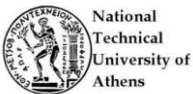


D2.1

Evaluation of the identified governance tools for their inclusion in the RGF



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Introduction

- D2.1 identifies, evaluates and gives a selection of existing risk governance models/tools/approaches to be included in the Risk Governance Framework (RGF)
- All the tools have been mapped and described according to the needs of WP3 for the design of the platform.
- Two new developments are described that will facilitate the use of the tools
- D2.1 gives a non-exhaustive description of tools that could help to integrate broader considerations (ethical and societal aspects) in the NANORIGO Risk Governance Framework, and to identify the steps in the NRGF where they can be used



Content. Existing tools

RA, fate release tools	LCA tools	Grouping	Risk evaluation	Risk management	tools for integration of SEE aspects	Computational
<p>Criteria for evaluation</p> <p>15 tools selected</p> <p>Unique aspects of tool</p> <p>Mapping of tools</p> <p>Description of tools</p>	<p>Criteria for evaluation</p> <p>Evaluated and selected tools:</p> <ul style="list-style-type: none"> • LC Thinking tools (1) • Tools for LCIA (3) • LC Inventory Databases (2) • LCA softwares (4) <p>Additional resources:</p> <ul style="list-style-type: none"> •Published nanospecific LC Inventory Data •Published Nanospecific CF •Strategies for calculation of nanospecific CF <p>Guidance through the tools</p>	<p>Criteria for evaluation</p> <p>6 tools + 9 approaches selected</p> <p>Mapping</p> <p>Connection</p> <p>Description of grouping tools</p>	<p>4 Tools/models</p> <ul style="list-style-type: none"> • Methodologies: MCDA, ELECTRE TRI, SMAA TRI • Value of information (VOL) <p>Description of tools/models</p>	<p>4 Tools/models</p> <p>SbD implementation platform</p> <p>Additional resources:</p> <ul style="list-style-type: none"> •Guidances •NRV and OEL •Guidances for waste management <p>Description of all tools and resources</p>	<p>Overview of 19 tools</p>	<p>Criteria for evaluation</p> <p>QSAR/QSPR</p> <p>PBPK</p> <p>Description of tools</p> <p>Nanoinformatics projects:</p> <p>NMBP -14: EU Horizon NanoInformatIX and NanoSolveIT</p>

Content. New developments

CoDo, a Combined Dosimetry model to help link *in vitro* data to *in vivo* exposures

It can link the responses observed *in vitro* to the corresponding *in vivo* doses.

Dose response library

It has been developed by simulation MPPD/ISDD
Dose guidance for tools and data integrity

Documentation
CoDo - CCombined Dosimetry model User Guide
Daina Romeo



Reviewer
Dr. Peter Wick
Particles/Biology Interaction Lab
Empa - Switzerland
November 1, 2020

<i>in silico</i> model	Data group	Data sub-group	Descriptor	Input/Output (I/O) for <i>in silico</i> model	Description
	Particle System		Particle system		unique identifier
			Material		chemical composition of NP (SiO ₂ , TiO ₂ , Fe ₃ O ₄ ...)
			Density (g/cm ³)		density of material at standard conditions
			Effective Density (MPPD) (g/cm ³)	I	density of NP, considering potential pore volume fraction <i>in vivo</i> (air)
			Effective Density (ISDD) (g/cm ³)	I	density of NP, considering potential pore volume fraction <i>in vitro</i> (fluid)
			Size (nm)	I	particle diameter of NP (monodispersity and spherical shape assumed)
<i>In vivo</i> (MPPD)	Exposure Condition (constant)		MPPD settings (for constant exposure scenario, i.e. at a fixed tidal volume)		
			Aerosol Conc. (mg/m ³)	I	NP concentration in the aerosol
			Exposure time/day (h)	I	duration of NP exposure per day
			# of days	I	number of consecutive exposure days



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Conclusions

- D2.1 provides an extensive overview of published/available tools and approaches for the different steps of the NRGF as defined in WP3
- Despite the availability of many tools and approaches, none of them is fit for all purposes, making it necessary to incorporate several tools covering different aspects into the RGF.
- There is a plethora of tools available for Step 2 of the RGF. However there is a dearth of tools and approaches for the other steps. An effective risk governance framework will require effective tools and approaches for the other steps that will have to be integrated into the platform in the future.
- This is a very dynamic field so the final recommendation is to continually update the tools and approaches in the RGF framework with the new content that may become available:

