caLIBRAte

A new EU-project answering to the H2020 call NMP30-2015: Next generation tools for risk governance of nanomaterials

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NATIONAL RESEARCH
CENTRE FOR THE WORKING ENVIRONMENT

Key details of caLIBRAte

- **Coordinator: NRCWE (KA Jensen)**

- **24 Partners**
  - **21 from Europe (2 Switzerland)**
  - **2 from USA**
  - **1 from South Africa**

Ambition

Move state-of-the-art in nanosafety research into a versatile risk governance framework for assessment and management of human and environmental risks of MN and MN-enabled products.

- **Budget ca. 9.7 Mio € (ca. 10.3 Mio $) – ca. 8 Mio € from the EC**
- **Duration: 42 Months starting May 1, 2016.**

TNO innovation for life

DTU
Technical University of Denmark

NIA
Nanotechnology Industries Association

INERIS
maîtriser le risque
pour un développement durable

eawag
aquatic research

LEITAT
managing your technologies
Technological Center
member of TECNIO

misvik biology

NERC SCIENCE OF THE ENVIRONMENT

Green Decissions

National Institute for Public Health and the Environment
Ministry of Health, Welfare and S

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nanotec IT

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EMPA
Materials Science & Technolo

Finnish Institute of Occupational Health

VENETIARUM UNIVERSITAS IN DOMO FOSCARI

GAIKER
ik4 research alliance

RTI INTERNATIONAL

DIALOGIK

Duke UNIVERSITY

NATIONAL HEALTH LABORATORY SERVICE
NATIONAL INSTITUTE FOR OCCUPATIONAL HEALTH

The NMP30 call – The challenge

- The **conventional risk assessment approach, … is inadequate** for enabling safe use for newly developed materials in the fast moving market of nanomaterials.
- Challenge is to **build a state-of-the art and flexible risk banding tool to keep pace with developments** in innovation and risk research **by harvesting** and implementing **results from** concluded, ongoing and planned **research in next generation risk governance frameworks**.
- **The risk analysis is still technically and methodologically limited** and **associated with a high uncertainty**
- **Stakeholders' concerns**, including those of the insurance sector, **and risk perception should be understood and communicated**.
- **Risk acceptance** is strongly affected by a clear understanding of the risks, the benefits and the uncertainties perceived on equity and trust.

The NMP30 call – The challenge

- The **conventional risk assessment approach, … is inadequate** for enabling safe use for n… …et of nanomater…
- Challenge… **tool to keep pace** … **harvesting** and implem… **esearch in next gene…**
- **The risk a… …ed** and **associate…**
- **Stakehold… …and risk perceptio…**
- **Risk acceptance** is strongly affected by a clear understanding of the risks, the benefits and the uncertainties perceived on equity and trust.

On Governance

EU Code of Conduct
(All EU members accepted and signed)

Implementation NOT a success

Stakeholders wants:
exposure limits, exposure data, models)
(All adhere to REACH system)

