Governance of Nanomaterials as Laboratory for RRI

Jutta Jahnel

INSTITUTE FOR TECHNOLOGY ASSESSMENT AND SYSTEMS ANALYSIS (ITAS)

Responsible Research and Innovation (RRI)

- RRI - a vague term with wide ranging impacts:
  - Used as an embrella term, buzzword, open signifier, boundary object and abstract framing programme,
  - With a dominant impact on science and technology policies: EU 1291 (2013),
  - Reframing our understanding of science, technology and society

- Proposed working definition in the EU (von Schomberg 2013):
  RRI is a „**transparent, interactive process** by which societal actors and innovators become **mutually responsive** to each other with a view to the **(ethical) acceptability, sustainability and societal desirability** of the innovation process and its marketable products“

- Proposed quality criteria for identifying RRI (Wickson and Carew 2014):
  socially relevant & solution oriented, sustainability centered & future scanning, diverse & deliberative, reflexive & responsive, rigorous & robust, creative & elegant, honest & accountable

Emergence of RRI

Initial questions:

- Continuous evolving concept or spirit (Zeitgeist)?
- Discontinuous break, paradigm shift, social-intellectual movement?

- Normative and epistemic motivations for implementation:
  - **Substantive:** achieving special ends/outcomes (decision-making, quality of products, sustainability, better society) – addressing expectations, epistemic assessment aspects, anticipatory dimension
  - **Procedural:** the right thing to do (transparent, open, adaptive processes) – addressing interactions and process-based norms, such as inclusiveness, responsiveness
  - **Instrumental:** Secure particular ends (economic growth, trust, acceptance) – addressing the political and rhetoric dimension

Risk Governance of Nanomaterials

- Nanotechnology is a **new and emerging** technology with a high potential of applications whilst a high degree of uncertainty regarding health and environmental effects of nanomaterials
- There are normative and epistemic motivations to implement principles of RRI
- **„Responsible turn“ of risk governance of nanomaterials** (Grunwald 2014, Kjolberg and Strand 2011):
  - Development of Code of Conducts (EC 2008)
  - Increased importance of the precautionary principle
  - Involvement of stakeholders and the general public
  - Re-designed analytical and scientific procedures

Specified question:

- Risk governance of nanomaterials is a **„test case** for a new sort of governance“ (Tallacchini 2009) or a **root of RRI**?

Governance beyond Conventions

- Governance distributes responsibility across the traditional walls between science, politics and citizens (Kjolberg and Strand 2011)
- Governace includes:
  - the conventionally recognised elements of risk analysis: risk assessment, risk management, and risk communication (NRC 1996),
  - matters of institutional design, technical methodology, legislative procedure and political accountability (Ely et al. 2009),
  - more general provisions for building and using scientific knowledge, for fostering innovation and technical competences, and for promoting social and organisational learning (Ely et al. 2009)
- Governance moderates between traditional and new aspects.

Risk Assessment: The Tradition

- RA is a prerequisite of **science-based** risk management and means the quantification of the probability of harmful effects caused by exposure to an agent (NRC 1983).
- RA „is the interpretative and analytical framework used to evaluate research findings related to environmental threats for public health decision making“ (Rodricks and Levy 2012).
- Classical paradigm for chemical RA (OECD 2003):

  1. Exposure assessment: availablity of the agent
  2. Hazard identification: potential to cause harm, toxicology
  3. Hazard characterization: dose-response relationship
  4. Risk characterization: quotient between expected exposure and the No-Observed-Adverse-Effect-Level

- Risk Assessors in the EU: Scientific Committees of the European Commission (SCHER, SCCS, SCENIHR, EFSA)

Risk Assessment: Theoretical presumptions

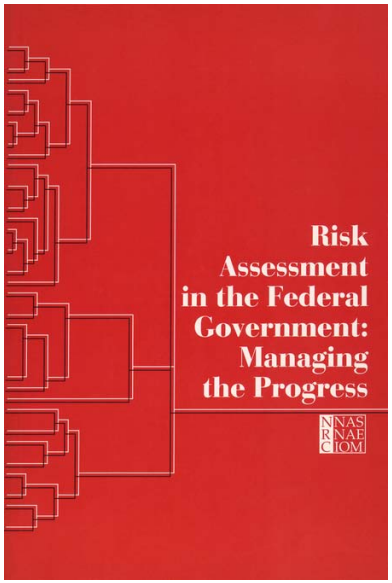
- **Actors**: Risk assessors are neutral, desinterested, independent, objective experts (positivism)
- **Substantive aspects**: **results-based legitimacy**
  Persuasive power of evidence
  (uncertainty is managed by assumptions or defaults)
  Mono-causal toxicological perspective
  (one chemical one disease at a time without systemic effects)
- **Procedural aspects: procedurally-based legitimacy**
  Well-established and formalized process („standard practice“), democratic quality (public consultations, transparent legislation), institutional separation from risk management in the EU

