



Challenges in organisation & research of risk governance of Nanotechnologies

Monique Groenewold, RIVM

6TH SAFERA Symposium *Safety in the new economy and energy transition*

May 19, 2022



NANORIGO: Grant N°814530

RiskGONE: Grant N°814425

Gov4Nano: Grant N°814401

Content

- Short introduction Risk Governance
- State of the art in EU research on Nano Risk Governance
 - NMBP-13 projects: expected impact and results
- Changing policy ambitions: green deal and Chemical Strategy for Sustainability, new demands for nanotechnology
- Regulatory Research needs: results of two Gov4Nano summits

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Innovation

Risk

Benefits

Regulations

Production

Communication

Perception





Governance



Risk governance

Governance refers to the actions, processes, traditions and institutions by which authority is exercised and decisions are taken and implemented.

- Involves **Multi-disciplinary** sciences and
- **multi-stakeholder** approaches
- A FRAMEWORK for risk governance is based on a defined and structured **process** to addressing **risk** in a comprehensive and holistic manner
 - Identification
 - Assessment (hazard, exposure, vulnerability)
 - Evaluation of acceptability, decision-making
 - Management and regulatory-relevant recommendations
 - Communication of risks

There exist already many 'frameworks' and tools, primarily for risk and safety assessment of nanotechnology

Environment International 95 (2016) 36–53

Contents lists available at ScienceDirect

Environment International

journal homepage: www.elsevier.com/locate/envint

ELSEVIER

Review article

Frameworks and tools for risk assessment of manufactured nanomaterials

Danail Hristozov ^{a,*}, Stefania Gottardo ^b, Elena Semenzin ^a, Agnes Oomen ^c, Peter Bos ^c, Willie Peijnenburg ^d, Martie van Tongeren ^d, Bernd Nowack ^e, Neil Hunt ^f, Andrea Brunelli ^a, Janeck J. Scott-Fordsmand ^g, Lang Tran ^d, Antonio Marcomini ^a

Nano Today (2014) 9, 546–549

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/nanotoday

ELSEVIER

NEWS AND OPINIONS

A unified framework for nanosafety is needed

Janeck J. Scott-Fordsmand ^{a,*}, S. Pozzi-Mucelli ^b, L. Tran ^c, K. Aschberger ^d, S. Sabella ^e, U. Vogel ^f, C. Poland ^c, D. Balharry ^g, T. Fernandes ^g, S. Gottardo ^d, S. Hankin ^c, M.G.J. Hartl ^g, N.B. Hartmann ^{d,1}, D. Hristozov ^b, K. Hund-Rinke ^h, H. Johnston ^g, A. Marcomini ^b, O. Panzer ⁱ, D. Roncato ^j, A.T. Saber ^f, H. Wallin ^f, V. Stone ^g

nature nanotechnology

ARTICLES

<https://doi.org/10.1038/541565-018-0120-4>

A framework for sustainable nanomaterial selection hazard, a

Mark M. Falinski ¹, and Julie B. Zimmer

Engineered nanomaterials



RISK GOVERNANCE AND RESEARCH & INNOVATION PRIORITIES IN NANOTECHNOLOGIES

FIRST BRIEFING REPORT WITH A FOCUS ON FOOD, HEALTH AND THE ENERGY SECTOR



Home Events Nano-Risk Governance Portal NanoSafety Cluster Week Partners Results Reso

News / Get involved: Test risk governance models

Get involved: Test risk governance models

Are you involved in activities concerning R&D, production, marketing, use, risk assessment and management, inspection, insurance, etc. caLIBRAte invites you to get involved in the project and test one of the models identified as potentially suitable:

- Nanosafer Control Banding
- GUIDEnano
- LICARA nanoscan
- BAUA Sprayexpo 2.3
- Stoffenmanager Nano
- ANSES CB Nanotool
- Control banding nanotool
- Precautionary Matrix
- ISO / TS 12901-2
- ConsExpo Nano
- SimpleBox4Nano (SB4N)
- SUNDs

The caLIBRAte framework will link different nano-specific models and methods into a system-of-systems (SoS), which companies can use for the assessment, prioritisation and management of occupational, consumer and environmental risks associated with production and use. The models will be aligned to support decisions along the research and innovation value chain, from basic research to market launch.

So, what else do we need?

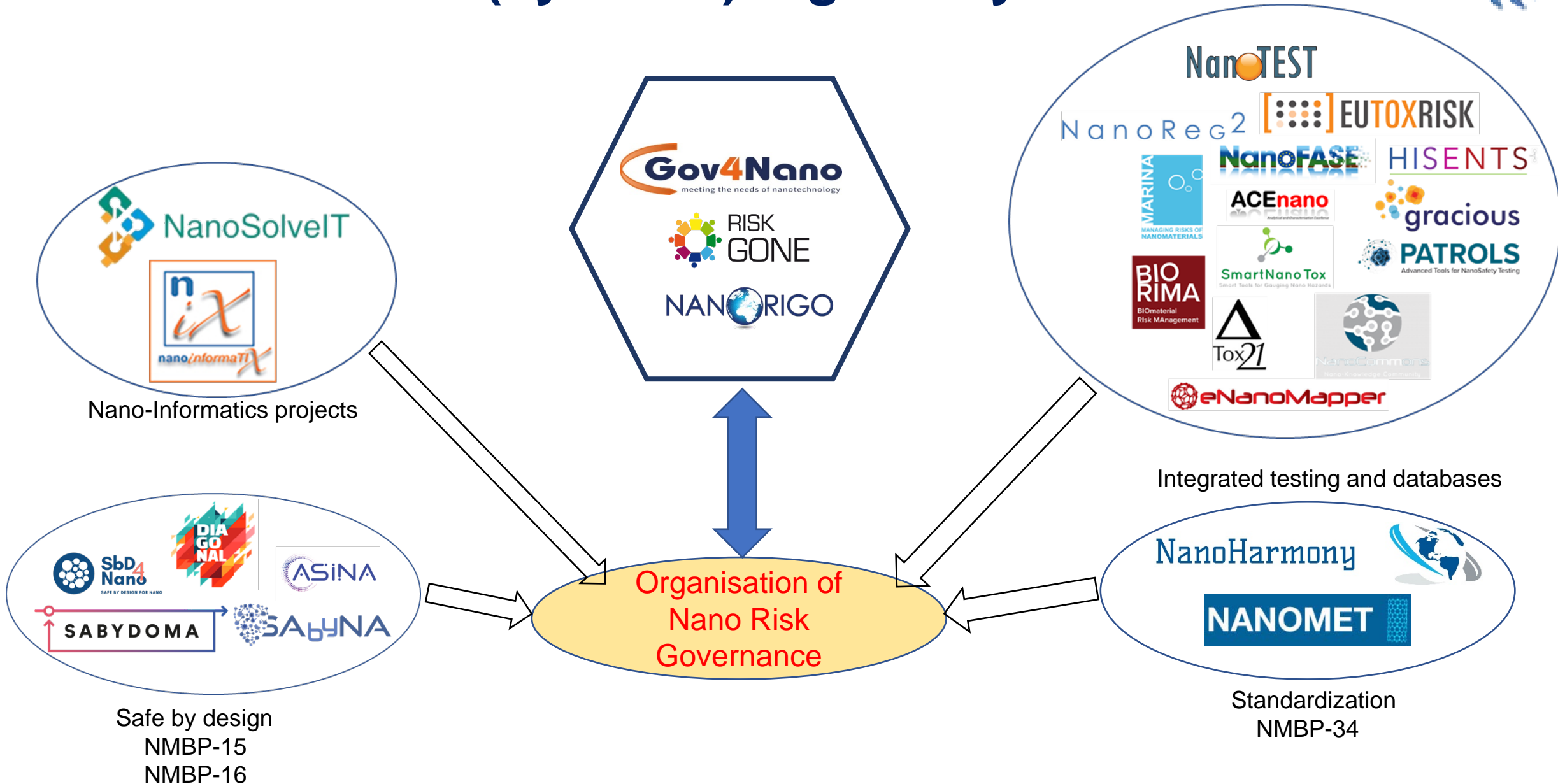
Framework for nanotechnology risk governance

1. **Integrate** important concepts, principles and tools
2. Access to **data** and guidance on how to obtain high quality data / outcome of knowledge-based risk assessment
3. Access to **tools** for risk assessment and risk management
4. Provide recommendation on **responsible** and transparent communication between **stakeholders**
5. Support to identify future scientific and regulatory research needs: address **current as well as future challenges**

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Research work in (dynamic) regulatory context



Societal challenge

- Nanotechnology has high economic potential and thereby impacts a broad range of industries and applications
- Interaction of engineered nanomaterials with the living environment is complex and is marked by uncertainty and ambiguity
- Urgent need to develop appropriate risk governance structures, to ensure full potential through trust of all stakeholders



- €8.6M budget
- 01/19 to 12/22
- 32 partners
- 15 countries
- Coordinated by RIVM (NL)
- Grant agreement No. 814401

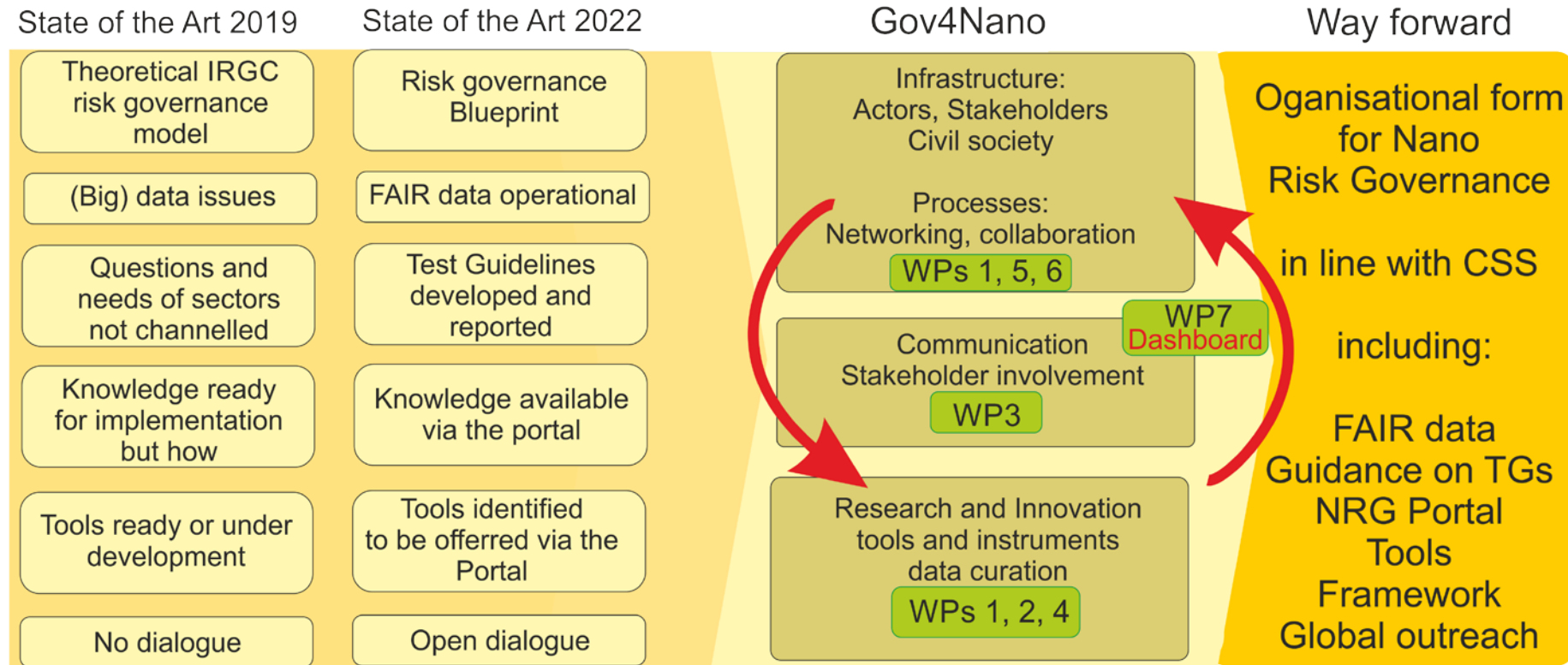


- €4.7M budget
- 01/19 to 02/23
- 28 partners
- 14 countries
- Coordinated by Aarhus (DK)
- Grant agreement No. 814530



