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Do we need a framework for risk governance of nanotechnology ?

NANORIGO European Union's Horizon 2020 research and innovation programme grant agreement No 814530

NANORIGO

In collaboration with Gov4Nano and RiskGONE

irgc international risk governance center

École polytechnique fédérale de Lausanne

A framework for 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
- 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

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There exists already many 'frameworks' and tools for risk and safety assessment

Environment International 95 (2016) 36–53

Contents lists available at ScienceDirect

Environment International

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

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 Pe
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nature nanotechnology

ARTICLES

https://doi.org/10.1038/s41565-018-0120-

A framework for sustainable nanomaterial selection and design based on performance, hazard, and economic considerations

ree L. Plata[1], Shauhrat S. Chopra[2,3], Thomas L. Theis[2], Leanne M. Gilbertson
in[1,5*]

ENMs) and ENM-enabled products have emerged as potentially high-performance replacement
chemicals. As such, there is an urgent need to incorporate environmental and human health ob
l design processes. Here, an adapted framework based on the Ashby material selection strateg
election and design process, which includes functional performance as well as environmental
s. The utility of this framework is demonstrated through two case studies, the design and selec
and conductive polymers, including ENMs, ENM-enabled products and their alternatives. Furt
both the comparative efficacy and impacts at two scales: (i) a broad scale, where chemical/m
ared for primary decision-making, and (ii) within a chemical/material class, where physicochem
to tailor the desired performance and environmental impact profile. Development and implen
inform decision-making for the implementation of ENMs to facilitate promising applications
iences.

Nano Today (2014) 9, 546–549

Available online at www.sciencedirect.com

ScienceDirect

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

nanotoday

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]

So what else do we need?
See the IRGC risk governance framework (2005, 2017, applied to nanotechnology in 2006)

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

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See also: CWA 16649: Emerging Risk Management Framework

developed in the iNTeg-risk FP7 project
and also:
- IRGC guidelines for the governance of emerging risks,
- forthcoming ISO31050

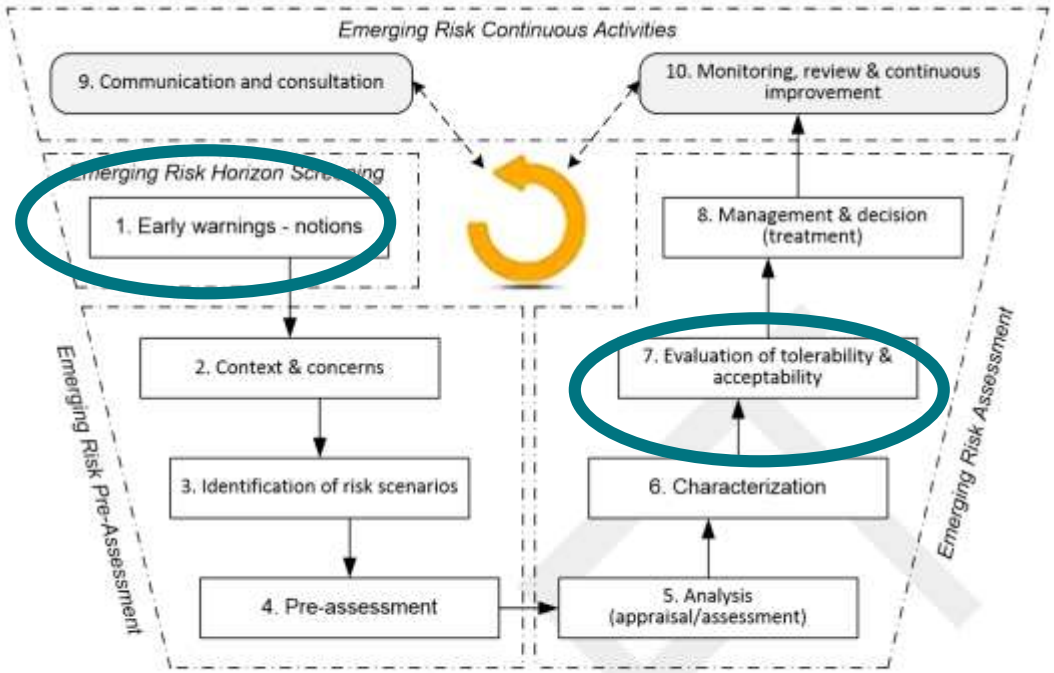

Figure 9 — The 10 steps of the ERMF

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Today's objectives are to:

develop a Nanotechnology Risk Governance Framework based on

1. sources of **high-quality data** and **guidance on data quality** and knowledge-based risk assessment
2. integration of the most appropriate **technical tools**
3. establishing new channels for **responsible and transparent communication** between stakeholders based on quality information and valuable feedback, and
4. setting up **plans for future** scientific and regulatory research that meet social, ethical and environmental aspects, and ensure data completeness, consistency and maximum synergy with other actions, and broad international cooperation.

