Manufactured Nanomaterials & Risk Governance

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From Risk to Governance (from components to system)

- 1970s: Risk = Probability x Consequence
- 1980s: Risk = Hazard x Exposure x Effects
  = Threat x Vulnerability x Consequence
- 2000s: Risk ~f (H x E x E_{ff})

$m_{H1} m_{H1} \ldots m_{Hn}$ m_{E1} $m_{E1} \ldots m_{En}$ m_{Eff1} $m_{Eff2} \ldots m_{Effn}$

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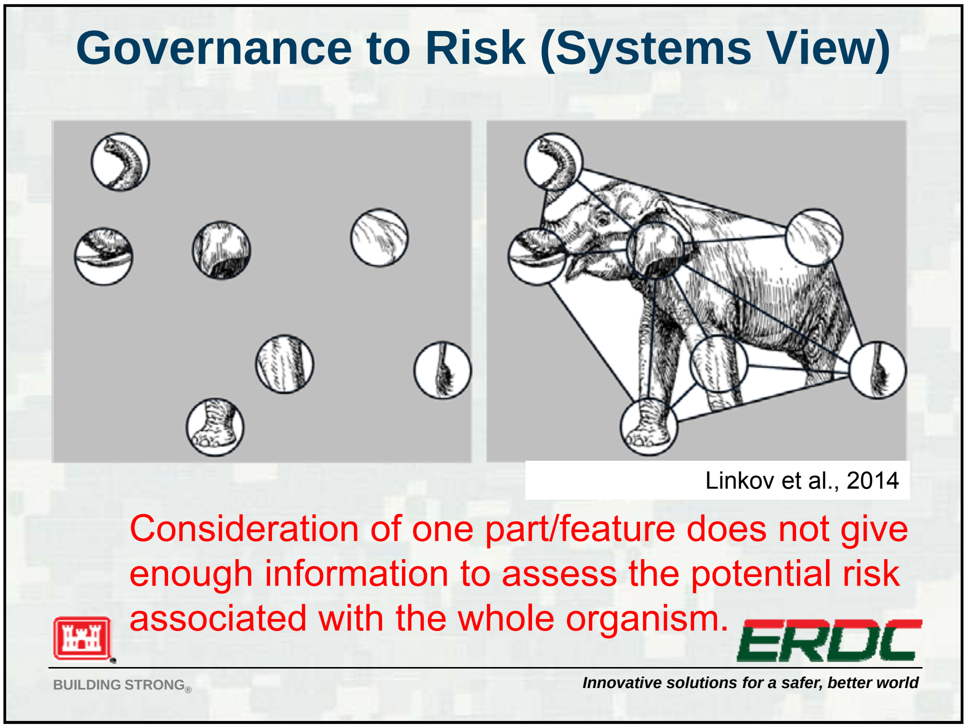
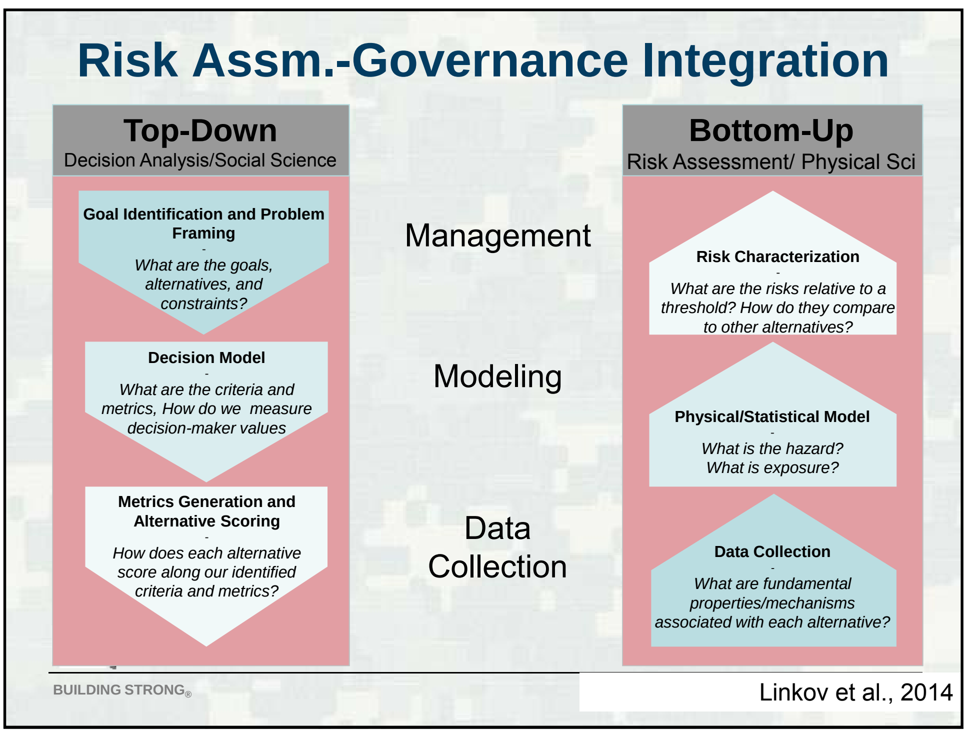


