

Manufactured Nanomaterials & Risk Governance

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Risk management and decision making for complex systems: *what are our options?*

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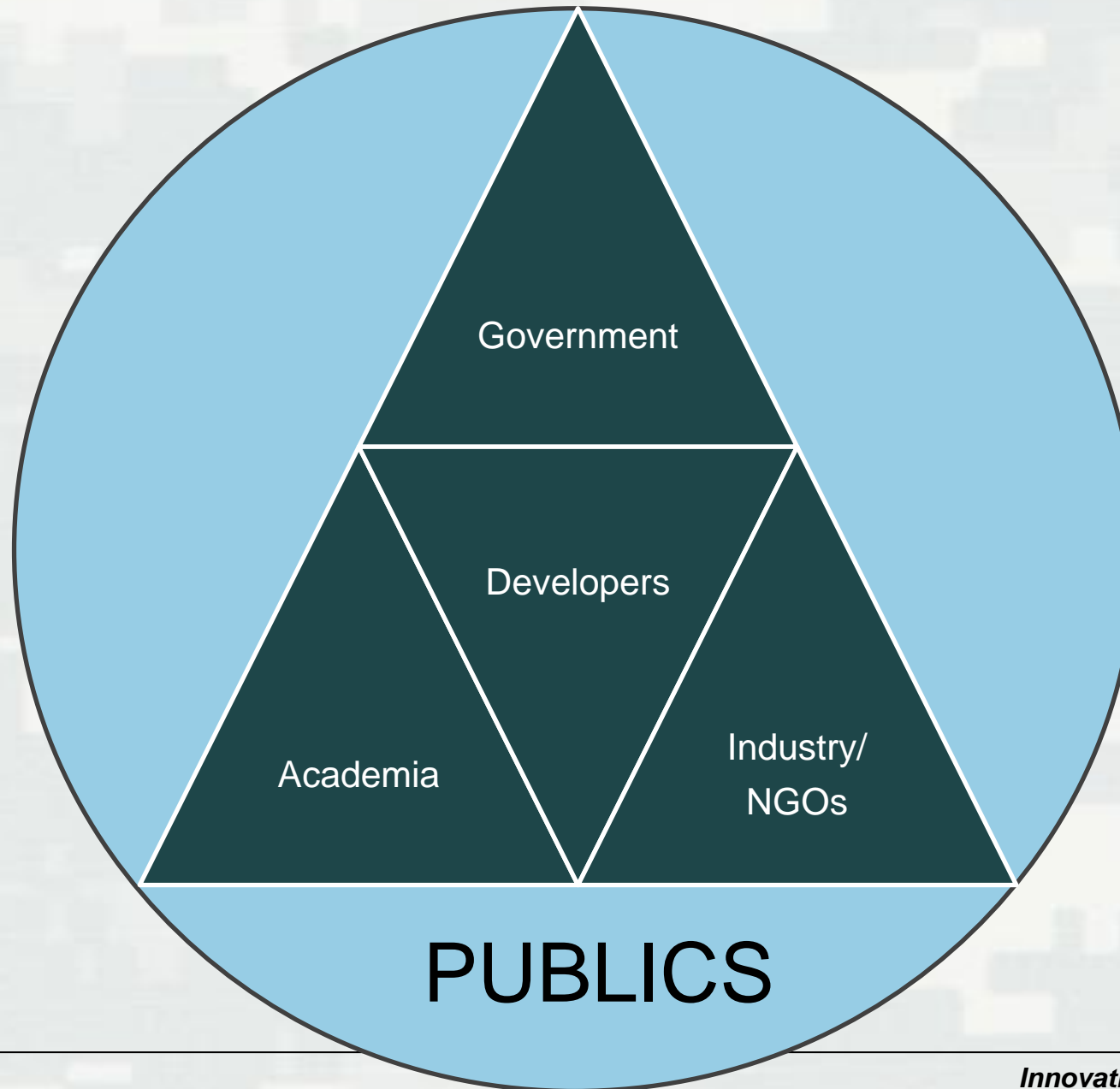


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Developers
inform the state
of science.



Science *is not*
implemented
and reviewed in
a vacuum.