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Process

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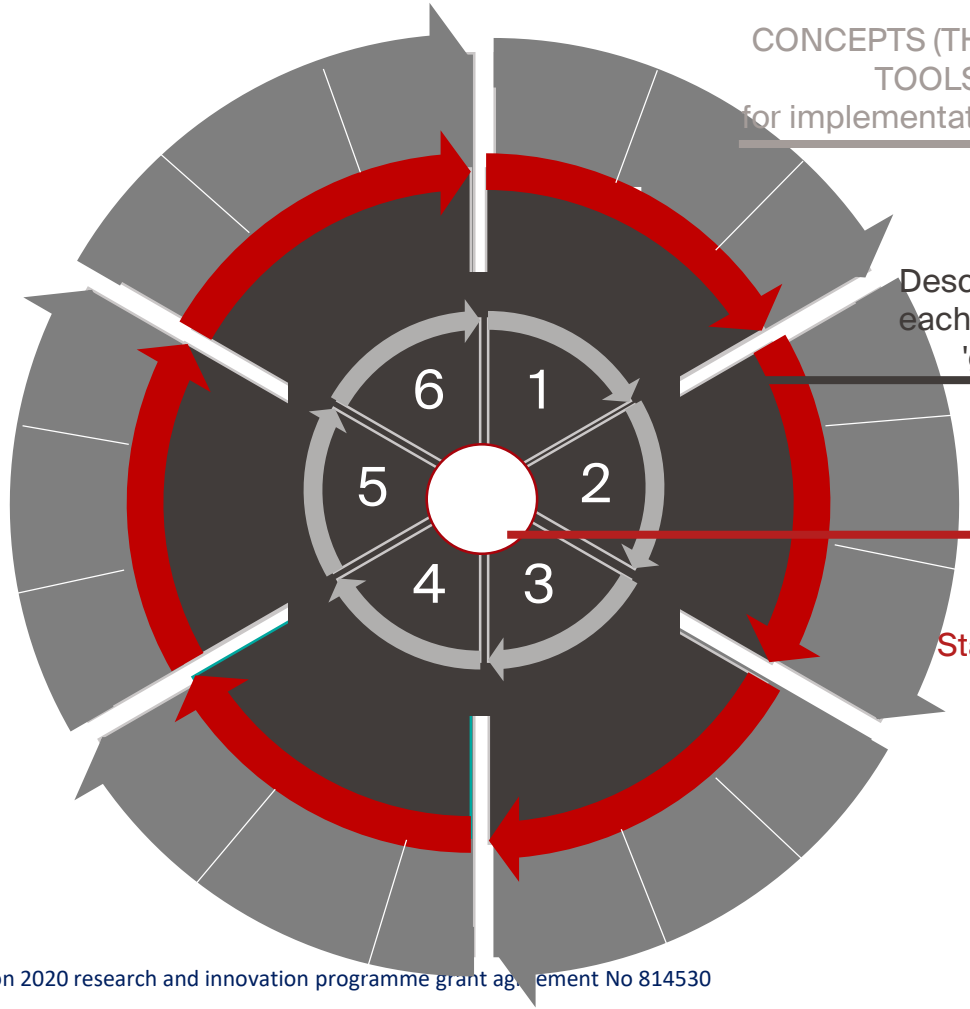
A framework for nano-technology risk governance must be an **integrator** of important, **concepts**, **principles** and **tools** recognized as relevant and accurate to address **current and future challenges** of nano-technology governance.



CONCEPTS (THEORIES), PRACTICAL TOOLS and ILLUSTRATIONS for implementation of each step of the process

PROCESS
Description of why and how each step can contribute to 'good risk governance'"