Linkov, I., Wood, M., Bates, M. (2014). Scientific Convergence: Dealing with the Elephant in the Room. Environmental Science and Technology 48:10539–10540



Linkov, I., Anklam, E., Collier, Z., DiMase, D., Renn, O. (2014). Risk-Based Standards: Integrating Top-Down and Bottom-Up Approaches. Environment, Systems, and Decisions 34:134-137.

SRANSC White Paper

- White paper for SRANSC discusses 6 such tool groups through view of scholarly literature
  - Commissioned in July 2015
  - Webinar discussion October 2015
  - Preliminary Dissemination – Early 2016
  - Further review, revision, and submission to journal: March 2017
- Strategies and methods are used to guide governance building

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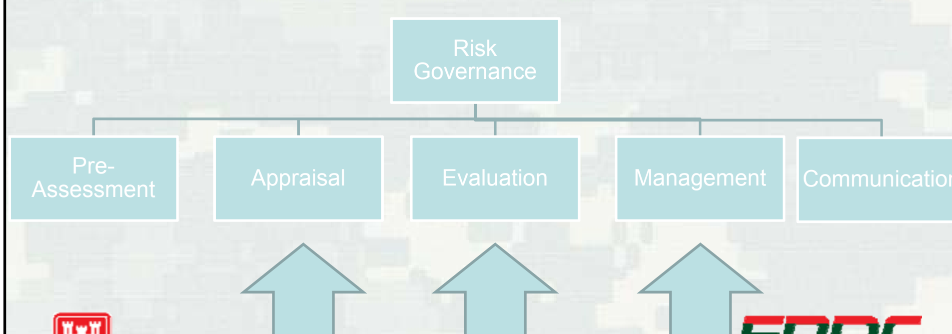
Moving Toward Risk Governance

International Risk Governance Council –
Breakdown of Risk Governance & our focus



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Methods & Tools for RG

- Cost-Benefit Analysis
- Hazard/Exposure Assessment
- Life-Cycle Assessment
- Adaptive Management
- Control Banding
- Decision Analysis