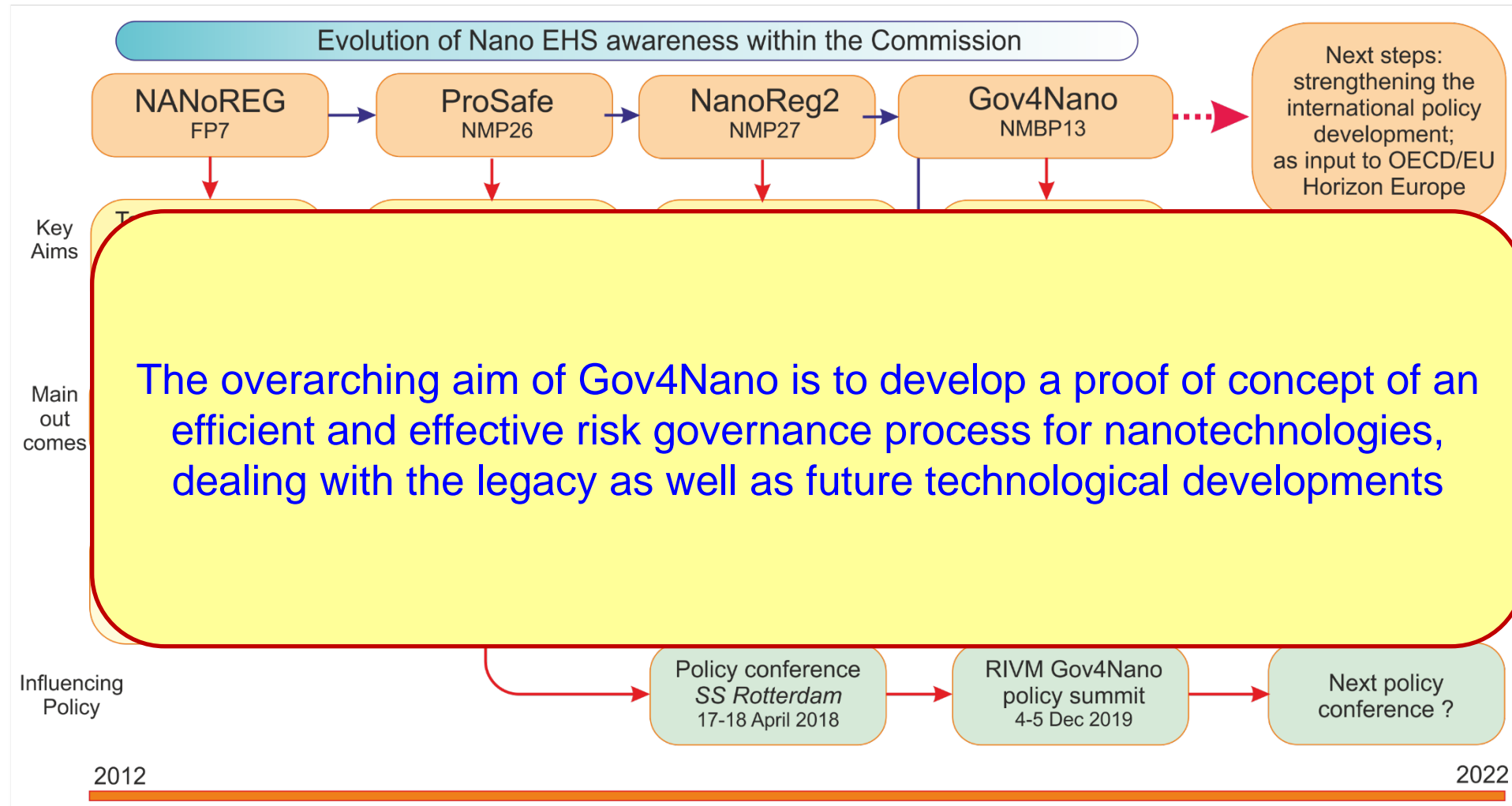
- €5M budget
- 01/19 to 02/23
- 22 partners
- 17 countries
- Coordinated by NILU (NO)
- Grant agreement No. 814425

Setting the scene: the need for Gov4Nano

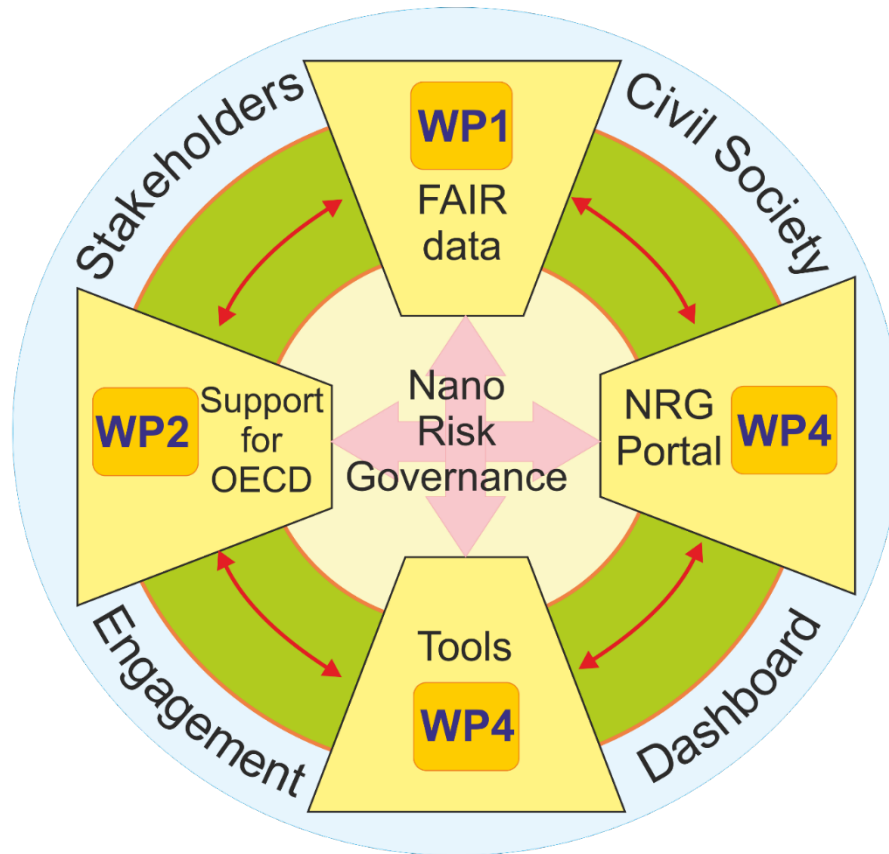


Agile and adaptable: meeting the changing needs of society

The process to Gov4Nano and the aims



Key building blocks for Nano Risk Governance



- **Cover all domains:** chemicals, biocides, consumers, food, medicine
- **Connect** key organizations and stakeholders (EU and global)
- **Integrate** important concepts, principles and tools
- Access to **data** and guidance on how to obtain high quality data
- Access to **tools** for risk assessment and risk management
- Support to identify future scientific and regulatory research needs
- Address **current & future challenges**
- **Responsible** and **transparent** communication between **stakeholders**

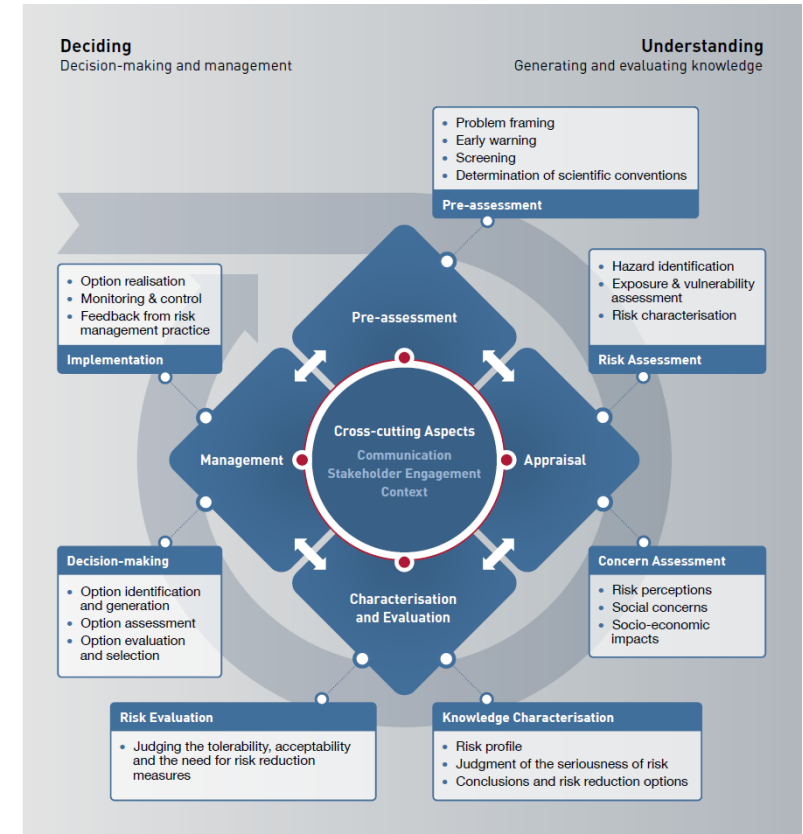
Outcome

- Proof of concept of an effective risk governance process
- Operational Nanotechnology Risk Governance Framework
- Nano Risk Governance Portal
- Blue print for an organization for Nano Risk Governance



Nano Risk Governance Framework

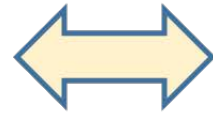
- All domains: chemicals, biocides, consumers, food, medicine
- Connecting key organizations and stakeholders (EU and global)
- Decision making framework
- Future-proof based on International Risk Governance Council
- Integrates scientific data and operational tools
- Participative and pro-active role for stakeholders
- Based on existing risk governance infrastructure



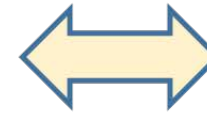
<https://irgc.org/risk-governance/irgc-risk-governance-framework/>

Nano Risk Governance Framework

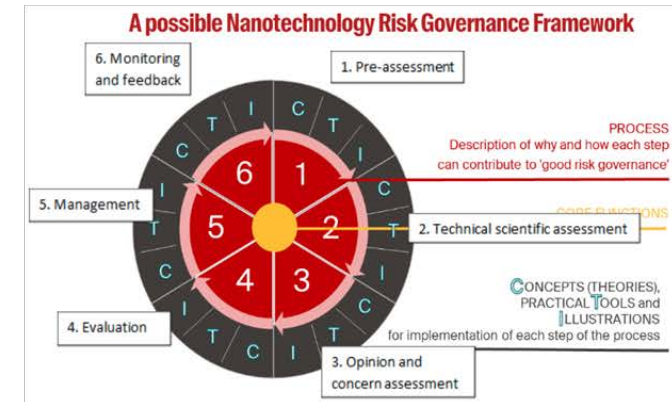
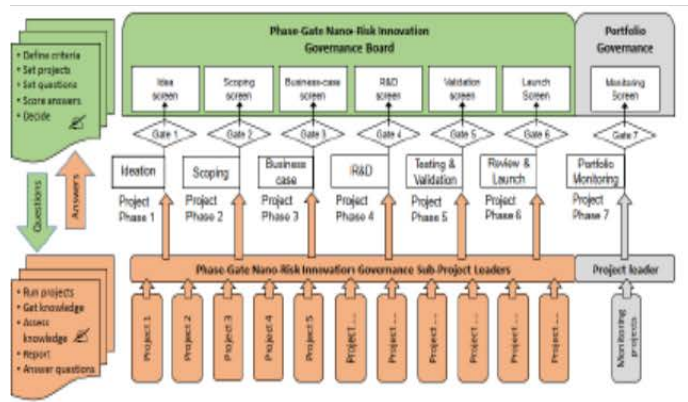
Validated framework and tools



