



Gov4Nano: Meeting the needs of nanotechnology

making use of the legacy
of NanoReg2

Adriënne Sips, RIVM/NL

*This project has received funding from the European Union's Horizon 2020
Research and Innovation Programme under Grant Agreement 814401*



Gov4Nano: Facts and figures



Collaboration between 32 partners from:
11 EU Member States
1 Associated State (CH)
3 countries outside Europe (US, ZA, KR)



Involvement of industry (NIA, CEFIC, SOLVAY, ...)

Involvement of regulatory agencies (ECHA, EFSA)



Links to OECD, ISO, CEN

Links to former and ongoing H2020 and EU FP7 projects



Total costs \approx 8.6 M€, (including non-EU funded)



48 months duration; start January 2019



Gov4Nano overarching goal



develop a proof of concept of



an efficient and effective risk governance process for nanotechnologies,

dealing with the legacy as well as future technological developments.



STATE OF THE ART

Uncertainty about (especially longterm) health risks

Knowledge development in silo's

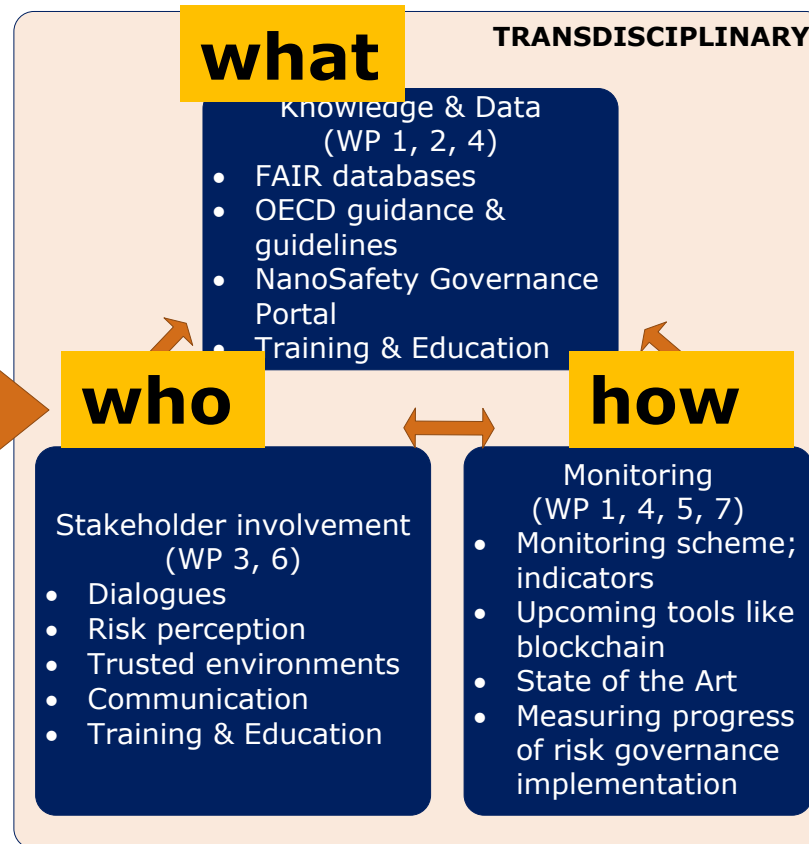
Urgency of nanospecific risk governance not adequately addressed

Big data, insufficiently exploited, not FAIR

Safety and innovation insufficiently connected

Insufficient dialogue between stakeholders and with civil society

Gov4Nano



WAY FORWARD

DESIGN OF NRCG
Theoretical Risk Governance Model

ESTABLISHED
NRCG
Operational Risk Governance Model



Gov4Nano: FAIRness of data infrastructure



- An international EHS nano alliance to agree on standards, ontologies, FAIR principles
- Working towards machine learning and Artificial Intelligence (data mining)
- Stimulate the EU Initiative on the European Open Science Cloud with GO-FAIR Initiative (NL/DE)
- Defining minimal data sets, required in all EHS nano databases



FAIR data	NanoReg2	Gov4Nano
Findable	collaboration with NANoREG, Calibrate, etc.	Expanding to other projects and initiatives
Accessible	ontologies	Also link to EMMC and NanoCOMMONS work
Interoperable		
Reusable	First steps in industry case studies	Collaboration with new nanoinformatics projects