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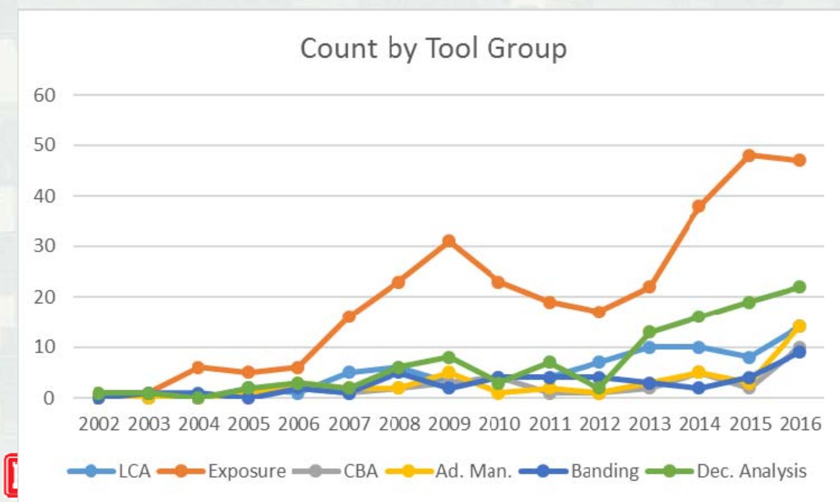
Literature Synthesis Results (n=429)



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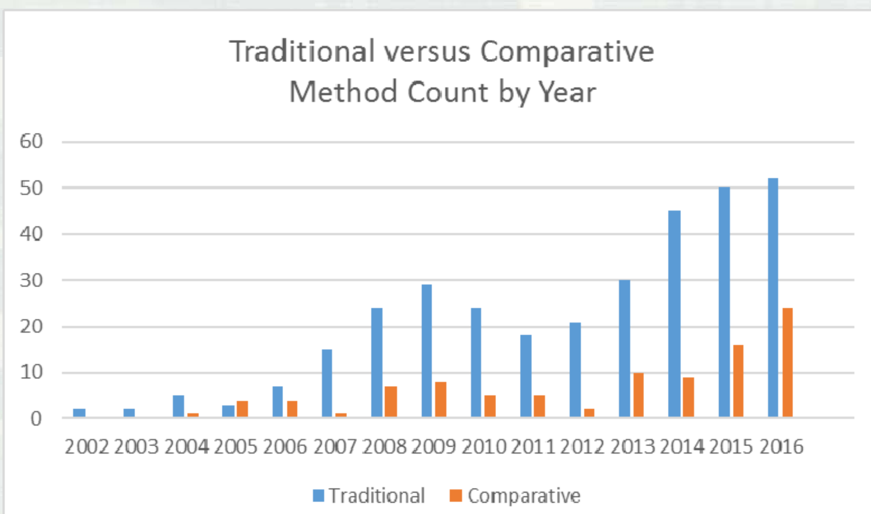
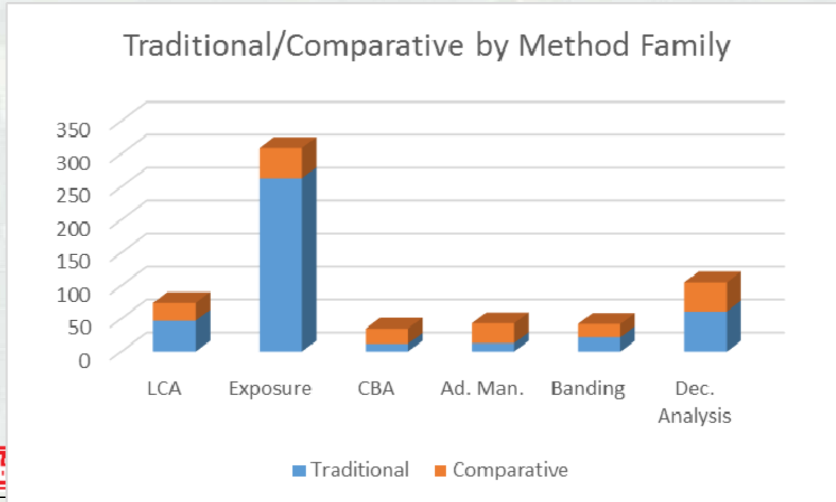
Framing Tool Groups

- Two General Frameworks:
- Traditional, Risk-Based
  - ► Centered on traditional assessment of risk components
    - Hazard, exposure, consequences
- Approaches centered on comparison
  - ► Analysis of alternatives – novel or conventional comparison of risk
  - ► Centered on Risk Avoidance (avoid risk by avoiding risky technology/material where possible)