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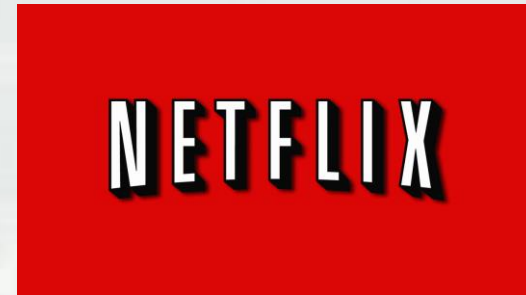
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Disruptive Innovation

- “Playing the Game Differently”
- Creates a New Market
- Transforms or Destroys Current Market
- Products Become
 - ▶ Simpler
 - ▶ More Affordable
 - ▶ More Accessible
 - ▶ Customizable
- Drives Growth

Old vs. New

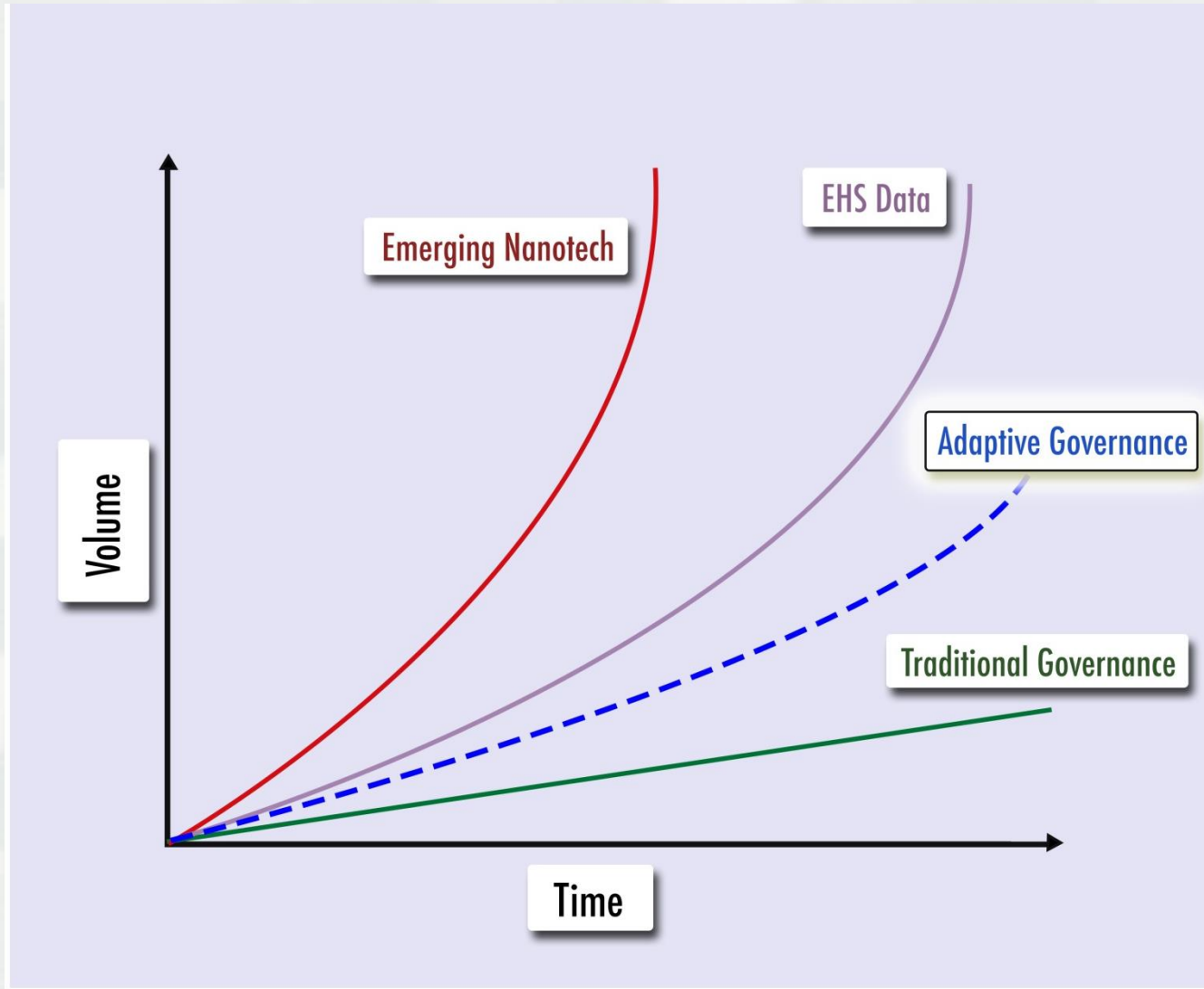


The Challenges of Emerging Technology Innovation

- Pace of invention and innovation is growing
 - ▶ Likewise, getting further refined and specified
 - ▶ Revolutionary potential to benefit health – pressures to innovate
- For public health, also breaching existing scientific knowledge