The traditional model of the ‚social contract of science‘ (Guston 2000)

General Limitations of RA: Back to Reality

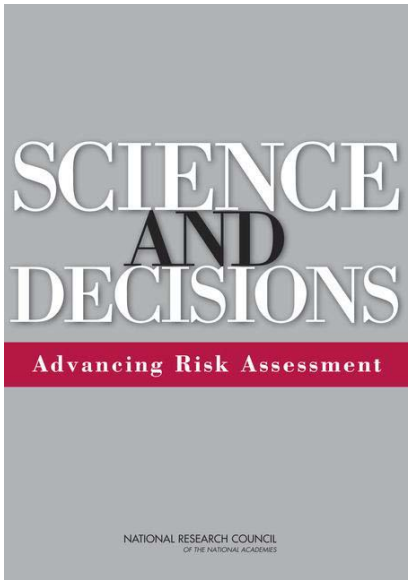
- **Actors:**
  Ambiguity among experts, equivocalness, no consensus,
  Missing plurality of actors, perspectives, and knowledge,
  Scientists determine means and ends (e.g. what should be studied).
- **Substantive aspects:**
  Reliability of data: uncertainty, ambiguity, and ignorance,
  Comparability of data: different experts use different parts of evidence,
  Huge amount of data: information overload,
  Utility of data: support for decision making is questioned.
- **Procedural aspects:**
  Complex technical procedure, ‚academic exercise‘
  No common and adequate terminology and communication,
  Lack of trustworthiness and transparency
  Artificial separation of scientific and normative aspects.

From the Red Book to the Silver Book



Continuous development of chemical RA:

- Framework for Ecological RA **(EPA 1992)**
- Risk Characterization: Science Policy Handbook **(EPA 2000)**
- Framework for Cumulative RA **(EPA 2003)**
- Framework for Assessing Health Risk of Environmental Exposures to Children **(EPA 2006)**

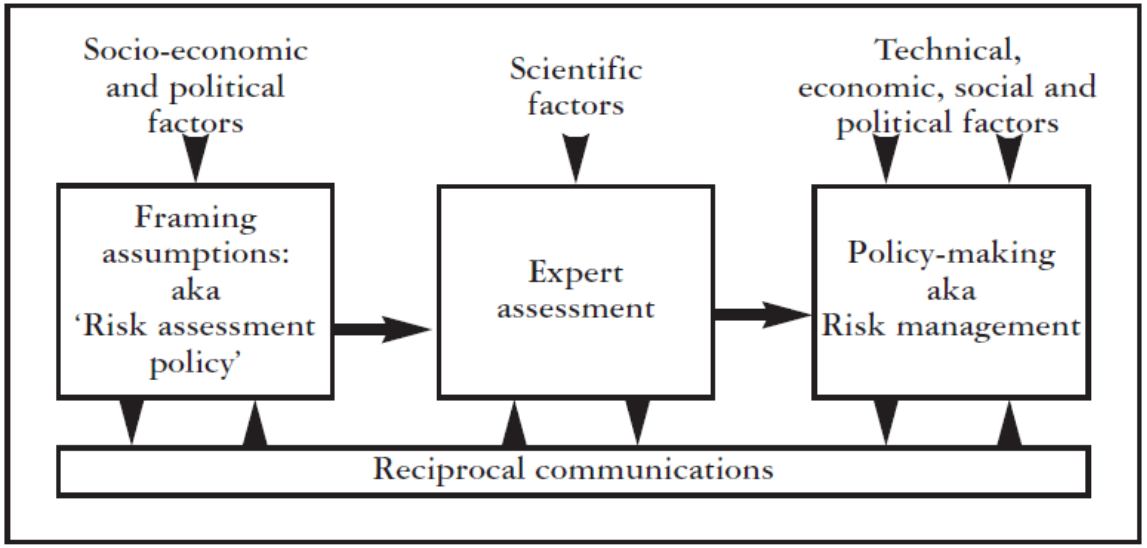


Evidence-based decision making (**NRC 1983**):
Scientific deliberations (**RA**) and political deliberations (**Risk Management**) take place in separate compartments, risk management is based on a scientific RA with an uni-directional information flow