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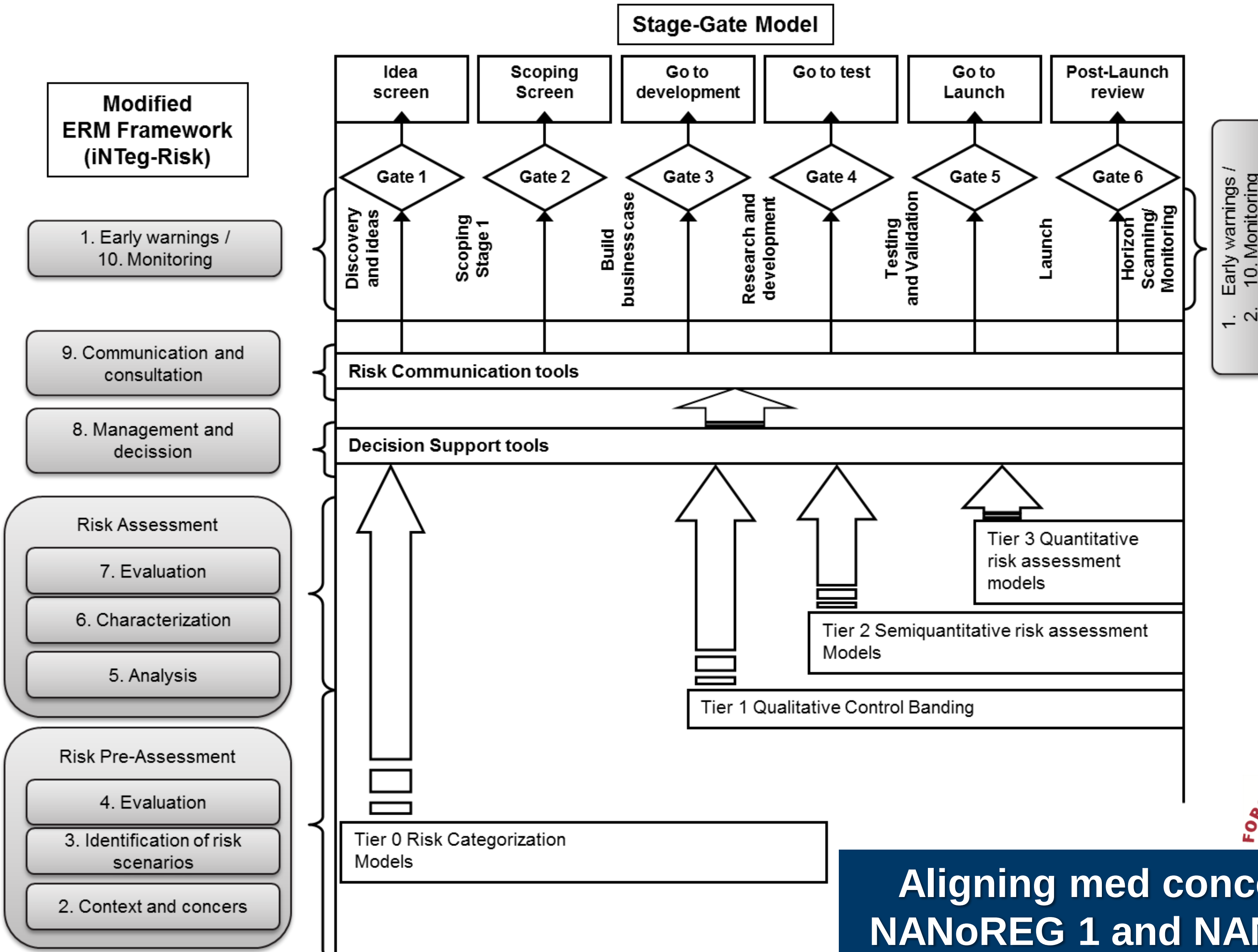
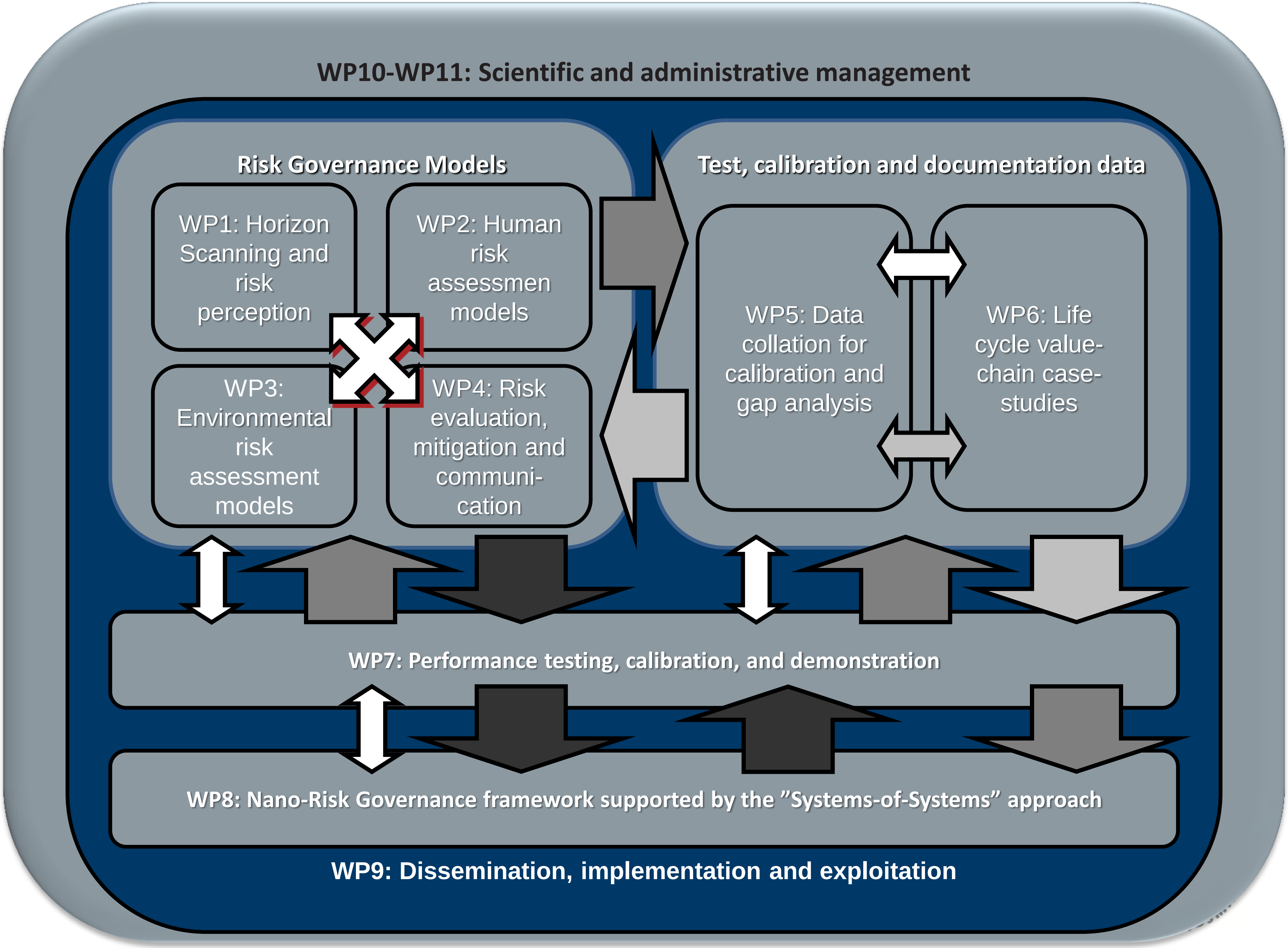
Expected Impact