 - ▶ Nanotechnology, synthetic biology/systems engineering, many others
- Existing governance structures are not designed to deal with fast-paced innovation of this magnitude
 - ▶ Made for deliberative and thorough testing process
 - ▶ Behave differently than conventional technologies, defy existing knowledge of hazard and exposure assessment



“The Pacing Problem” of Governance



No matter how sophisticated risk assessment becomes, a gap will always exist between new material introduction and risk characterization & management.

Adaptive Governance:

Iterative improvements to governance of materials or activities as more information becomes available

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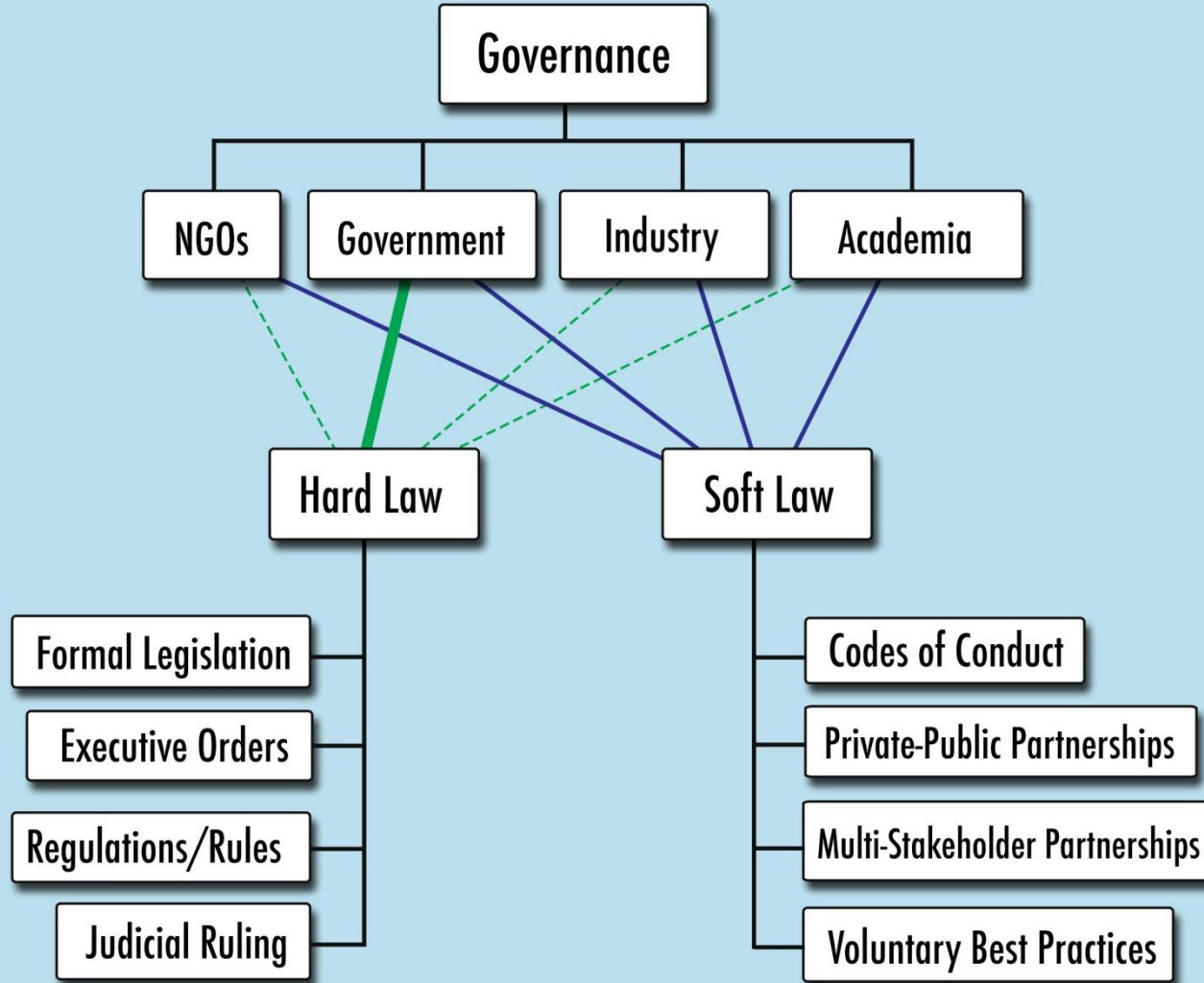


