Challenges to Risk Assessment, Governance, and Management for Nanotechnology

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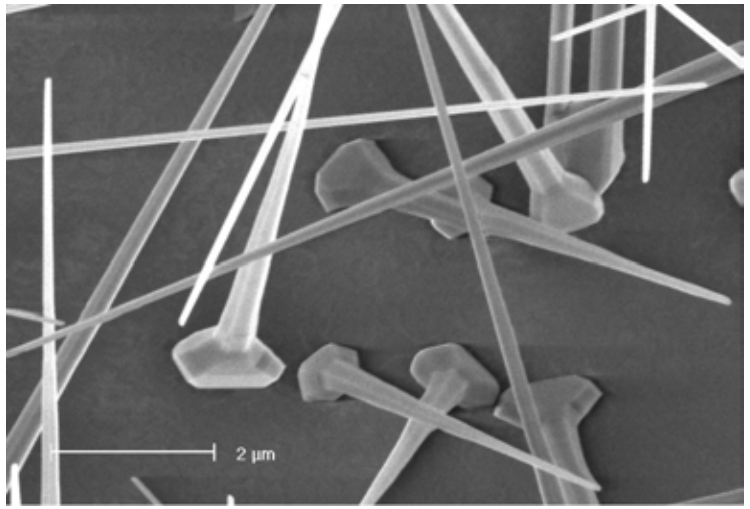

Nzo "Niño-nails"
(Jive Liu-Duke Univ.)

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New Approaches Needed

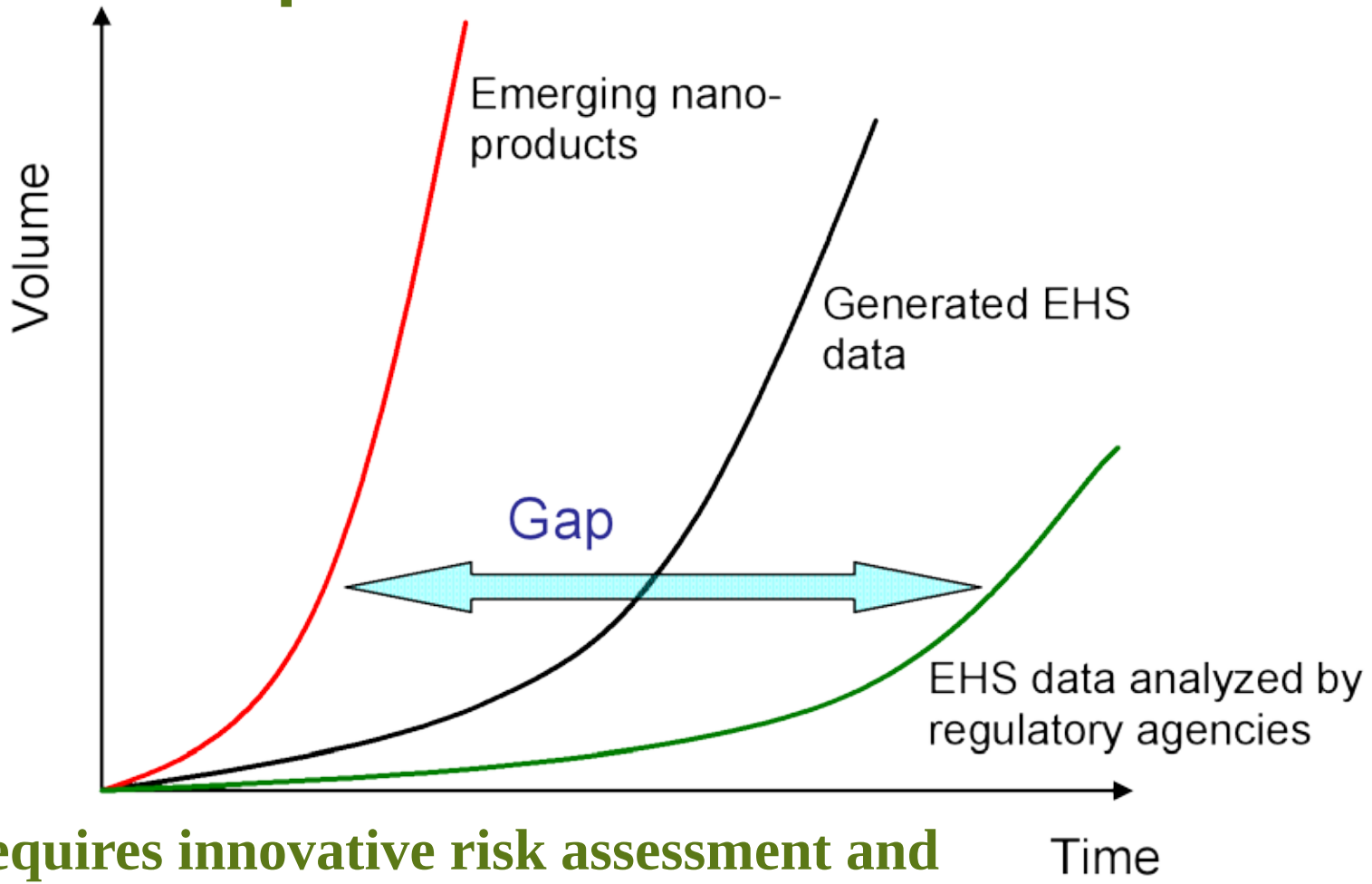
"Traditional governance mechanisms such as statutory enactments and/or … notice and comment rulemakings are thought by some to be challenging and possibly ill-suited tools for addressing potential EHS risks posed by the fast pace of evolving nanotechnologies. Even if these tools are believed suitable, most government agencies are of the view that they now lack sufficient data and information to make informed judgments on the potential hazards and risks of nonsocial materials, and it may take years not months, to obtain needed data."