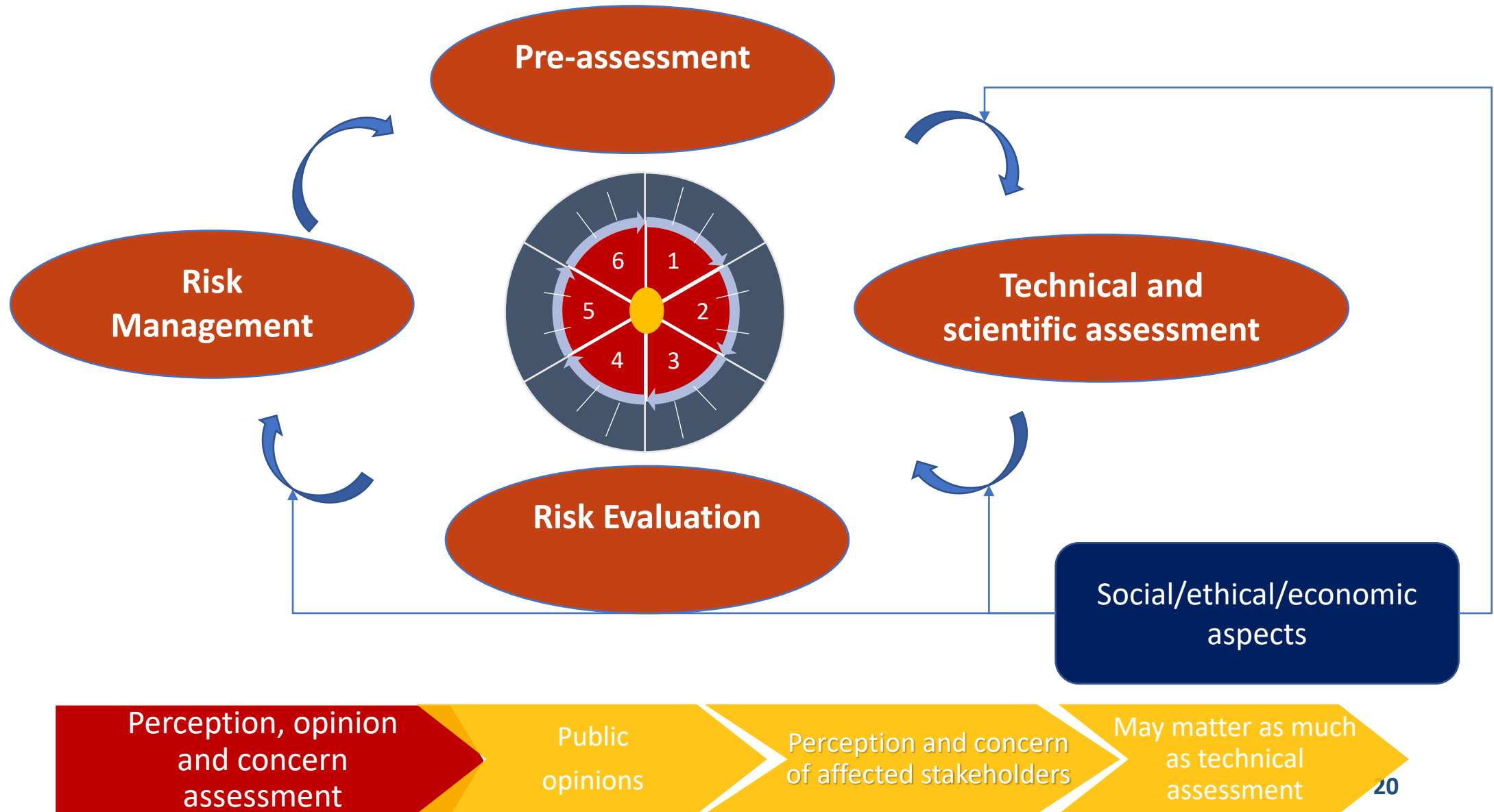
Software Architecture



Stakeholder involvement

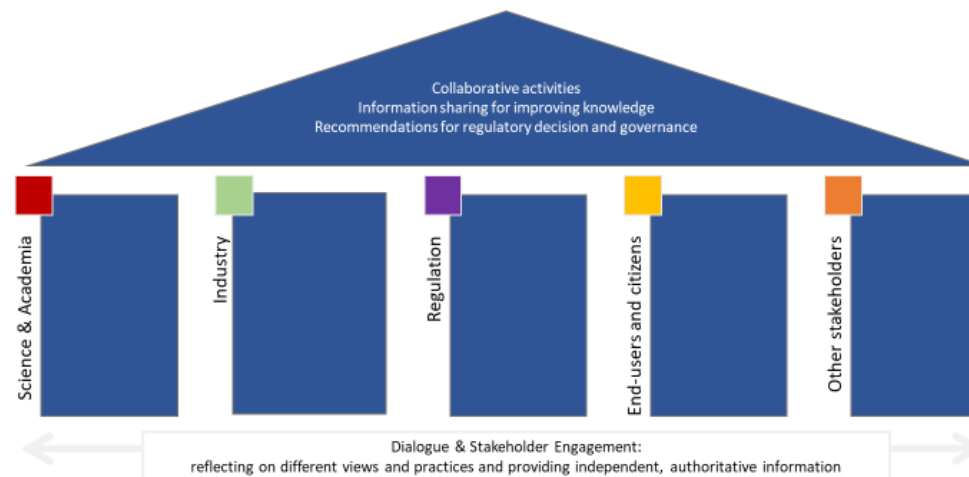


Nano Risk Governance Framework – under construction

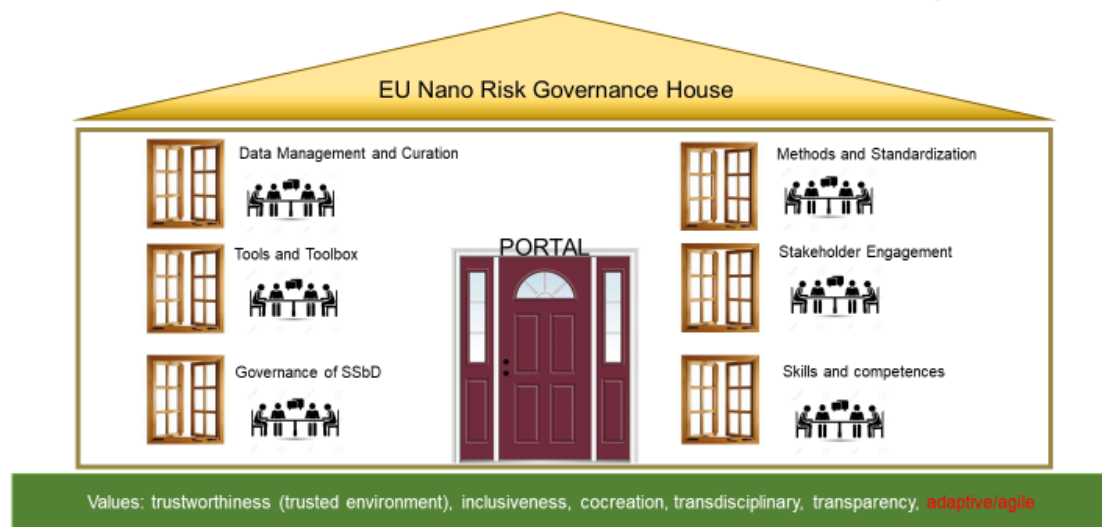
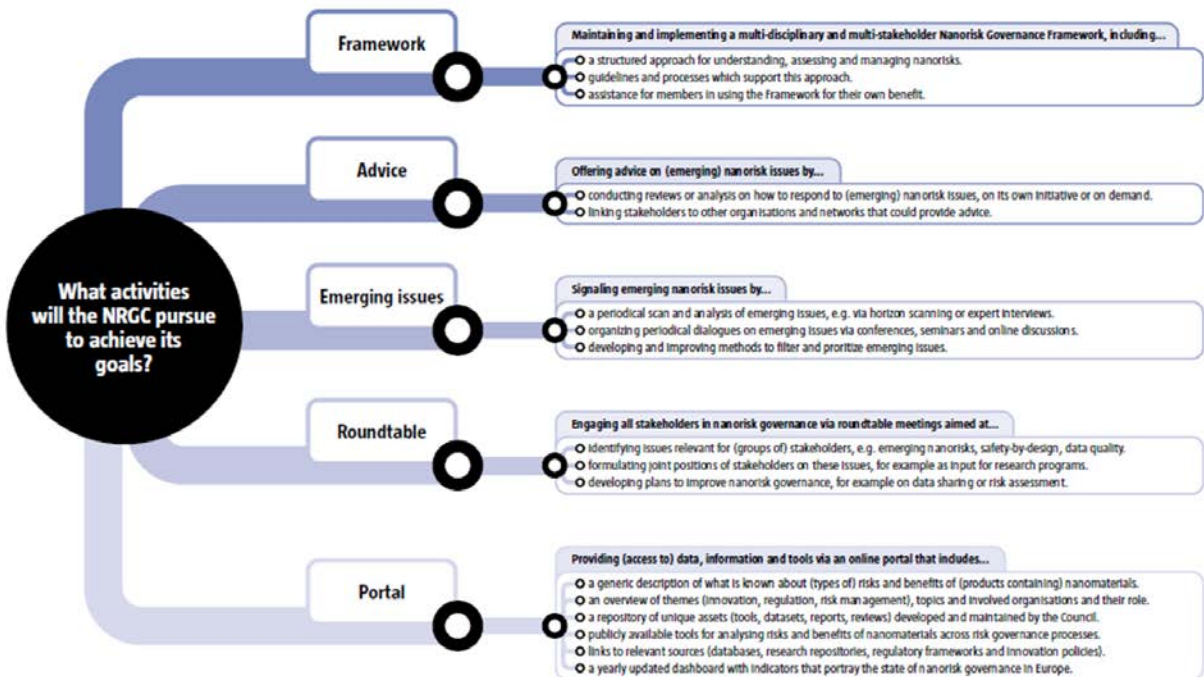


Organisation for Nano Risk Governance

- The main purpose is: fostering safe and sustainable development and use of nanomaterials in Europe.
- Put the framework into practice
- Overarching, independent, trustworthy body
- Bridge between knowledge generators and decision makers
- Services for all stakeholders



A new concept: the EU Nano Risk Governance House




 Gov4Nano: Grant N°814401
 NANORIGO: Grant N°814530
 RiskGONE: Grant N°814425

Ambition: To foster safe and sustainable development, use and disposal of (products containing) nanomaterials in Europe

Nano Risk Governance Portal

- Infrastructure integrates academic, industry and regulatory information
- Support decision making framework & council
- Validated state-of-the-art tools
- NANoREG, caLIBRAte, NanoCommons & NanoReg²
- QA/QC processes and decision tree
- Process for collection and harmonisation of data
- Covers applicability and acceptance (regulatory or industrial)

