Fostering a sustainable future:
Risk governance and the role of society in the development of nanotechnologies

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What is Risk Governance?

Risk governance *describes structures and processes for collective risk-related decision-making involving governmental and non-governmental actors* (Renn, 2008)

- Expands beyond the traditional elements of risk analysis:
  - *risk assessment, risk management, and risk communication*
- Recognition that assessment and management of risk occurs within social systems: 'acceptable risk' is often socially constructed, rather than objectively defined
- Cross-cutting, includes consideration of legal, institutional, social, and economic contexts in which risk is evaluated
- Involves the actors and stakeholders who represent those contexts

Risk Governance (cont'd)

- Rather than communication as 'information OUT', it invites dialogue and engagement with affected parties throughout the process:
  - Governments and agencies
  - Industries
  - Scientists and academia
  - Civil society / NGOs

  (at the local, regional, national, or global scales)
- Risk assessed and managed through a collection of actions by various parties
- Focus on transparency, inclusion, understanding of risk, and decisions

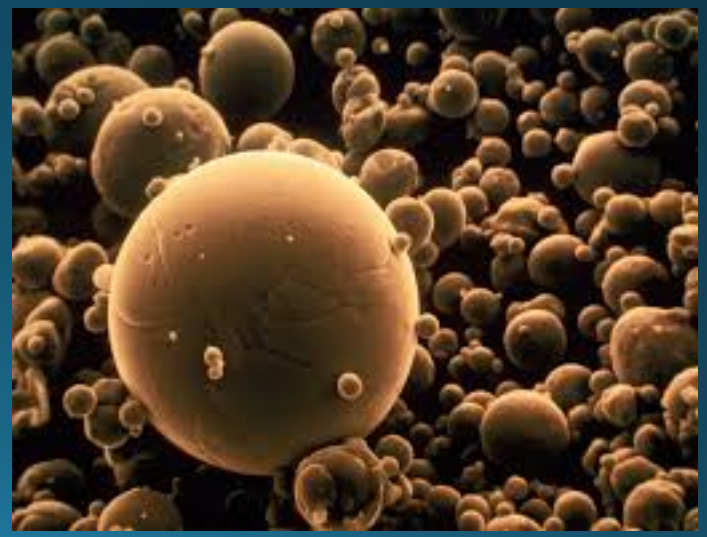
Nano through the lens of Risk Governance

Nanomaterials characterized by:

- Uncertainty - human health and environmental risks
- 'Different' behaviour compared to bulk materials
- Rapid growth, soon to be ubiquitous
- Clear benefits but uncertain risks

Risk Governance provides a framework for understanding complexities of nano in society

- Understanding risks
- Engagement and communication of risks
- Managing risks
- Decision making and policy



Understanding Risk

Risk Assessment

What supporting data do we need? What's available?

What tools and processes are available for assessing risk? Are they adequate?

- Data generation - characterization, toxicity, exposures
- Environmental Fate & Transport
- Life Cycle Assessment

- Development of new tools and techniques:
  - HTS, Alternative Test Strategies
  - *in silico* methods – QSARs, informatics
  - Databases as sharing and discovery tools
  - Decision support tools

SRA-ENMSG International Workshop, DC, 2014
Advancing Risk Assessment for NM using ATS

- Scientific Barriers
  - Difficult to test NMs using existing assays
  - Lack of standardized data (method development, validation)
  - High bar for validation – relevance, reproducibility
- Promote tiered-testing strategies
- Develop grouping, read-across, multi-models approach
- *Compliment* vs *replacement* of *in vivo* tests

The use of ATS in lieu of *in vivo* testing for regulatory risk assessment or management purposes is not yet at the level of general acceptance

(Nel et al 2013; Shatkin et al 2015 – under review)

Managing Risks

Do risks outweigh the benefits?

How to manage risks across life stages and for various users?

Are regulations adequate? Is there a need for new regulations?