CORE FUNCTIONS

Context and culture
Stakeholder involvement
Communication

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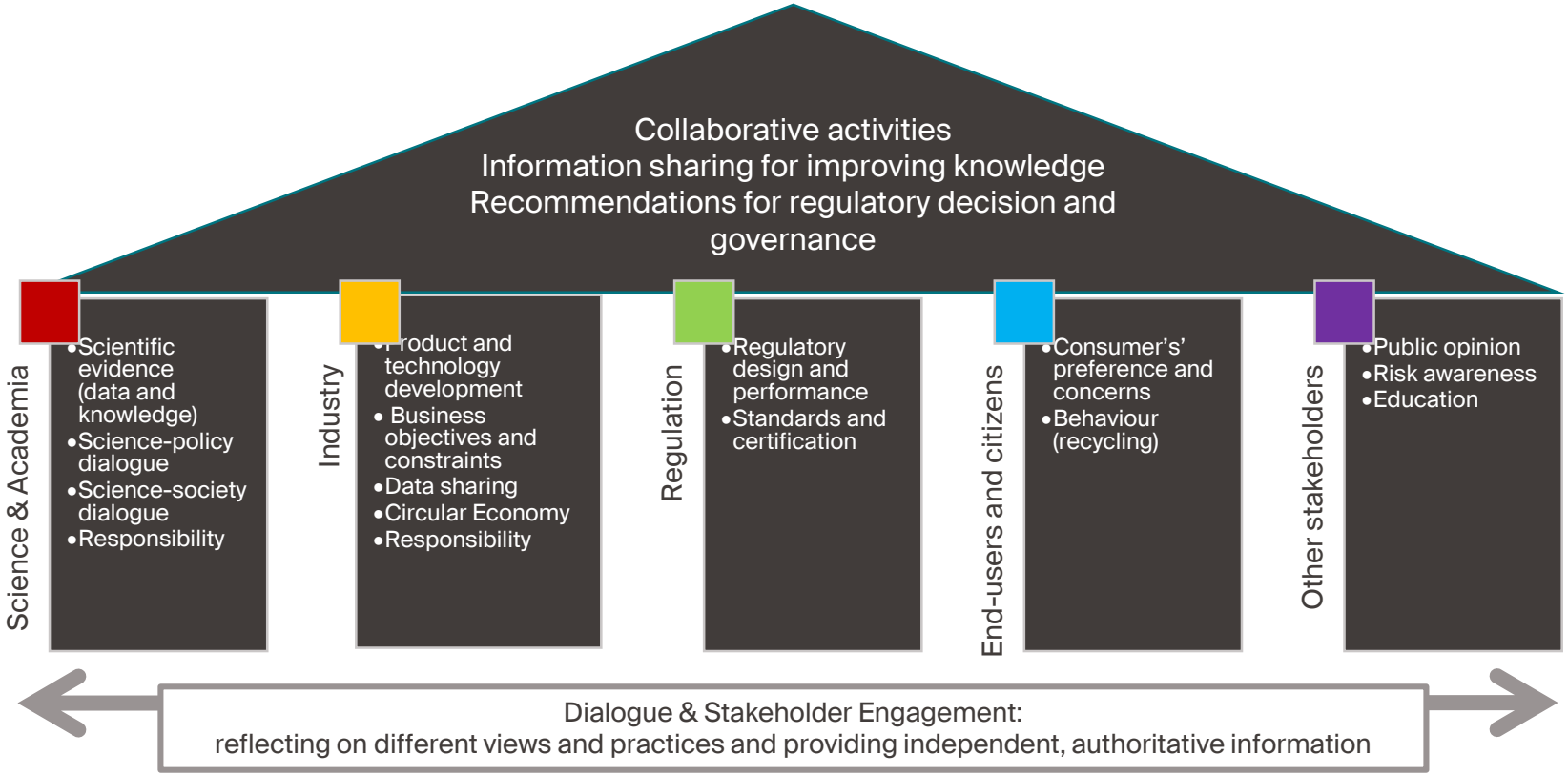
Each stakeholder comes with its own objectives, constraints, capacities.

Today's needs for the governance of nanotechnology should result from a top-down as well as bottom-up process



A framework for risk govenance could also help :

- Differentiate safety and risk
  - Risk = effect of uncertainty on objectives (ISO 31000)
    = uncertain consequences of an event or activity with respect to something that humans value (IRGC)
- Evaluate and decide on 'what is an acceptable risk?'
  - Risk acceptability varies across sectors, stakeholders, cultures and internationally
- Address tensions between precaution and innovation
  - Weighing benefits and risks, in view of intended purpose
  - Resolve trade-offs
- Propose guidelines for addressig needs and concerns related to long-term sustainabiliy and responsible research and innovation (RRI)
- Plan adaptability in regulatory frameworks
  - As knowledge increases and uncertainty is reduced
- Address with a common framework a range of issues related to emerging technologies
- Work towards the future
  - When nanotechnolgy is combined with other technologies, in complex nano-based systems

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