Content

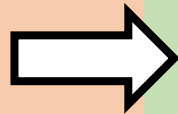
New NMBP-13 tools

Existing Tools from previous projects / Other developers (validated or evaluated)

FAIR DataBase(s)

Standards and Guidances

Selection of nodes

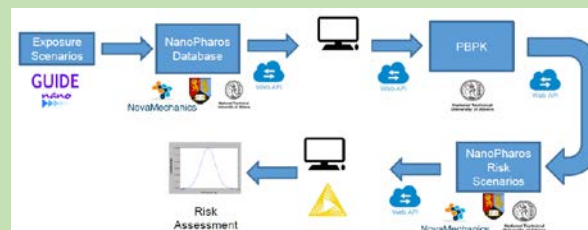


Possible interoperable Software Architecture

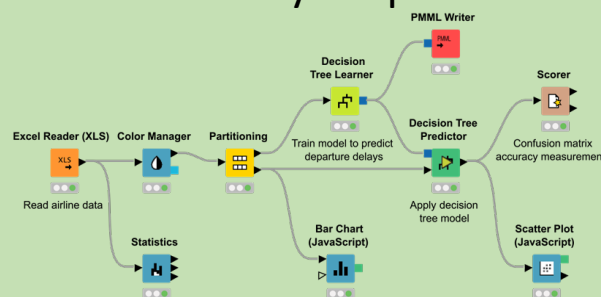
Technical Implementation



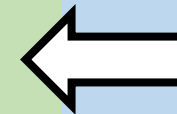
Docker



KNIME Analytics platform



Workflows



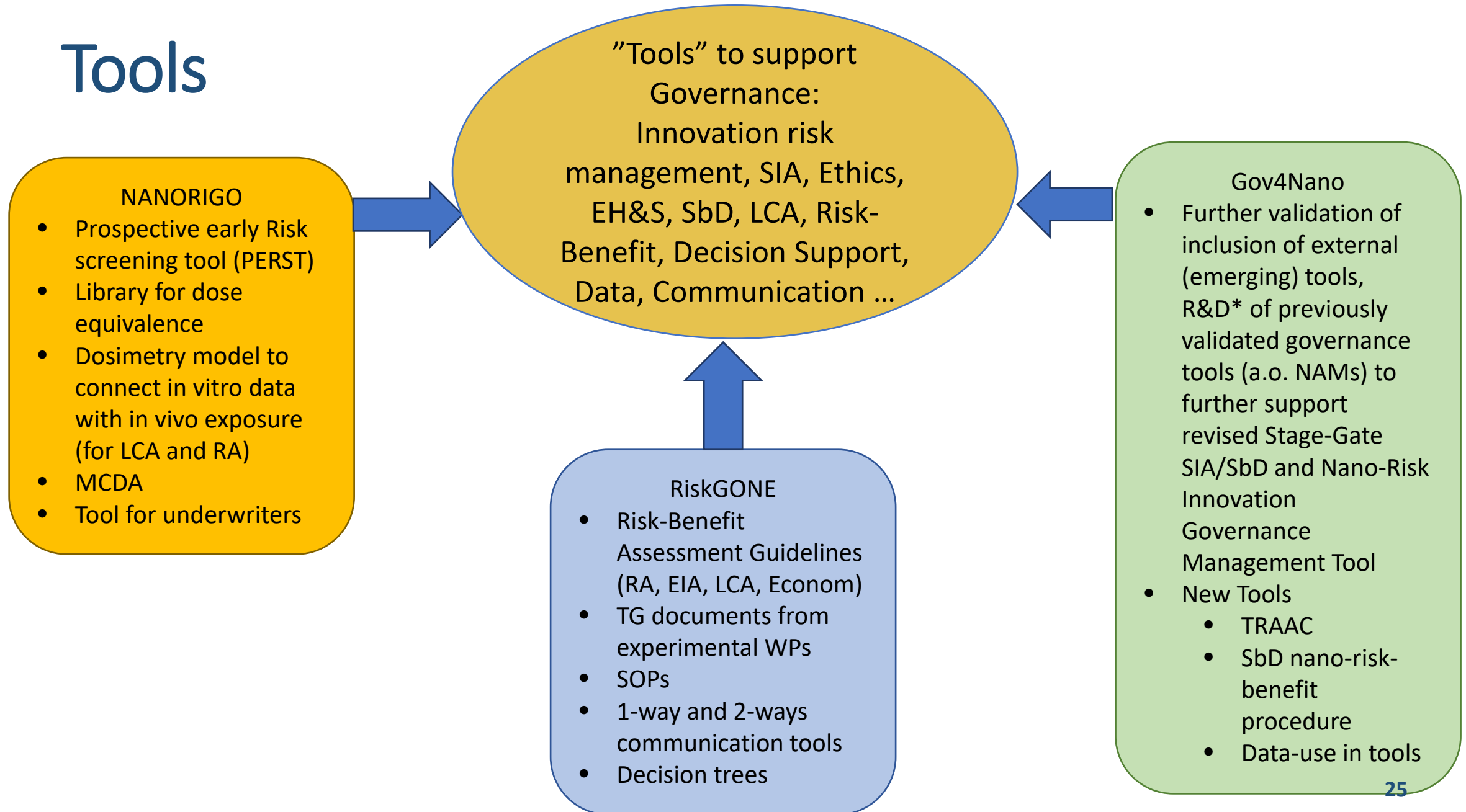
Guiding Logic

Nano Risk Governance Framework

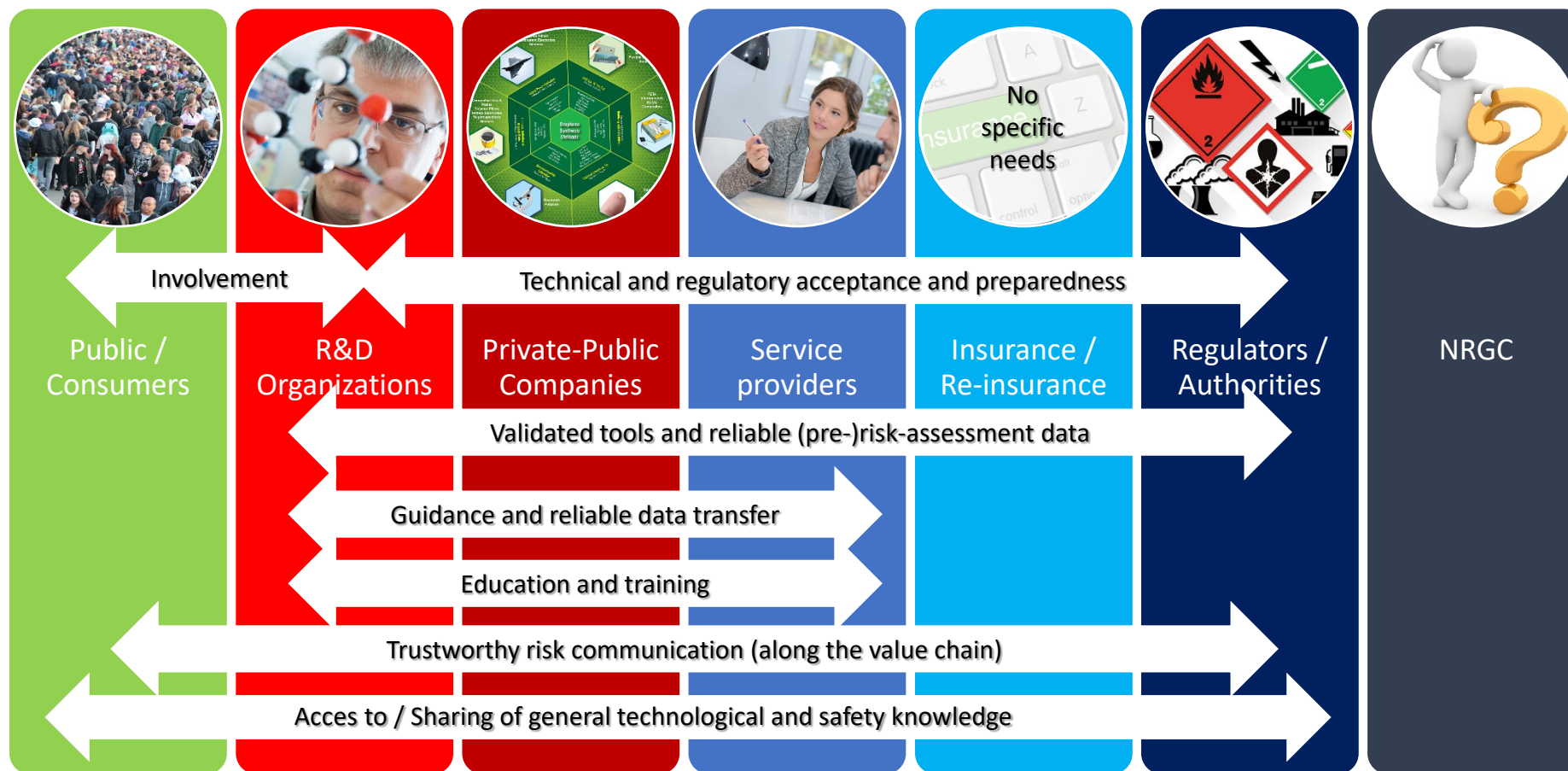
Building blocks

Guidance – Decision Trees

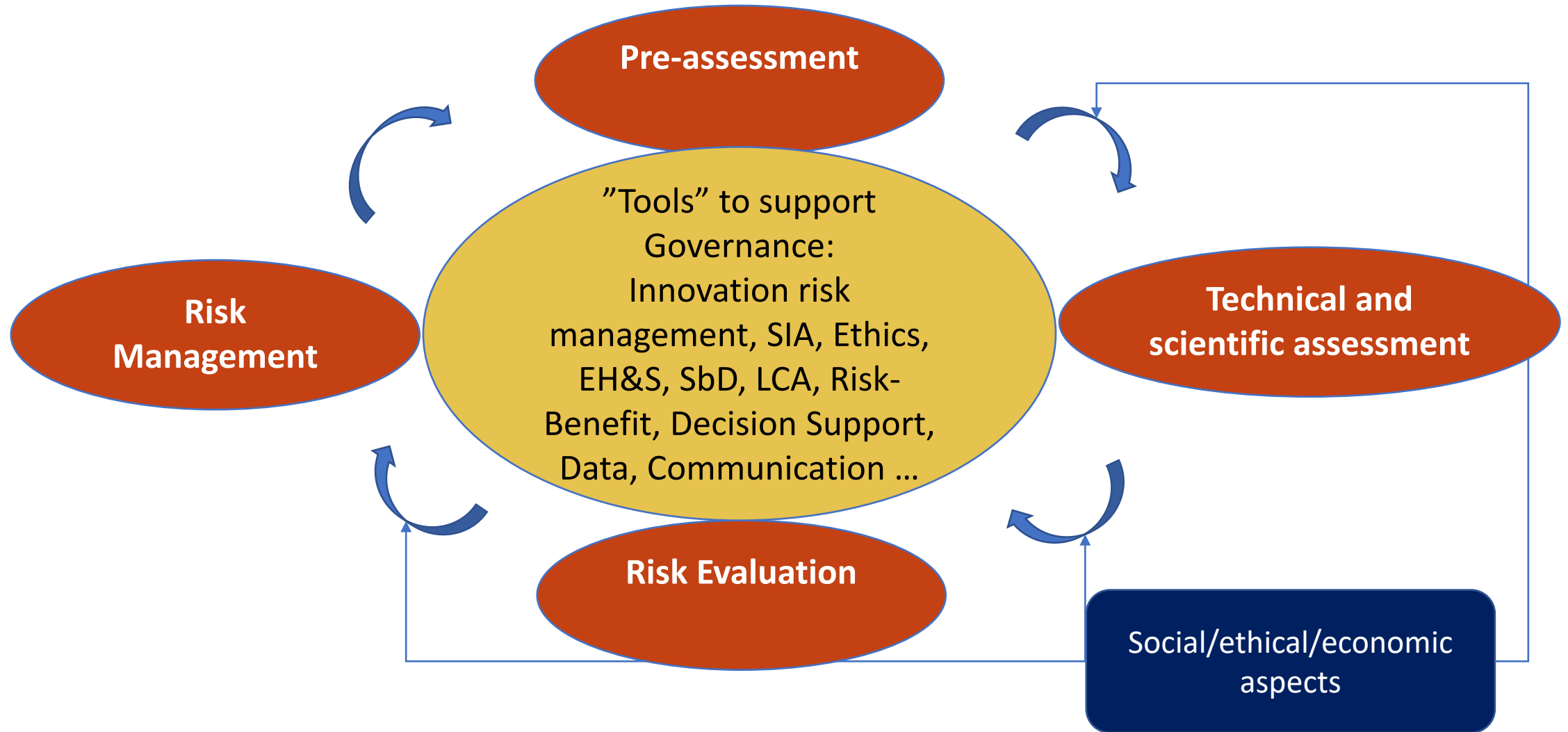
Tools



Main needs from stakeholders



Nano Risk Governance portal – under construction



Portal & tools - Scientific support for guidelines

- Collaboration with Malta Initiative to join (EU) forces
- Nano-specific adaptations of OECD TG/GD
- Dedicated regulatory risk research & experimental work
- Specific endpoints to be addressed: surface chemistry, solubility, reactivity and dustiness of nanomaterials, ecotoxicity and in vitro cytotoxicity and in vitro genotoxicity