- **A framework** for the risk governance of MNM entering the market by developing tools for risk appraisal, risk transfer and guidance for risk communication *(TRL 5 – technology validated in industrially relevant environments in the case of key enabling technologies)*
- **Demonstration** in specific industrial settings or industrial sectors of the feasibility of the developed approaches and tools through worked examples as case studies and pilots with outcomes as guidance, good practices and tools for risk management and risk communication
- **Leveraging and building** on current knowledge related to **hazard mapping, exposure and control banding and risk prioritization** as well on inter/national and company level **risk governance and risk dialogue** (key stakeholders including regulators and insurers)

The proposal is to establish a SoS NanoRiskGovernance Framework



Aligning med concepts in NANoREG 1 and NANoREG 2


WP10-WP11: Scientific and administrative management
Risk Governance Models
WP1: Horizon Scanning and risk perception
WP2: Human risk assessmen models
WP3: Environmental risk assessment models
WP4: Risk evaluation, mitigation and communi-cation
Test, calibration and documentation data
WP5: Data collation for calibration and gap analysis
WP6: Life cycle value-chain case-studies
WP7: Performance testing, calibration, and demonstration
WP8: Nano-Risk Governance framework supported by the "Systems-of-Systems" approach
WP9: Dissemination, implementation and exploitation

Some key R&D points in caLIBRAte

[test/calibrate/develop risk prioritisation (or banding) tools]

- **Establish and test computational toxicology and/or 'high concern grouping approaches' in risk banding tools to identify potential hot spots for risk**
- Link hazard and exposure (dose) assessment to establish scientifically documented 'risk bands' (include exposure management module)
- **Establish monitoring strategies to document the efficacy of risk mitigation (*e.g., risk radar, exposure control and monitoring*)**
- Align the tools and governance framework with user capacities and needs (users are industry, regulation, and insurance).
- **Enable assessment of acceptable uncertainty and risk by understanding the major processes for individual and societal decision-making.**
- Produce high-quality scientific/evidence-based hazard and exposure assessment tool(s) for regulatory decision making with guidance to identify important issues in risk assessment