Management Actions

Occupational exposures and controls

Attenuating hazards/exposures (i.e., Safe By Design)

Regulation

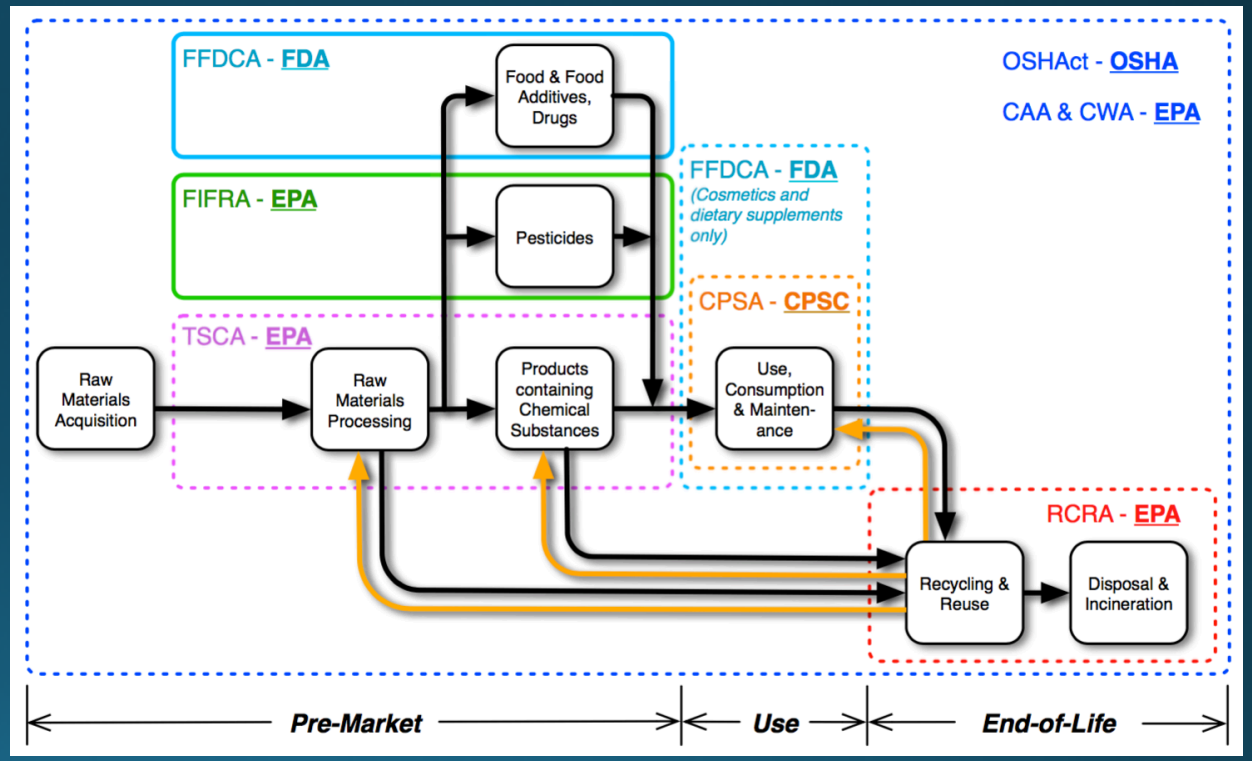
Top Down vs. Bottom Up

How to promote innovation while managing risk?

Do NMs slip through the cracks?

Regulation along the NM Life-Cycle

- Existing requirements not appropriate for nano
  - Mass-based applicability thresholds, exemptions
  - Definitions do not account for nano-specific properties or behavior (bulk)
  - Lack of tools and data – difficult to assess, regulate
- Path Forward
  - Limit CBI, improve data sharing
  - RA tool development
  - Full life-cycle stewardship, better integration between regulations



Beaudrie, C.E.H., Kandlikar, M., Satterfield, T. *From Cradle-to-Grave at the Nanoscale: Gaps in US Regulatory Oversight along the Nanomaterial Life Cycle*. Environmental Science & Technology, *47* (11), pp 5524–5534 (2013)