The Malta Initiative

The  Initiative –
A European Action to Develop OECD Test
Guidelines for Nanomaterials

- A joint route towards standardisation, testing guidelines and guidance documents.

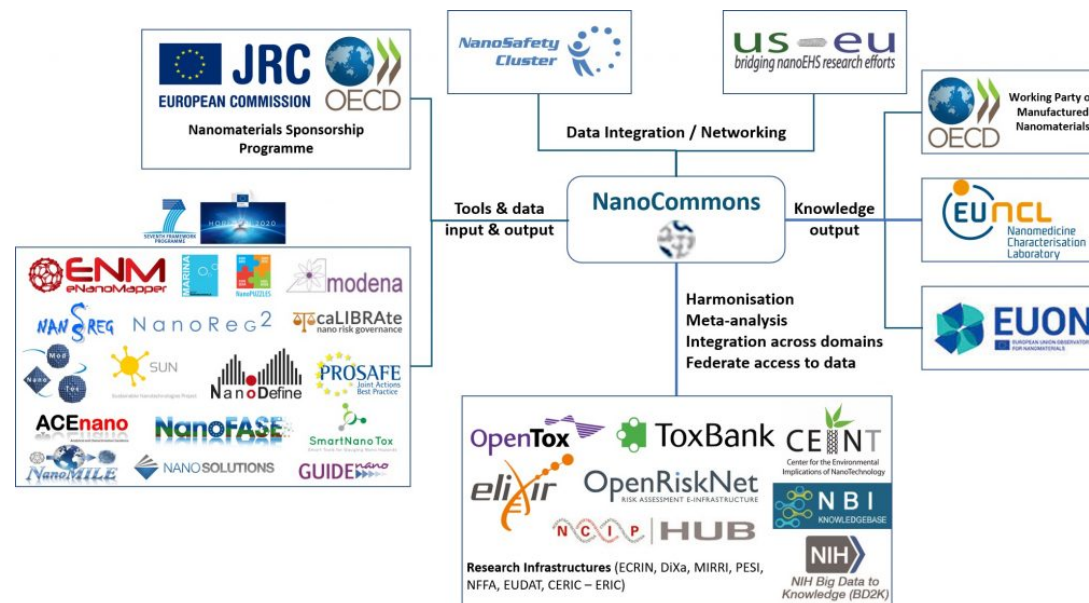
NanoHarmony



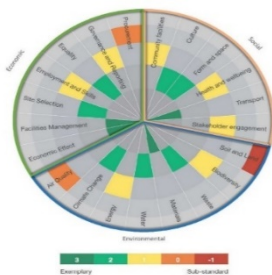
Testing and Assessment

Section 1 Physical Chemical Properties	Section 2 Effects on Biotic Systems	Section 3 Env. Fate and Behaviour	Section 4 Health Effects
<p>TG on determination of the (volume) specific surface area of manufactured nanomaterials (EU) WNT 1.3</p> <p>TG on particle size and size distribution of manufactured nanomaterials (DE) WNT 1.4</p> <p>GD on determination of solubility and dissolution rate of nanomaterials in water and relevant synthetic biological media (DK/DE) WNT 1.5</p> <p>GD on identification and quantification of the surface chemistry and coatings on nano- and microscale materials (DK/DE) WNT 1.6</p> <p>TG on determination of surface hydrophobicity of manufactured nanomaterials (EU) WNT 1.7</p> <p>TG on determination of the dustiness of manufactured nanomaterials (DK/FR) WNT 1.8</p>	<p>Adaptation of OECD TGs 201, 202 and 203 for the determination of the acute ecotoxicity of manufactured nanomaterials (EU) WPMN</p> <p><i>ENV/CBC/NANO(2021)7</i></p>	<p>TG on dissolution rate of nanomaterials in aquatic environment (DE) WNT 3.10</p> <p>TG for nanomaterial removal from wastewater (US) WNT 3.11</p> <p>GD on assessing the apparent accumulation potential for nanomaterials (ES) WNT 3.12</p> <p>GD to support implementation of TG 312 for nanomaterial safety testing (CA/DE) WNT 3.14</p> <p>GD on environmental abiotic transformation of nanomaterials (AT) WNT 3.16</p> <p>Scoping review for a tiered approach for reliable bioaccumulation assessment of manufactured nanomaterials in organisms minimising use of vertebrate tests (UK) WPMN</p> <p><i>ENV/CBC/NANO(2021)9</i></p> <p>Assessment of the durability of NMs and their surface ligands in env. surroundings (biodegradable/biodegradable) (SA/Korea) WPMN</p>	<p>GD on the adaptation of <i>in vitro</i> mammalian cell based genotoxicity TGs for testing of manufactured nanomaterials (EU)</p> <p>Applicability of the key event based TG 442D for <i>in vitro</i> skin sensitisation testing of nanomaterials (CH) WNT 4.133</p> <p>TG on toxicokinetics to accommodate testing of nanoparticles (NL/UK) WNT 4.146</p> <p>Integrated <i>in vitro</i> approach for the determination of the intestinal fate or orally ingested nanomaterials (IT) WPMN</p> <p><i>ENV/CBC/NANO(2021)8</i></p> <p>GD on the determination of concentrations of nanoparticles in biological samples for (eco)toxicity studies (UK) WNT</p>

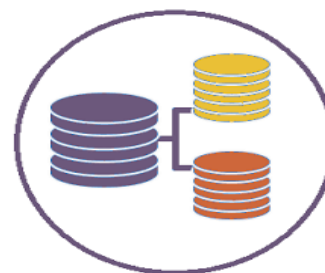
Data management – overall picture



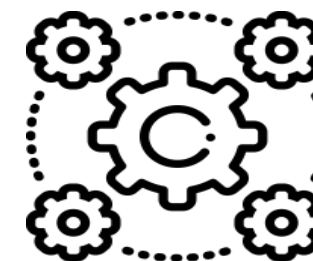
Data management plans



Quality/fitness for re-use scoring of datasets



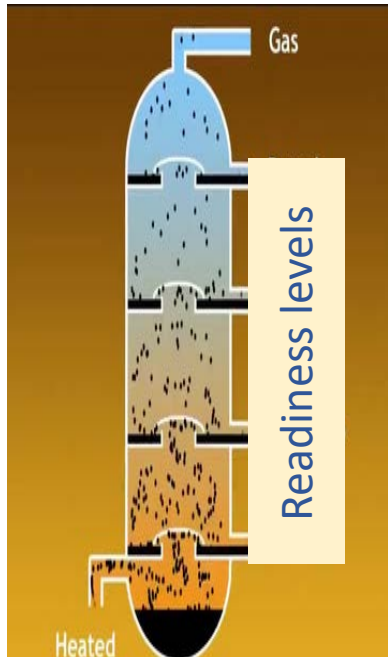
Datasets to support case studies



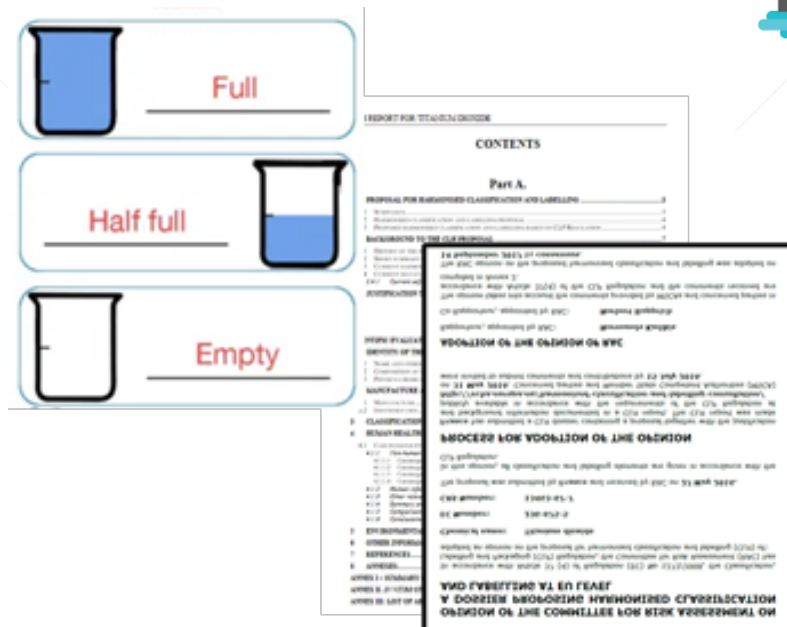
Interoperability and automation

Data management from concept to implementation.....

