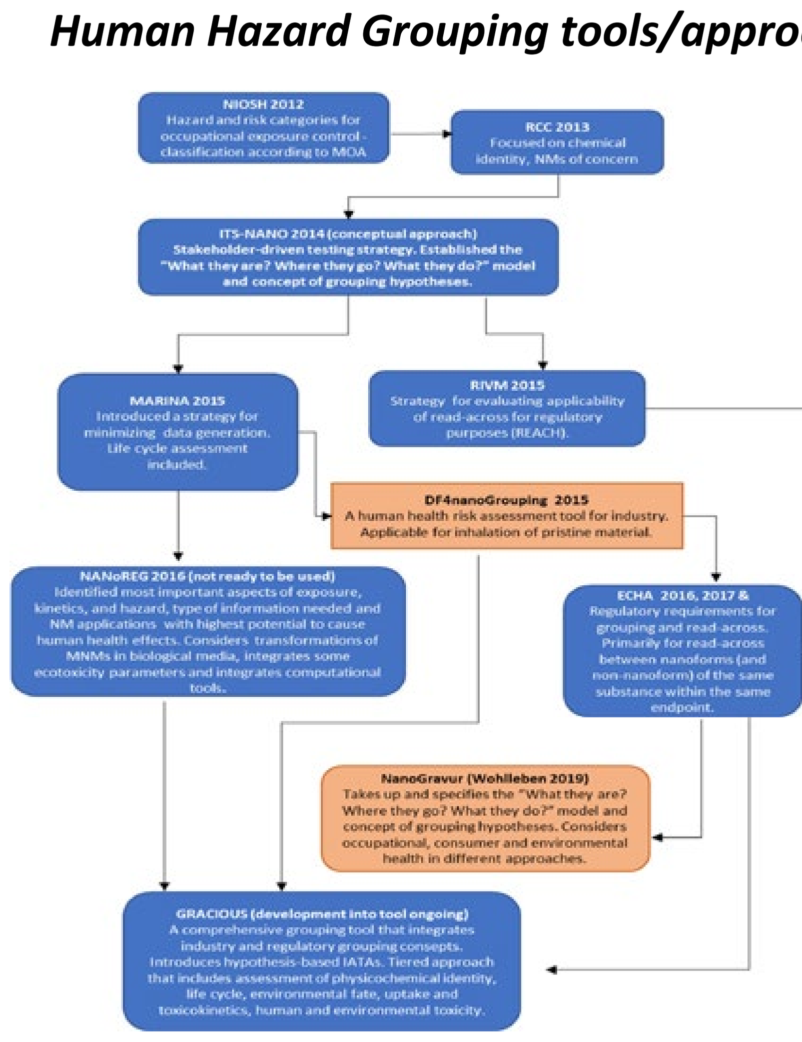
A total of 27 grouping approaches/tools were identified

Specific Criteria: Technology Readiness Level (TRL)

Tools = TRL high **Approaches = TRL low**

A linking system for guiding the user through some of the different tools/approaches is presented:

Human Hazard Grouping tools/approaches



Environmental Hazard Grouping tools/approaches

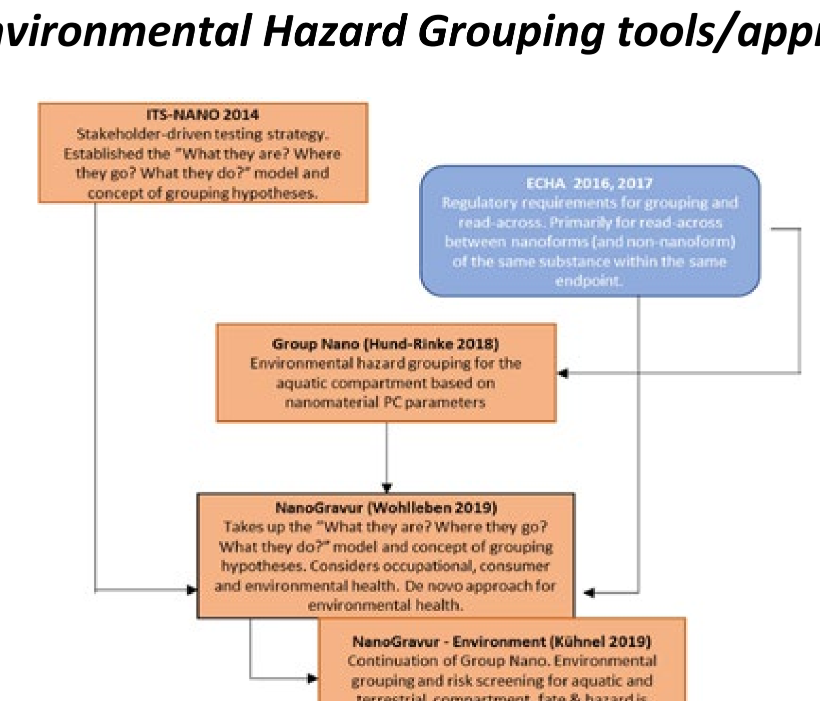


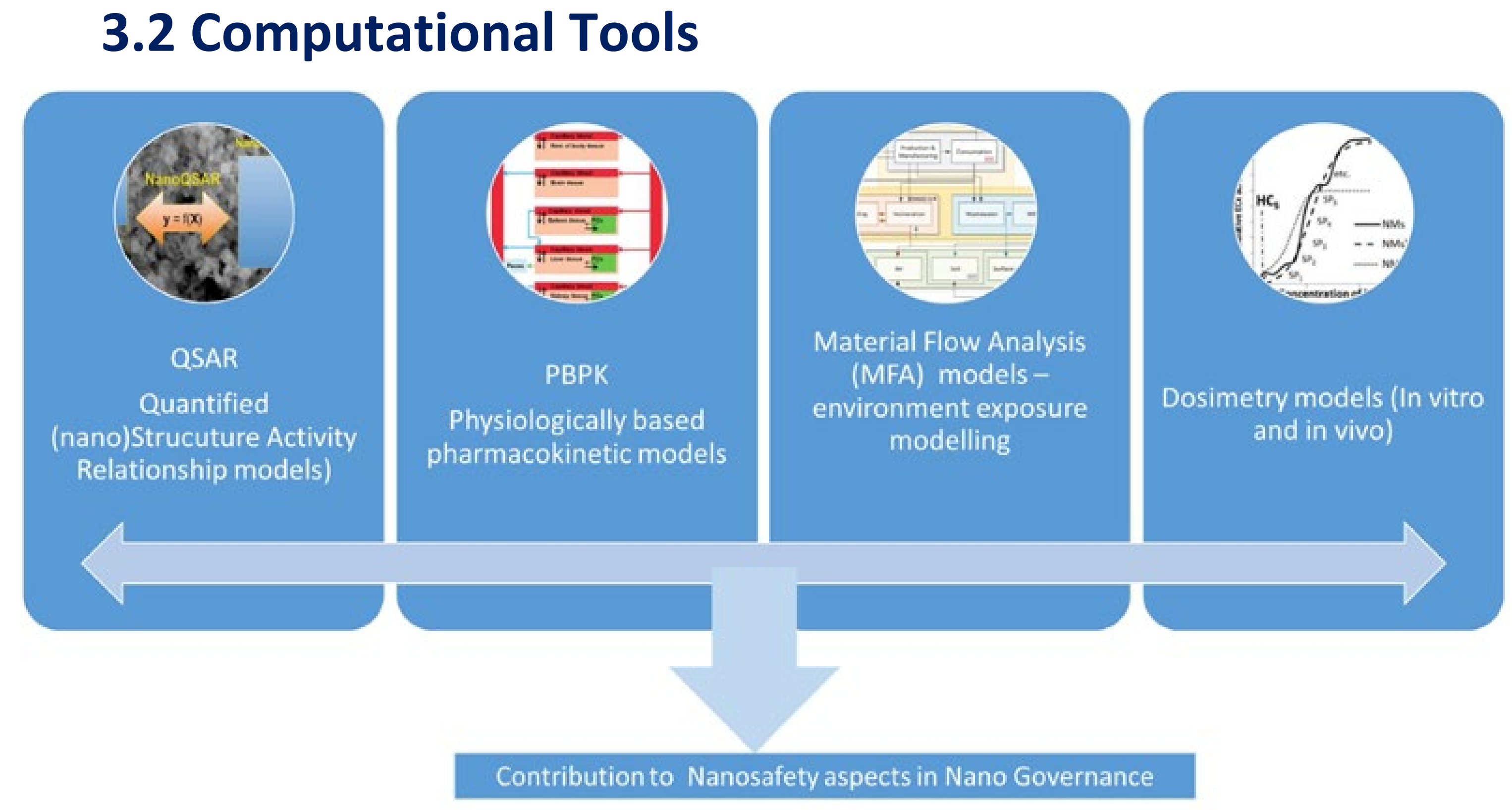
Fig. 2. Linking system representing the interconnection of the selected tools (Orange) and approaches (blue)

General Criteria: Scientific, technological and regulatory.

Importance: **Very High—High—Medium—Low**

From the 27 grouping approaches/tools identified, the evaluation resulted in the selection of **5 tools and 9 approaches**

3.2 Computational Tools



MODEL	☺	☹
QSAR	Fill data gaps. Regulatory purposes	Very few available address REACH endpoints
PBPK	Support info in chemical safety regulation, derivation of DNEL	Less reported than QSARs. In early stage of development for NMs
MFA-enviromental fate	Calculation of a predicted environmental concentration	Lack of analytical techniques
Dosimetry	Determine the internal dose following exposure (e.g. Inhalation)	Endpoint may vary for different durations or routes resulting in different internal doses

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