Further Complications – Decision Making & Regulation Under Uncertainty?

- What do we do when we don't know much?
 - ▶ Closed experimentation
 - ▶ Ask the experts
 - ▶ Modeling exercises – best/worst case scenarios?
- Work within the confines of your governance regime
 - ▶ Not always open and welcoming of innovation under uncertainty



Drivers of Governance

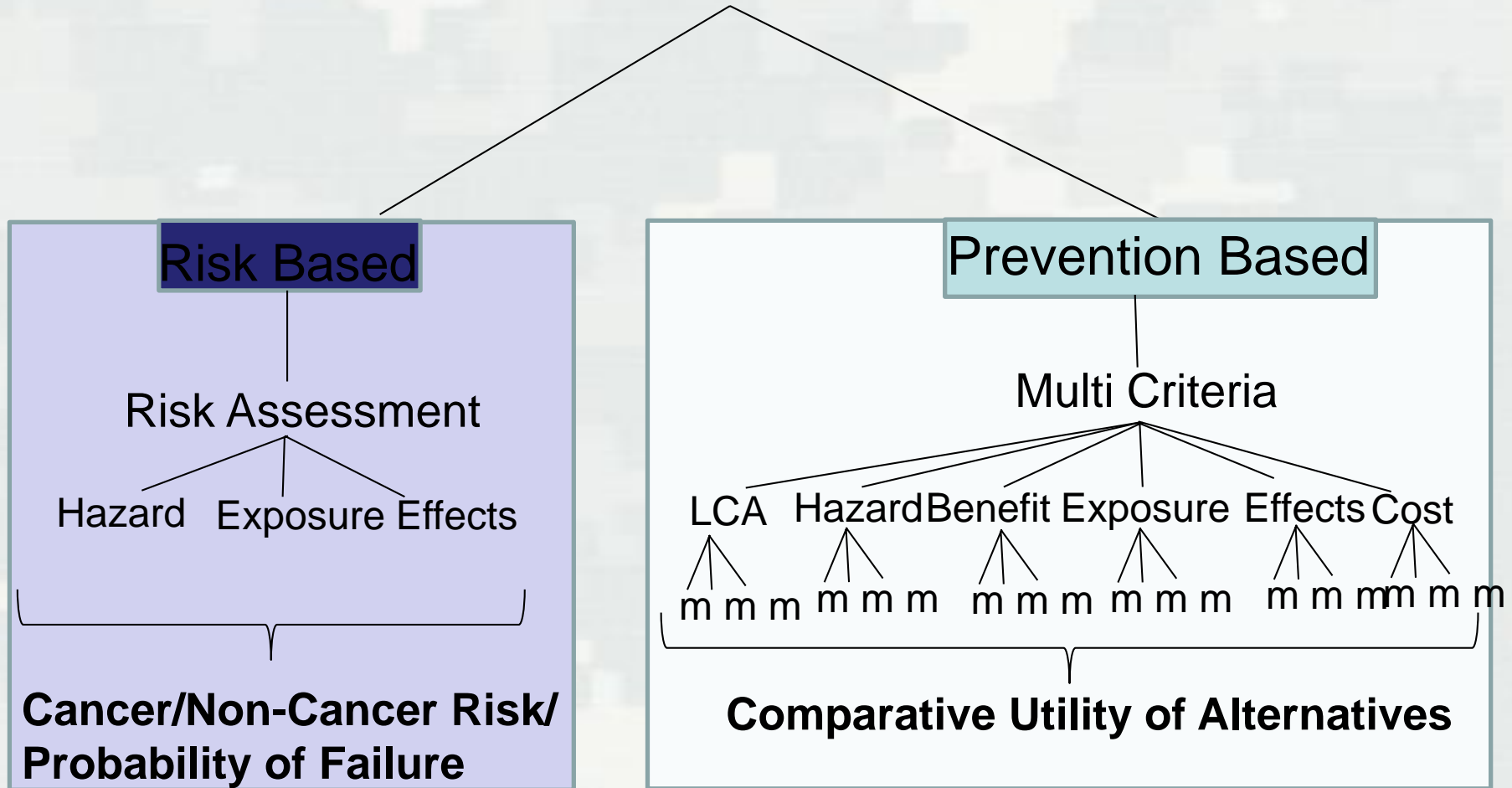


Methods & Tools for RG

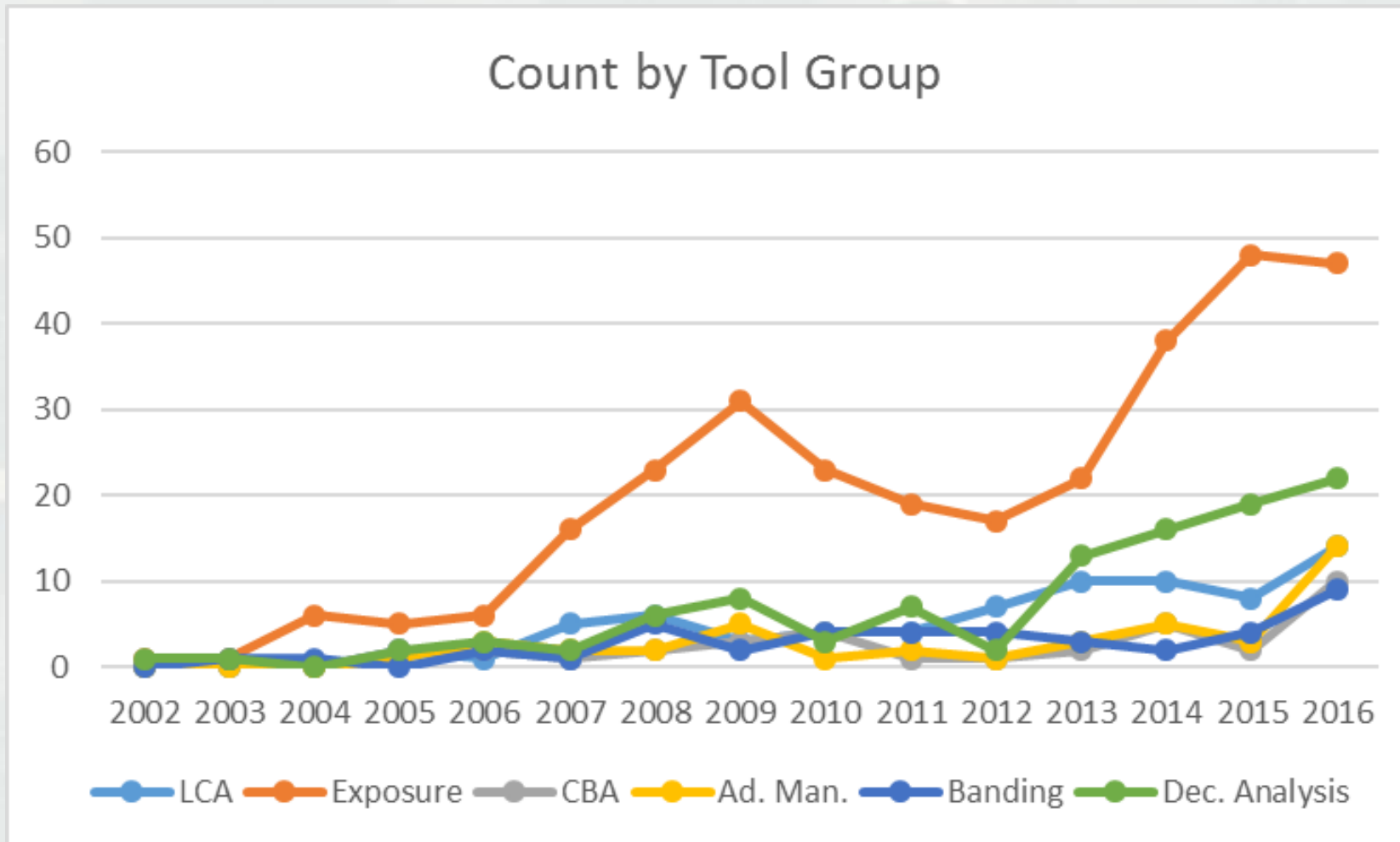
- Cost-Benefit Analysis
- Hazard/Exposure Assessment
- Life-Cycle Assessment
- Adaptive Management
- Control Banding
- Decision Analysis