Conceptualisation & user needs documentation



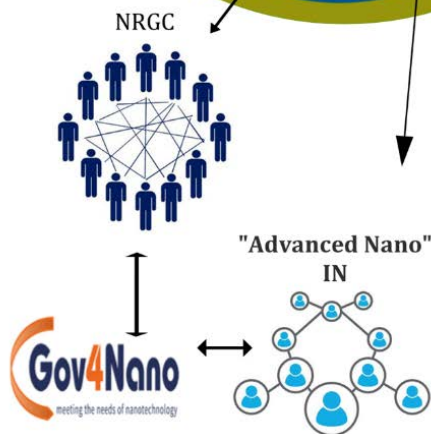
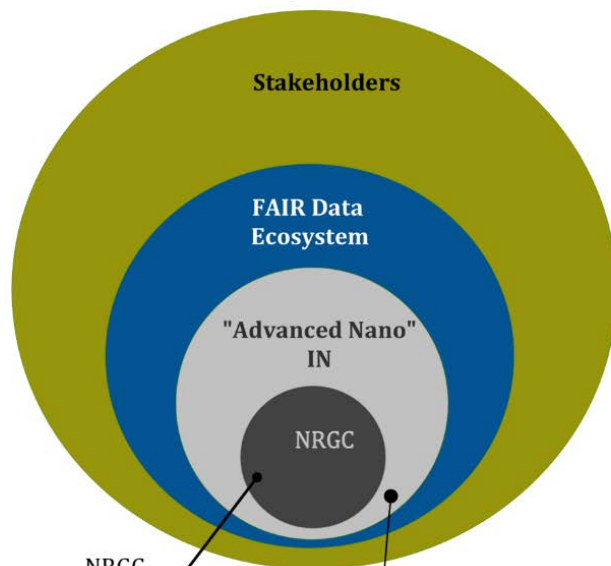
Community consensus on data standards (metadata, FAIR metrics) => stepwise SOP for data quality / re-usability



Operationalisation & automation (tooling) to facilitate data re-use, decision making & sustainability



FAIR databases are key – Findable, Accessible, Interoperable and Reusable



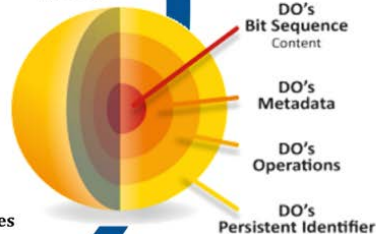
A free flow of high-quality, FAIR, NanoEHS data is essential for effective risk governance

- Science-based decision making
- Reuse of existing data
- Harmonisation of data templates

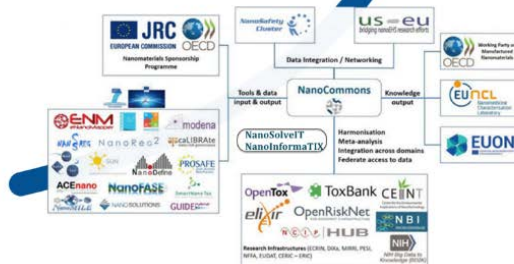
National, Industrial, Institutional, and local data repositories



FAIR Digital Objects (FDOs)

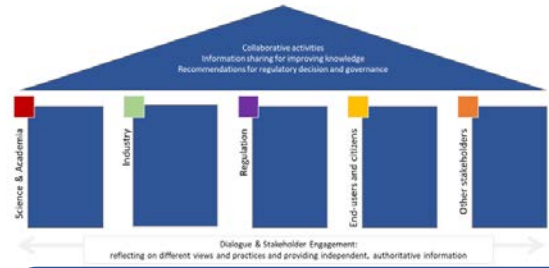


NanoEHS databases



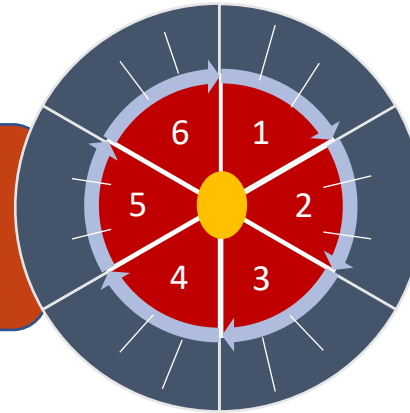
NANOEHS--GO FAIR IMPLEMENTATION NETWORK

www.go-fair.org/advancednano/



House of Nano-Risk Governance

Nano-Risk Governance Framework



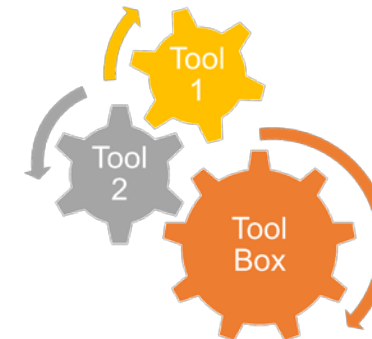
Nano-Risk Governance Portal

Guidances and guidelines

FAIR – databases

“Tools” to support Governance:
Innovation risk management, SIA, Ethics, EH&S, SbD, LCA, Risk-Benefit, Decision Support, Data, Communication ...

Stakeholder Needs and Priorities?

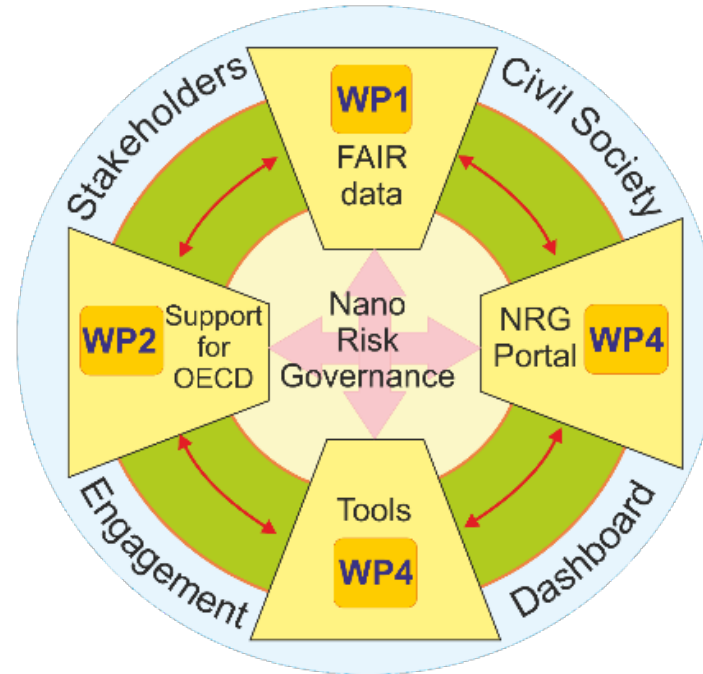


Suitable & Valid?

Systematic approach for efficient and effective Nano Risk Governance

- infrastructure for stakeholder engagement & collaboration
- networks for harmonization, improved data quality, international collaboration
- coordination and prioritization research needs for regulatory risk assessment
- monitoring system

- Access to **high quality data** & tools for decision making
- **Improved standardisation and validation process**



- Implementation **FAIR principles**
- **Risk governance portal and platforms:** knowledge & information sharing

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1. NEW POLICY AMBITIONS: EU Green Deal

The European Green Deal is about **improving the well-being of people**. Making Europe climate-neutral and protecting our natural habitat will be good for people, planet and economy. No one will be left behind.

The EU will:



Become
climate-neutral
by 2050



Protect human life,
animals and plants,
by cutting pollution



Help companies
become world leaders
in clean products and
technologies



Help ensure a
just and inclusive
transition

EU Strategies: providing direction and goals

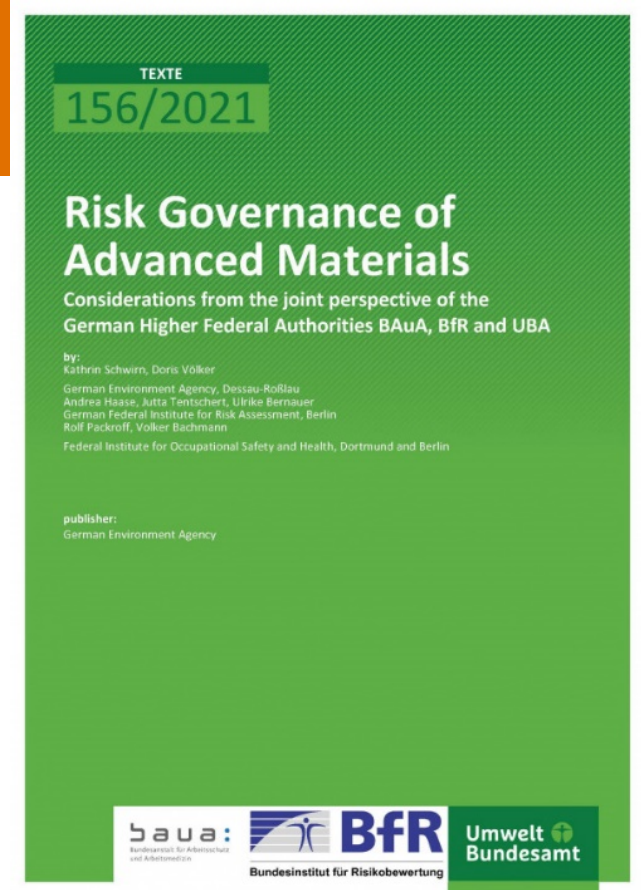


...many more..



Key role for new materials

Potential to provide technical solutions for pressing global challenges, i.e. for energy revolution, digitalisation, or health care



So PACE of development and application of (advanced) nanomaterials is stimulated by GD policy ambitions – MODERN INNOVATION POLICY

URGENCY for solutions

Pollution crosses 'planetary boundary'

The production of plastics and other pollutants now outstrips our ability to monitor it and threatens global ecosystems. Researchers at the Stockholm Resilience Centre conclude that **chemical pollutants** have crossed a 'planetary boundary'. The concept stems from an influential 2009 *Nature* paper that suggested nine boundary conditions in the Earth system that could, if crossed, result in tipping points that could harm human life. At the time, the impact of chemical pollutants was not known — but now, we've gone too far, say the researchers. "The total mass of plastics now exceeds the total mass of all living mammals," says ecotoxicologist and study author Bethanie Carney Almroth. "That to me is a pretty clear indication that we've crossed a boundary on chemical pollution." The authors call for a global organization focused on industrial waste products,

ENVIRONMENTAL
Science & Technology

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Policy Analysis

Outside the Safe Operating Space of the Planetary Boundary for Novel Entities

Linn Persson,* Bethanie M. Carney Almroth, Christopher D. Collins, Sarah Cornell, Cynthia A. de Wit,* Miriam L. Diamond, Peter Fantke, Martin Hassellöv, Matthew MacLeod, Morten W. Ryberg, Peter Søgaard Jørgensen, Patricia Villarrubia-Gómez, Zhanyun Wang, and Michael Zwicky Hauschild