Gov4Nano: scientific support for OECD TG &GD



- Part of the so-called Malta Initiative to join (EU) forces to accelerate the nano-specific adaptations of OECD TG/GD for e.g. physicochemical characterization, transformation, exposure and hazard assessment.
- Joint action of various European MS, supported by Republic of Korea & South Africa
- Dedicated regulatory risk research - experimental work and the translation of scientific results for regulatory adaptation or additional guidance
- Specific endpoints to be addressed: surface chemistry, solubility, reactivity and dustiness of nanomaterials



Gov4Nano: engaging society

- From concerned people to involved people
- Activities focus on: listen, ask, understand, inform
- Develop a programme for civil society for sensitisation and create awareness about nanotechnology leading to the ability to ask the right questions



Gov4Nano: from science to toolbox

- A portal encompassing all types of tools and guidance for building on trust among stakeholders & for effective dialogues
- Covers the process to applicability and acceptance (regulatory or industrial)
- Consolidate and provide tools initiated in projects like NANoREG, NanoReg2, caLIBRAtE and Sun
- Activities in support of implementation of the portal and train the users

Towards accepted and applied tools

	NanoReg2	Gov4Nano
Toolbox	SIA toolbox SbD implementation platform	Uptake in portal; basis for SbD tools
Acceptance	Raising awareness, including pilots on applicability by industry	Developing process on how to come to acceptance
Application	Industry case studies	Way of working

Gov4Nano: Nano Risk Governance Council

- NRGC is a missing element in the current governance landscape for nanotechnology
- Transformation of IRGC's risk governance model for nanotechnology towards a transdisciplinary and operational model
- The ultimate success or failure of the NRGC will depend on the extent to which it is recognised as having (i) independence, (ii) authority, (iii) integrity and (iv) trust (values not easily granted)



Gov4Nano: interaction stakeholders

- Formation of stakeholders community
- Background and force field analysis of industrial and regulatory stakeholders
- Engaging industry and authorities within NRGCS stakeholder community
- Engaging global translational nano-innovation and nanosafety research community within NRGCS
- Aligning risk governance with on-going global efforts for standardisation and harmonisation of methods

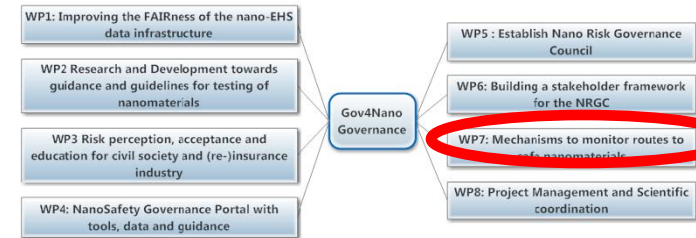


Towards

	NanoReg2	Gov4Nano
Facilitating stakeholder interaction	Concept of Trusted Environment	How to put TE concept into practice
	Identifying barriers for SbD	Take them into account in NRGC

Gov4Nano: mechanisms to monitor progress

- Develop a methodology for monitoring progress in risk governance of nanotechnologies in Europe and beyond
- Identify instruments that the NRGC can apply to monitor scientific evidence and emerging needs in order to ensure that the newly generated open data adheres to the minimum data requirements across the different sectors (chemicals, biocides, cosmetics, food, medicine)
- Blockchain as one of those instruments: applicability, feasibility, design criteria
- These instruments will be developed during the project and will become the cockpit tools for the NRGC to continuously evaluate its own agility for governance initiatives



Monitoring progress

	NanoReg2	Gov4Nano
Communicating efforts	SbD scenarios	Further development, outcomes as (part of) indicator
	First steps in exploring relevant topics that can serve as indicator	Development and application of a set of relevant indicators

How could NanoReg2 support Gov4Nano

- Outcomes; describe the status of your products, ready for acceptance, for implementation, by whom? Etc.
- Active distribution of your products to newly started projects like Gov4Nano, NANoRIGO, RISKGONE, but also to the new nanoinformatics projects
- Active input to the NSC subcluster regulation and governance