Nanotechnologies and Society

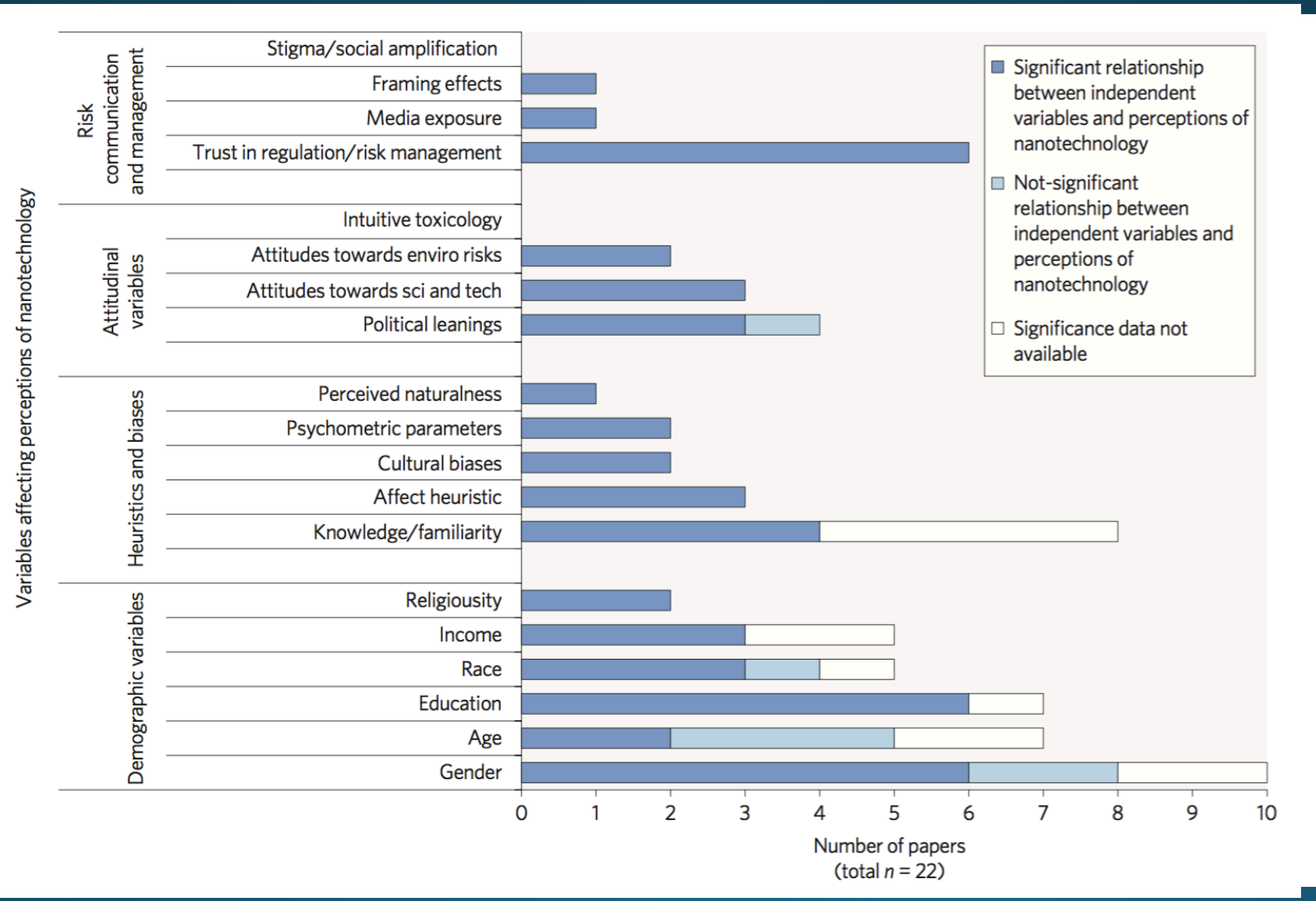
Risk Perceptions

How are risks understood by the public? By scientists and other experts?

How will NMs be received? Will they be accepted/rejected?

What factors drive perceptions of benefits and risks?

- Can inform how to engage, communicate risks
- What gets attention depends largely upon perceptions



Satterfield, T., Kandlikar, M, **Beaudrie, C.E.H.**, Conti, J., Harthorn, B.H. *Anticipating the Perceived Risk of Nanotechnologies: Will They Be Like Other Controversial Technologies?* Nature Nanotechnology 4, 752-758, (2009)

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Risk Communication

- Consent, labeling, warnings
- Education and outreach (with stakeholders, incl. public, scientists and technologists)

Foresight, Engagement, and Integration

- Anticipatory governance – How can we manage risks early, promote reflexivity, engage and construct visions of the future?

Conclusion

Fostering a sustainable future for nanotechnologies means:

- Engaging civil society, governments, public, industries in the process of innovation, and understanding and managing risks
- Integrating scientific, economic, social, and cultural perspectives
- Integrating across the natural, engineering, and social sciences

Presentations

- **LCA and stakeholder engagement -** Kaitlin Vortherms, ASU
- **Science communication in nanotechnology teams -** Margaret M. Brooks, ASU
- **Perceptions – Predicting factors impacting attitudes and acceptance -** Rajani Ganesh Pillai
- **Adoption of ATS within Regulatory Frameworks -** Tim Malloy, CEIN UCLA
- **Engagement and training with scientists and engineers -** Ira Bennett and Rae Ostman, ASU

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