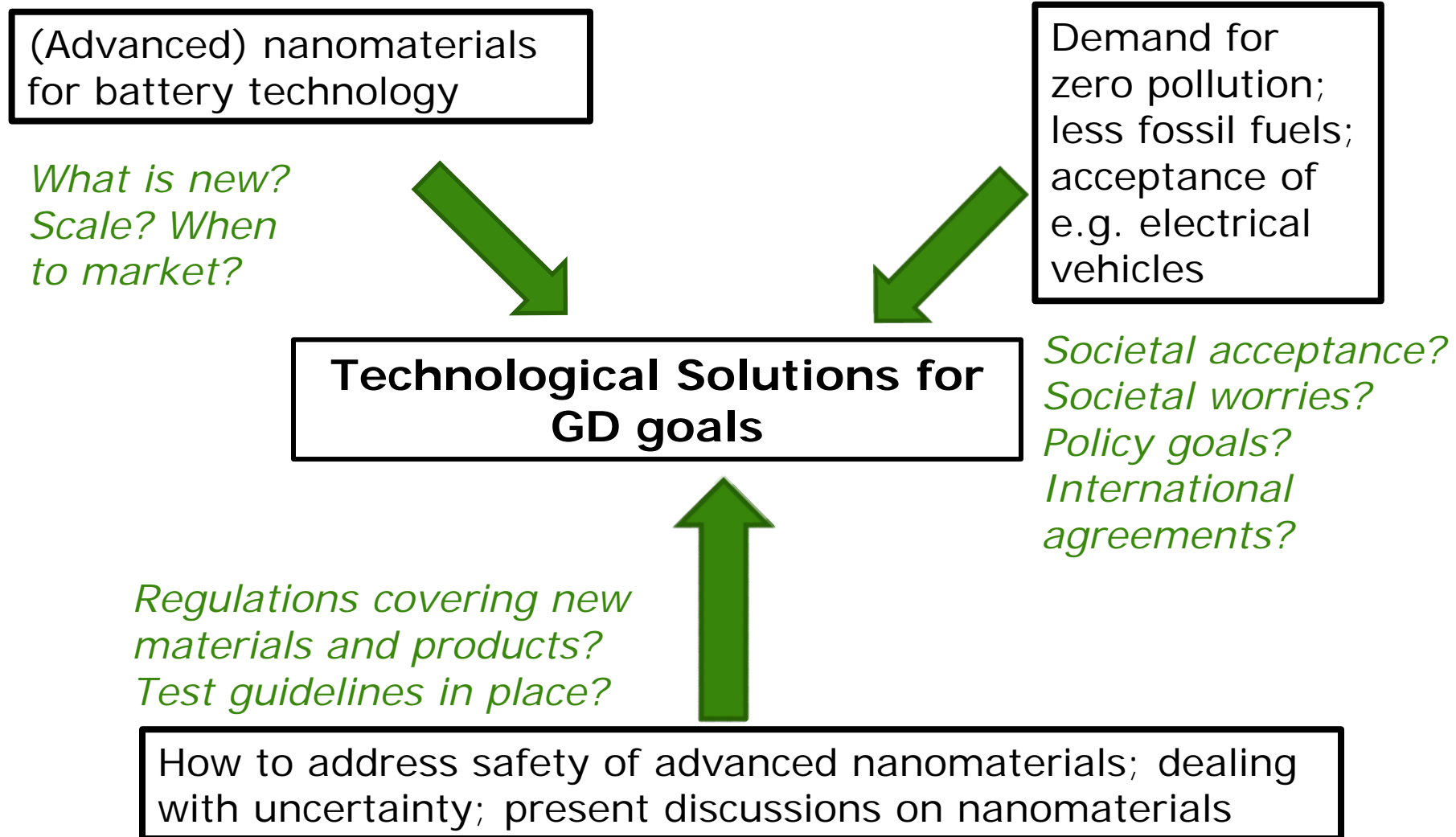
January
2022

Cite This: <https://doi.org/10.1021/acs.est.1c04158>

Read Online

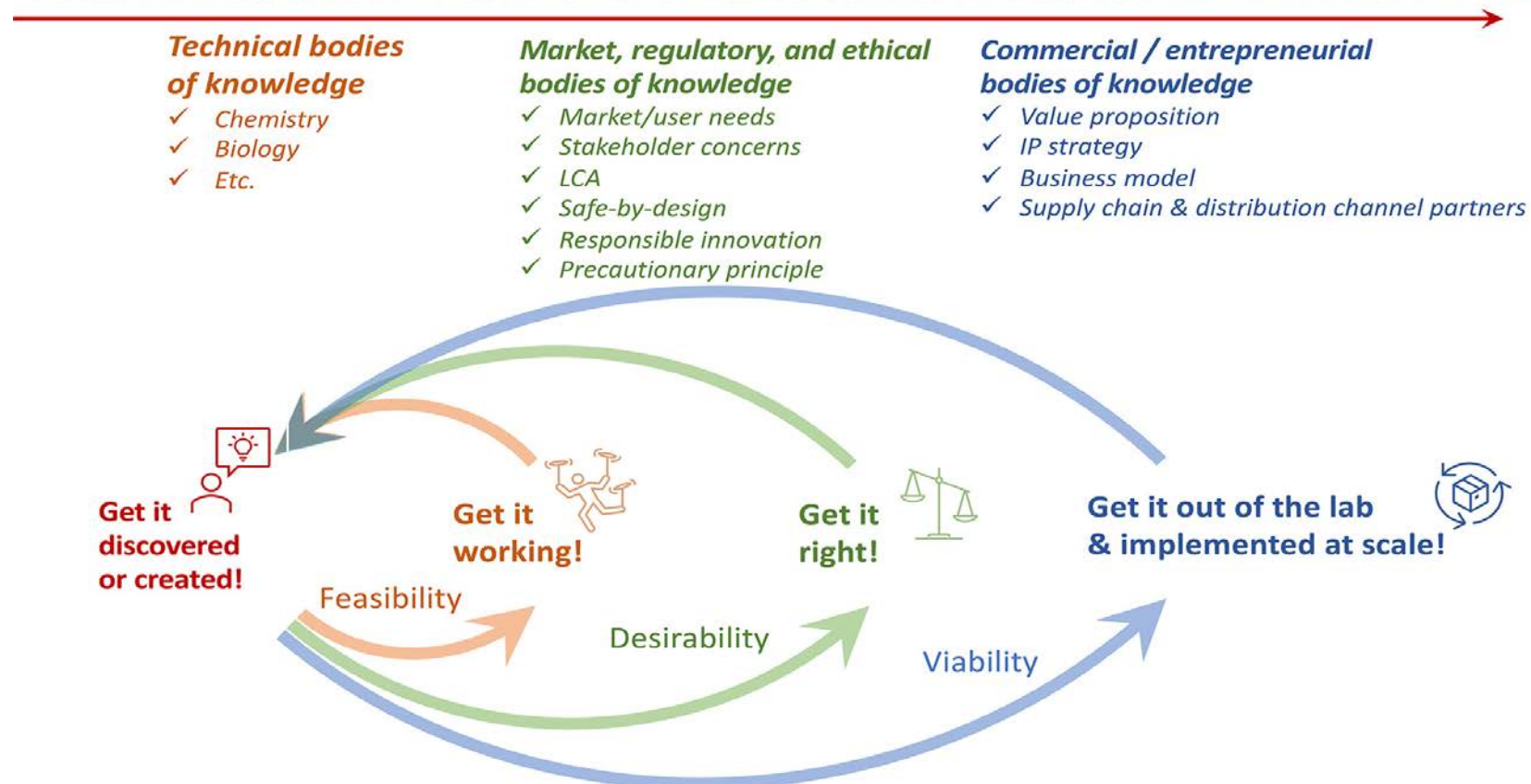


Technological solutions, regulatory perspective



2. New technology development, new nanomaterials

Circular knowledge translation: Increasing relevance of flowing diverse bodies of knowledge into lab activities early and often



Circular knowledge translation. Created by Wojciech Chrzanowski, Goretty Dias, Steven Maguire, and Elicia Maine, 2021.

Nanotechnology for a Sustainable Future: Addressing Global Challenges with the International Network4Sustainable Nanotechnology. Pokrajac et al. ACSnano; December 2021 DOI: (10.1021/acsnano.1c10919)

3. NEW CHEMICALS RISK ASSESSMENT

PARC: HE-partnership programme (2022-2029) – coordinated by ANSES, France -



New techniques; new analytical methods

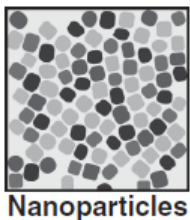
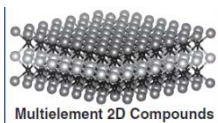
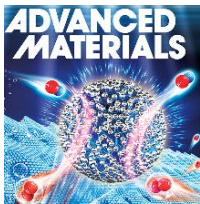
Machine learning & AI

New Alternative Methods: NAMs

Etc.

3 developments affecting RA of nano

New materials for innovations



INNOVATION CHALLENGES

SCIENTIFIC/RA CHALLENGES

POLICY AND SOCIETAL CHALLENGES

Present

2030-2050

Challenges	R&I needs	Objectives	Actions	Outcomes
<ul style="list-style-type: none"> Number & quality of scientists Clearer leadership Increased scientific excellence rates Separate policy frameworks Accredited data banks Lock-in skills High quality projects Transdisciplinary public health issues 	<ul style="list-style-type: none"> Science - interdisciplinary to drive regulatory innovation Innovating the digital, new networks and approaches Measuring performance - innovation Expansion across sectors New R&I approach - researchers and divisions support SMEs MSI data and open and interoperable systems Training for new skills Improved communication 	<ul style="list-style-type: none"> Transparency and consistency in risk assessment Multi-disciplinary network to identify and agree on R&I needs and support uptake of safety into regulatory chemical risk assessment Lead R&I activities supporting the current regulatory risk assessment processes and responding to emerging challenges Strengthen capacities and build new EU-wide, non-regulatory capabilities to support chemical risk assessment 	<ul style="list-style-type: none"> Support a common science policy agenda Adopt a monitoring and reporting mechanism Create and strengthen networks & collaborations Drive innovation in regulatory risk assessment before new legislation and standards Support and contribute to R&I jobs Enhance expertise, information and skills Expand communication across stakeholders groups 	<ul style="list-style-type: none"> A sustainable Europe with MS capabilities for chemical risk assessment Support the innovation-driven and activities with new business, legal and technological Empower the European Commission Green Deal initiatives by providing R&I jobs in chemicals Minimise the negative impacts of chemicals on human health and the environment Support the implementation of workers' non-chemical risks Support the mobilisation of industry for a digital economy Accelerate the social responsibility of chemical companies

New chemicals RA



**Non-toxic
Zero pollution
Sustainability**

EU Strategies: Chemicals Strategy for Sustainability

OBJECTIVES

- better protect citizens and the environment
- boost innovation for safe and sustainable chemicals

ACTIONS relevant for risk assessment nanomaterials

- banning the most harmful chemicals in consumer products – only essential use
- account for mixture effects
- boosting SSbD
- establishing a simpler “one substance one assessment” process for the risk and hazard assessment of chemicals
- playing a leading role globally by championing and promoting high standards



EU Strategies: Chemicals Strategy for Sustainability

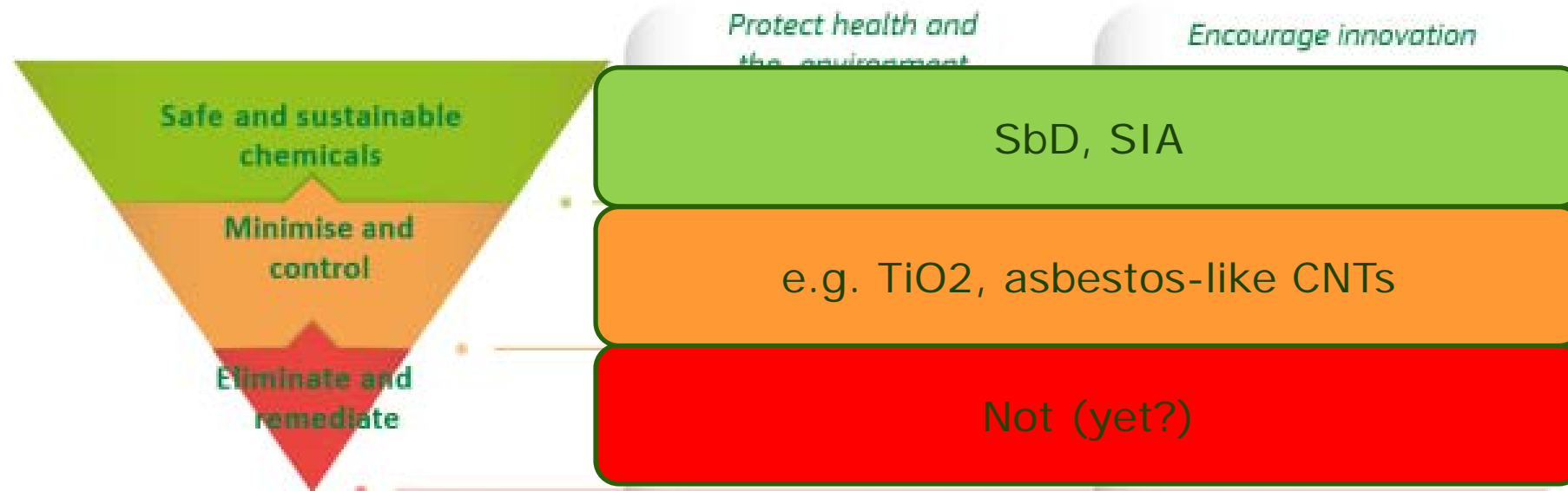


Figure: The toxic-free hierarchy – a new hierarchy in chemicals management

Nano dossier: keeping pace with policy ambitions

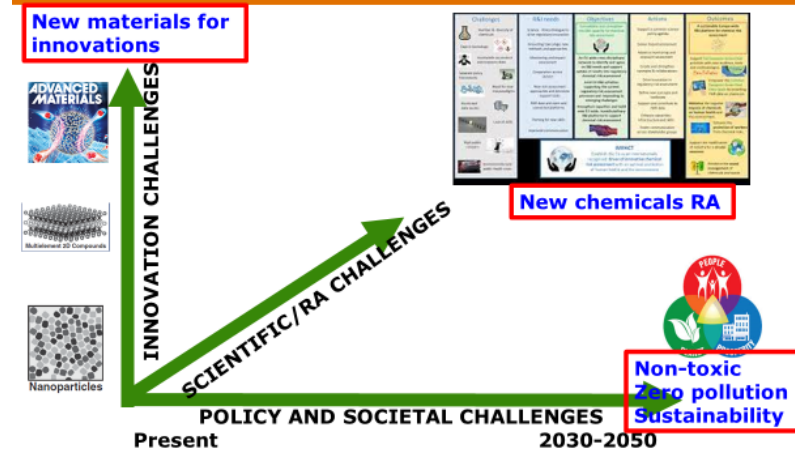
EXAMPLES	FOCUS
Elaboration on toxicological endpoints	Additional toxicological endpoints: immunotox, ED, neurotox, respiratory effects, specific organs
Elaboration on specific populations	Vulnerable groups, e.g. children
Harmonization, standardization	Development of standardized methods
Innovation in chemicals risk assessment	New techniques, digitization (like AI), etc.
Do no harm to man and its environment	Safe, sustainable, circular
Transregulatory	One substance, one assessment
Safe-by-Design	Safe-and-Sustainable-by-Design