- Lynn Bergeson, The New Business of Nanotechnology: Exploring Commercial Opportunities and Risks (2008)

Forget Nanotechnology

- Take a step back
  - ž What approaches are available for assessing risks of ANY “new” technology given…..
    - Uncertainty
    - Limited public interest until “problems” are observed
  - ž Definition of “Niño” for risk assessment and governance are not well defined
    - Novel chemistry, exposure route, both

Emergence of NEW Technology in Comparison to Generated EHS data



Requires innovative risk assessment and management and methods to deal with uncertainty

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from Linked and Satterstrom, 2008

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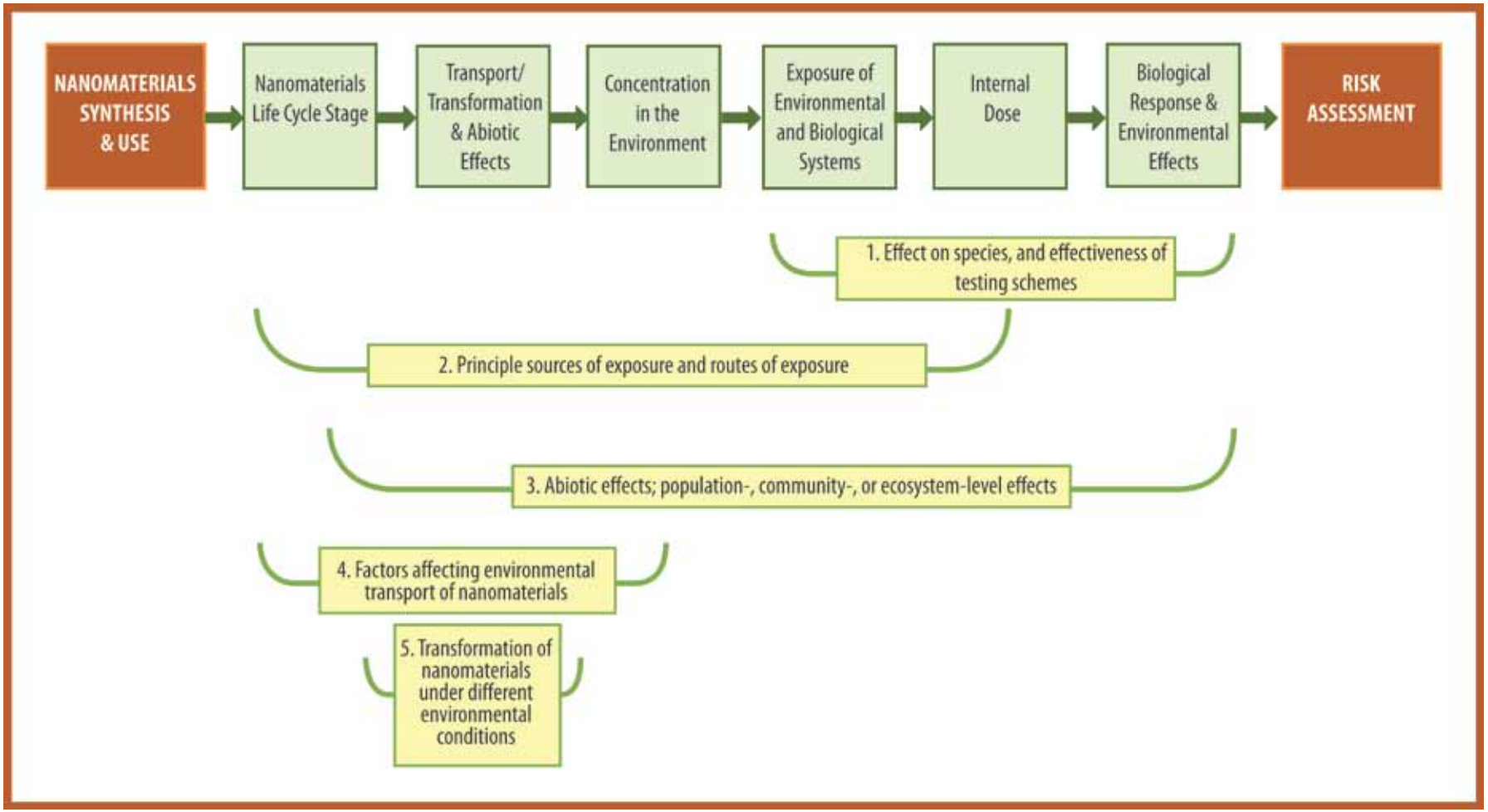
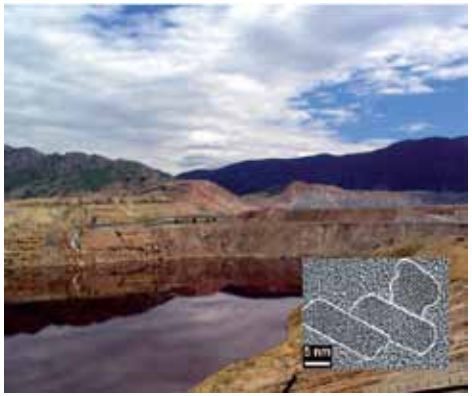
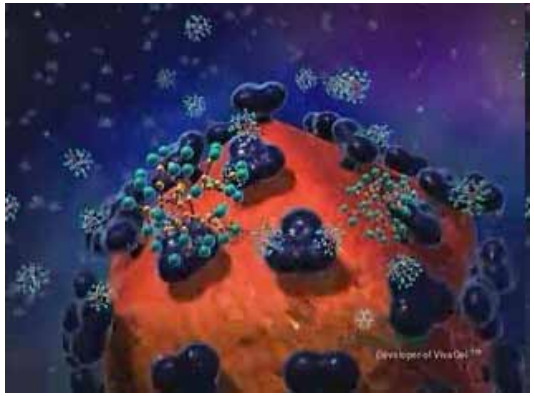
NNIN Federal EHS Research Strategy 2008