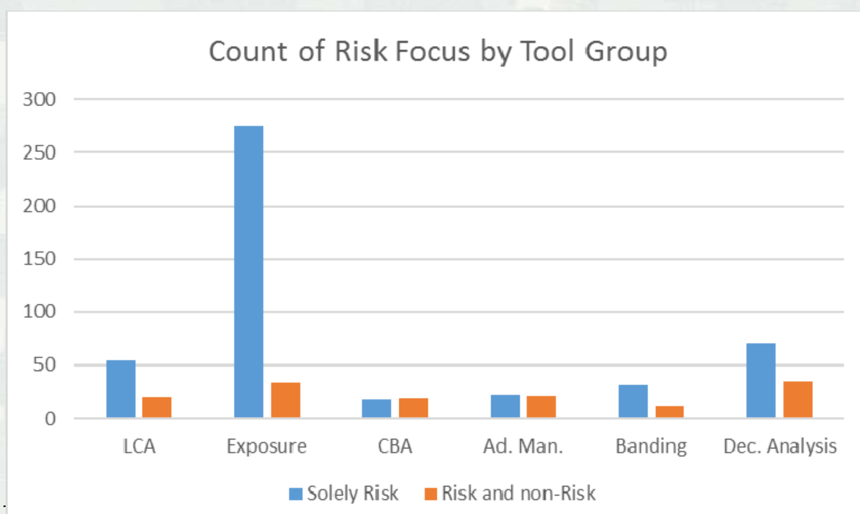
Literature Synthesis Results

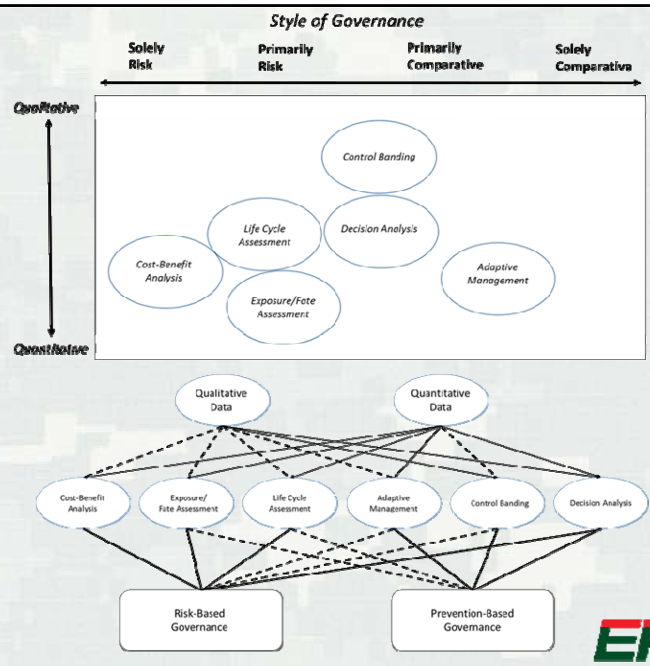


Literature Synthesis Results



Literature Synthesis Results





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Governance

- Governance refers to the actions, processes, traditions and institutions by which authority is exercised and decisions are taken and implemented.
  - ► Risk governance applies the principles of good governance to the identification, assessment, management and communication of risks

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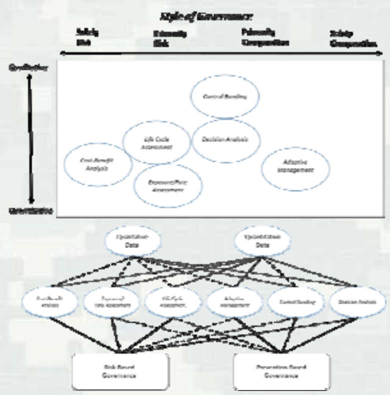
Tools are helpful, but not necessarily "Good" Governance