Risk-based decision making (**NRC 2009**):
Co-dynamic linear model, framing and problem formulation as an inclusive up-stream process, separated from RA

Re-design of the Science and Decision relation

Co-dynamic linear model (NRC 2009): Silver Book
scientific deliberations are ‚sandwiched' between up-stream and down-stream policy deliberations with a bi-directional information flow, up-stream risk management comprises framing assumptions with substantive, procedural or interpretative aspects of RA



According to E. Millstone 2010

Parallel developments in different risk contexts

Evolved new frameworks for risk governance (2006-2009):

- Co-dynamic linear model **for chemicals** (NRC 2009), framing and problem formulation as an inclusive up-stream process
- Risk governance framework (IRGC 2006):
  Circular co-evolutionary model **for technologies**, a dynamic process with iterations and feedback introducing „concern assessment“ besides the conventional RA
- General framework for the precautionary and inclusive governance of **food** safety in Europe (Dreyer and Renn 2009):
  Cyclical, iterative and adaptive process with a separated framing step and different assessment types: presumption of prevention, precautionary assessment, concern assessment and conventional RA

The ‚disappearance‘ of boundaries between the laboratory and the environment (Arnaldi 2014)

Comparison of the Different Models

	Red Book	Silver Book	IRGC Model	Food Safety Governance
Publikation Time	NRC (1983)	NRC (2009)	IRGC (2006)	Dreyer and Renn (2009)
Narrative	Evidence-based decision making	Risk-based decision making	Science in policy making	Precautionary and inclusive governance
Application	Conventional chemicals	New chemicals	Technologies	Food (product)
Science and decision steps	Risk assessment Risk management	Problem formulation and scoping Risk assessment Risk management	Pre-assessment Risk appraisal Tolerability and acceptability judgement Risk management	Framing Assessment Evaluation Risk management
Process design (Structure)	Linear, uni-directional	Co-dynamic linear, bi-directional, adaptive	Open, cyclical, iterative, interlinked, co-evolutionary	Cyclical, iterative, adaptive, inclusive, precautionary

Common Aspects in Structure and Narratives

- **Making framing assumptions explicit** (substantive, procedural, interpretative) and **separated** from the expert assessment
- Framing assumptions understood as socially variable judgements
- Integrating **stakeholder and public participation** at the knowledge-creation phase (framing, concern assessment)
- Opening-up scientific risk assessment and anticipation
- Moving **from an academic expercise through interdisciplinarity to transdisciplinarity**
- Transforming inclusion, openness, transparency and responsibility into practice (Normative principles of **good governance,** CEC 2001)
- Changing linear uni-directional and rigid processes to **cyclical, iterative, adaptive and „responsive“ network approaches**
- Improving communication and **interactions** between the two mutually influenced compartments of science and decisions

RRI is a Higher Abstraction Level

	Silver Book	IRGC Model	Food Safety Governance	RRI
Narrative	Risk-based decision making	Science in policy making	Precautionary and inclusive governance	Co-responsibility Science with and for society
Application	Substances	Technologies	Products	Research, Innovation
Process design (Structure)	Co-dynamic linear, bi-directional, adaptive	Open, cyclical, iterative, interlinked, co-evolutionary	Cyclical, iterative, adaptive, inclusive, precautionary	Network approach, interactive, mutual responsive

… for different types of applications
… for changed approaches to governance
… evolved from a continuous trend of organising responsibility (Arnaldi 2014)

Risk governance of nanomaterials is **one case and one root of RRI**

Responsible Innovation and Technology Assessment (RITA):

Ulrich Dewald, Stefan Böschen, Torsten Fleischer, Armin Grunwald, Julia Hahn, Reinhard Heil, Jutta Jahnel, Stefanie Seitz, Carsten Bolz

Science and Decisions:

Christian Büscher, Jutta Jahnel

Risk Governance of Nanomaterials:

Torsten Fleischer, Stefanie Seitz, Jutta Jahnel

Thank you for your attention

Jutta.Jahnel@kit.edu