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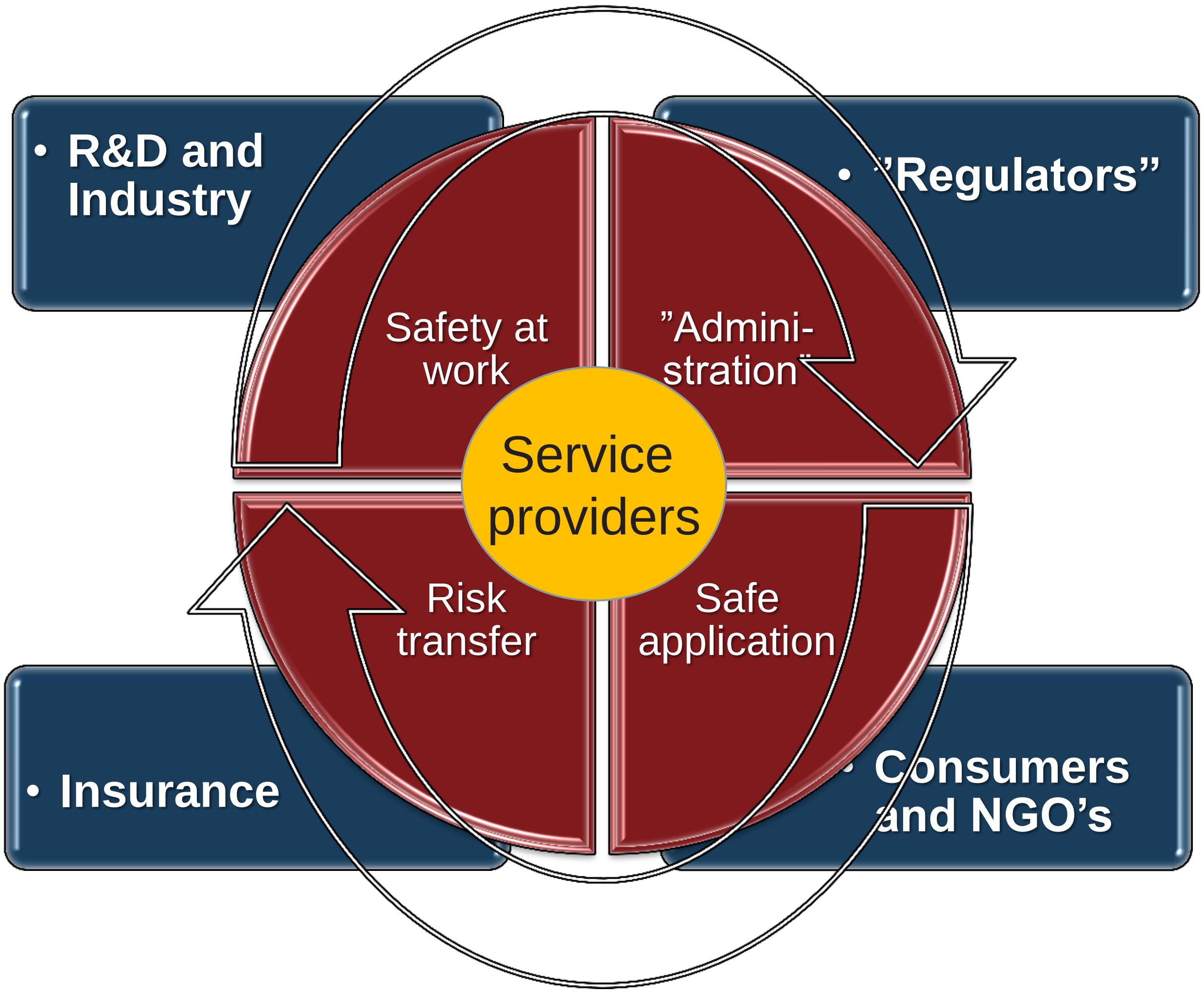
Stakeholder involvement prioritized



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