Needs beyond toxicological knowledge

- Knowledge and information sharing:
how to organize?
- Innovation supportive regulations:
how to connect?
- Innovation in risk governance:
how to adapt?
- Co-creation:
how to operationalize?
- Dialogue:
do we have the skills and competences for it?
-

Risk Assessment nano/new materials - multidimensional



9



Content

- Short introduction Risk Governance
- State of the art in EU research on Nano Risk Governance
 - NMBP-13 projects: expected impact and results
- Changing policy ambitions: green deal and Chemical Strategy for Sustainability
- **Regulatory Research needs: results of two Gov4Nano summits**

Transregulatory risk assessment summit (2019 & 2022)

To provide a forum to discuss knowledge needs for risk assessment, and to translate these needs into research questions for the scientific Community

- **Share lessons:** facilitating mutual learning amongst experts and stakeholders in an interdisciplinary and inter-domain fashion.
- **Identify priorities:** ensuring most urgent scientific information needs and regulatory issues are integrated in policy research agenda, in support to regulatory oversight and compliance.
- **Promote harmonization:** finding common solutions to relevant topics such as data gaps, test guidelines and harmonization of methods.
- **Identify operational research agendas:** translate nano-specific issues in inputs for research agendas, funding mechanisms and other incentives to support and further develop risk analysis approaches, knowledge and data.



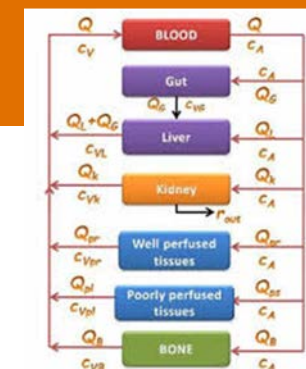
What do regulatory risk assessors want and need?

Ideal situation

- Regulatory requirements are in line with risk assessment needs
- Integration of knowledge among regulatory domains
- Consultation of regulatory risk assessors
- Structural inventory of knowledge gaps/needs
- Structural funding despite urgency of needs
- Monitoring system to ensure efficiency of process



Results RRAS and follow up survey I



Research question to pursue (challenge)

Develop case studies on prediction/measurement of the toxicokinetic behaviour, including transformation of NMs inside the body (internal exposure)

- transformation of NMs inside the body (internal exposure)
- testing methods
- measured data, considering issues of data quality and reliability

Use- to the extent possible- lessons learned from other nanomaterials

Regulatory risk assessment issues to overcome (scope)

Lack of knowledge on which physico-chemical characteristics are essential for risk assessment purposes within and across domains (definition)

Lack of guidance in dealing with toxico-kinetics of nanomaterials (exposure)

Lack of understanding of the exposure pathways inside (human) body and outside (human) body (exposure)

Lack of insight in reliability of in silico, in-vitro and in-vivo models toxico-kinetics and hazard (hazard)

Limited availability of exposure/ release case studies, including measurements and guidance on exposure data, toxicokinetic data (risk assessment/ risk management)

Data quality and reliability for the purpose of characterization and testing is questionable (definition)

Results RRAS and follow up survey II

Research question to pursue (challenge)	Regulatory risk assessment issues to overcome (scope)
<p>Identify the minimal panel of parameters to determine equivalence/similarity in the different areas of regulatory risk assessment (identity is covered in this), with respect to:</p> <ul style="list-style-type: none">- Phys-chem (intrinsic and extrinsic),- Biological interactions,- Toxicokinetics (ADME). <p>Speed up the adoption of described parameters</p> <p>Identify parameters and criteria for grouping and read across (equivalence)</p>	<p>Lack of knowledge on which physico-chemical characteristics are essential for risk assessment purposes within and across domains (definition).</p> <p>Lack of harmonised understanding of equivalence of nanomaterials in regulatory context (e.g. parameters and methods to test equivalence) (definition)</p> <p>Lack of grouping strategies (when are NM similar?) (definition)</p>

Equivalence



Similarity

Results RRAS and follow up survey III

Research question to pursue (challenge)

**Identify the usefulness of currently available non-nanomaterials exposure models for nanomaterials (external exposure).
If useful, validate the models for nanomaterials with measured data: share data, generate new data, incentives**

Regulatory risk assessment issues to overcome (scope)

Lack of validated exposure models (exposure)

Limited availability of exposure/ release case studies, including measurements and guidance on exposure data, toxicokinetic data (risk assessment/ risk management)



EXPOSURE

Main conclusion RRAS and survey

- RRAS results are confirmed by follow up survey amongst more risk assessors from different domains
- RRAS results support recommendations from the ProSafe White Paper (2017)
 - *Recommendation 6: Where possible, calls for nanosafety projects should be far more specific in giving clear instructions to ensure that data and results generated are of a type and form which allows their use in topics of regulatory relevance, such as choice of materials, test methods to be applied, SOPs and data management. The NanoSafety Cluster could play a role in defining such conditions.*
- Risk assessors expressed the need for more informal transregulatory exchange of views and issues

REF: ProSafe (2017) The ProSafe White paper: Towards a more effective and efficient governance and regulation of nanomaterials. last visited July 2020



2nd Regulatory Risk Assessment Summit (2022)



Keeping pace with European ambitions for safe and sustainable nanomaterials and products:

Main Actions

- banning most harmful chemicals in consumer products (unless essential) including PFAS;
- *"one substance one assessment"* for risk and hazard assessment of chemicals;
- account for the cocktail effect of chemicals when assessing risks from chemicals;
- boosting production and use of safe and sustainable by design chemicals;
- global role by promoting high standards and not exporting chemicals banned.

1. One substance one assessment
2. New endpoints for risk assessment (nano)

Paper in preparation: *Towards Standardisation of Testing of Nanomaterials for EU Regulatory Requirements*

- Analysis of regulatory requirements for different regulatory areas in the EU
- International nanosafety experts were consulted to identify associated scientific issues
- Identify which aspects require further action
- Overarching regulatory needs that are relevant for multiple regulatory requirements and across multiple regulatory areas include the needs to:
 1. resolve issues around nanomaterial dispersion stability and dosing in toxicity testing for human health endpoints
 2. further develop tests or guidance on nanomaterial degradation of nanomaterials
 3. further develop tests and guidance to measure (a)cellular reactivity of nanomaterials.



Summary

> Research needs

–Physico-chemical properties

- stability of the nanomaterials
- surface chemistry/reactivity

–Human health endpoints

- dispersion stability in biological media and related dosing in toxicity testing
- dermal exposure route
- endocrine disruption, immunotoxicity, neurotoxicity, reprotoxicity

–Environmental endpoints

- long-term testing (including interference of feed)
- biotic and abiotic degradation/transformation persistence
- interactions with natural (particulate) matter (adsorption/desorption, heteroaggregation)
mobility

ECHA-NMEG

Environment: **emission scenarios, relevant PECs**

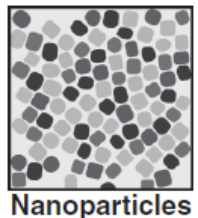
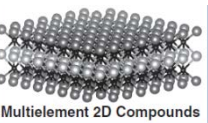
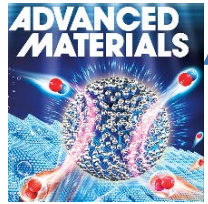
Human health: dermal absorption, **irritation & corrosion (skin/eye)**, reproduction/development toxicity, carcinogenicity/**long-term toxicity**



Chemicals Strategy for Sustainability
Towards a toxic-free environment



New materials for innovations



INNOVATION CHALLENGES

SCIENTIFIC/RA CHALLENGES

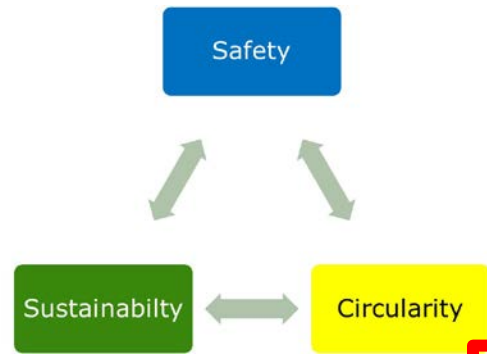
POLICY AND SOCIETAL CHALLENGES

Present

2030-2050

Challenges	R&I needs	Objectives	Actions	Outcomes
<ul style="list-style-type: none"> Number & diversity of laboratories Open to innovation Intermediate academic & commercial data Generate policy frameworks Need for new risk assessment Accelerated data access Lock of data High public concern Communication and public health issues 	<ul style="list-style-type: none"> Science: insufficient to drive regulatory innovation Knowing the gaps, how research and innovation Understanding and making a prediction Cooperation across sectors New EU research, innovation and digitalisation (Horizon 1000) Add data and open and interoperable platforms Training for new skills Improved communication 	<ul style="list-style-type: none"> Formulate and champion the RA cases for chemical RA innovation An EU wide cross-disciplinary network to identify and agree on R&I needs and support uptake of RA into regulatory chemical risk assessment Build similar platforms supporting the current regulatory risk assessment processes and responding to emerging challenges Strengthen capacities and build new EU wide, transdisciplinary RA platforms to support chemical risk assessment 	<ul style="list-style-type: none"> Develop a common science policy agenda Drive based assessment Adopt monitoring and reporting mechanism Develop and strengthen response & collaboration Drive innovation in regulatory risk assessment Settle new pathways and outcomes Support and contribute to risk data Enhance regulatory infrastructure and skills Enable communication across stakeholders 	<ul style="list-style-type: none"> A sustainable Europe with RA laboratories for chemical risk assessment Support the innovation for new data with new evidence, tools and methodologies Develop the European Chemical Innovation by breaking full data on chemicals Empower the European Chemical Green Deal Establish the regulatory benefits of chemicals on human health and the environment Support the implementation of industry for a decarbonised economy Develop science based management of chemicals innovation

New chemicals RA



Non-toxic
Zero pollution
Sustainability

Nanosafety community



Proactive

Share lessons learned

Open to finding solutions with other regulatory communities and domains



*Thank-you for
your attention*

Thanks to all partners and people in NMBP-13 projects

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Gov4Nano: Grant N°814401