- Quantitative Methods and tools help drive traditional risk assessment
- However, such quantitative guidance on hazard, exposure, and effects is not always available
- Also need to consider non-risk considerations of cost, societal benefit, ethics, implications, etc.
  - **Consider <u>all elements</u> of risk governance to drive "good" governance**



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Key Criteria for "good" risk governance

(IRGC 2015)

- **Substantive validity -** Evaluating outcomes by comparing them with reality.
  - Not always possible… as outcomes may be visible only after a long period or may not be visible at all.
- **Procedural validity -** Under pre-release, high uncertainty conditions associated with gene drives**.**
  - Assessing the quality of the process that led to the outcomes
  - Scientific validity of the approaches used
  - Regularly updated data and hypotheses
  - Openness and transparency
- **Reflexivity -** Evaluating relevance and quality of organizational processes
  - Do we need to do what we are doing?
  - If yes, are we doing it right?

Credit:
Jennifer Kuzma
N.C. State University

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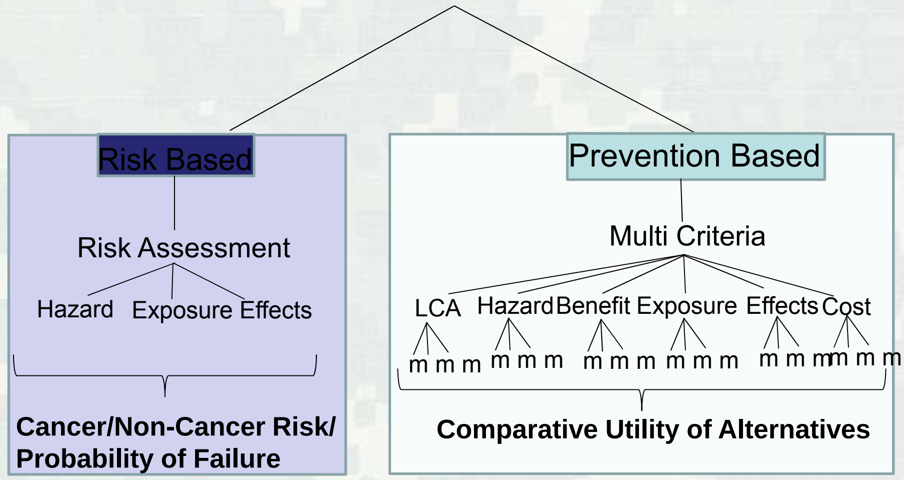
Proposed Risk Governance Framework



See Malloy et al (2016)

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ERDC

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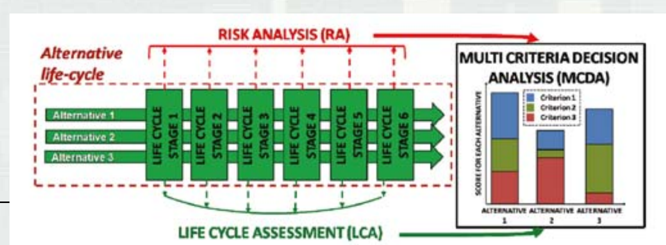
Malloy TF, Trump, B.D, Linkov I. (2016). Risk-Based and Prevention-Based Governance for Emerging Materials. Environ. Sci. Technol., 50:6822–6824.

Discussion

- These approaches can be used by a variety of stakeholders internationally
- Can be useful in otherwise disparate political, cultural, and regulatory traditions in various countries
  - ► Sometimes, multiple tools simultaneously



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Discussion

- As such, these approaches can help inform new strategies for MN risk governance
  - ► Meet the challenges of novel physical characteristics that could yield uncertain yet novel health risk
  - ► Incorporate information from a variety of quantitative and qualitative sources
  - ► *Depend heavily on input and output requirements!*

Concluding Thoughts

- RG is a complex effort
  - ► Particularly under high uncertainty
- Various tools exist to guide governance building exercises
  - ► Inform parameters for decision making
  - ► Structure an ambiguous or poorly defined decision context
- More is needed than traditional tools to facilitate nano governance