Risk Governance

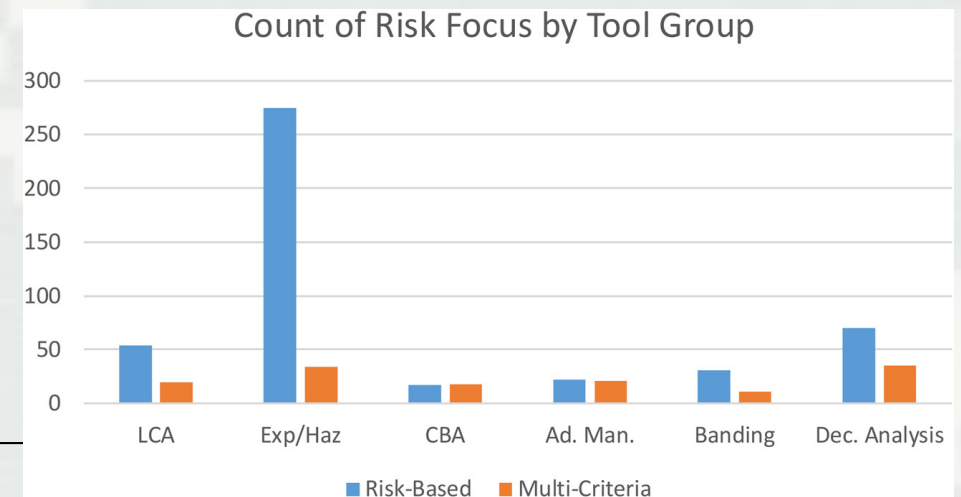
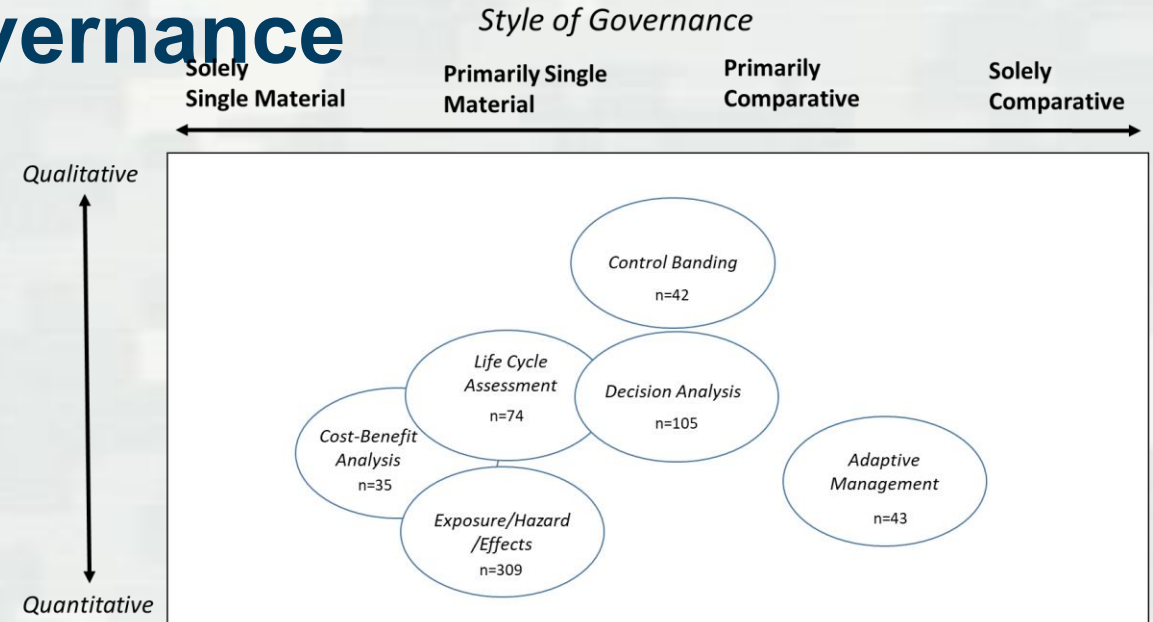


Literature Synthesis Results (n=429)



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 all elements of risk governance to drive “good” governance**



There are a lot of tools out there. What options are relevant for state/local decision makers?

- State and city governments have a tremendous amount of power to determine how goods and materials are:
 - ▶ acquired,
 - ▶ produced,
 - ▶ used,
 - ▶ consumed, and
 - ▶ disposed of within their boundaries

- Some are binding, others non-binding.



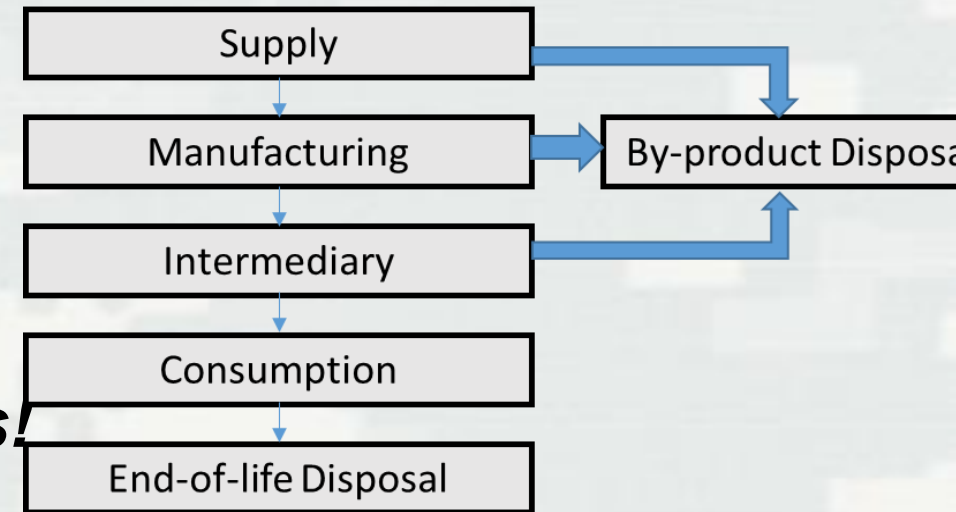
Typical mechanisms used by states and localities

- Blue-ribbon commissions
 - ▶ (e.g., *Policy Options for Regulating Marijuana in California*)
- Multi-Stakeholder Consortia
 - ▶ (e.g., NANOCAP and the 'no data, no market' rule)
- Public-Private Partnerships
 - ▶ (e.g., state-utility partnership in Massachusetts to operate in high-risk, high-volume areas of utility management and road paving)
- Direct research funding
 - ▶ Academic centers of excellence which view state-based risk assessment and management concerns (e.g., 'Risk Science Centers')
- Federal-State Partnerships
 - ▶ Congressional add-ins which formally join government agencies, companies, and universities with shared funding for a risk research problem



The Impact that States Can Have

- Must meet federal minimum requirements, but can be more stringent
- Material production and safety (ventilation, capture)
- Occupational health and safety requirements
- Safe transport and transshipment
 - ▶ Import and export of nanomaterials
- Consumer product safety
- Disposal and treatment requirements
- ***Insurance and Risk Transfer requirements***



Risk Assm.-Governance Integration