Traditional Risk Assessment





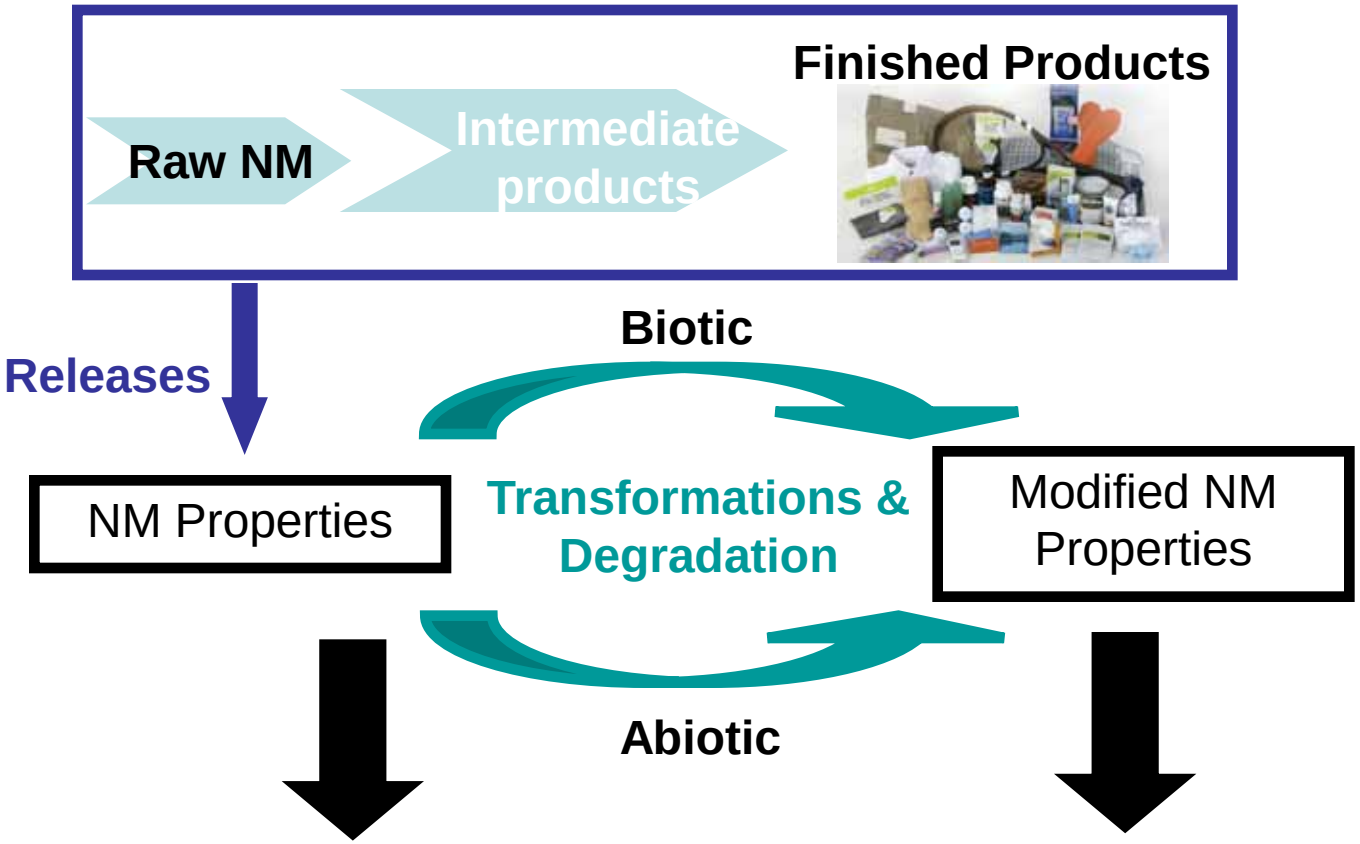
Exposure → Risk Characterization ← Effect

ü How do they travel?
ü What affects mobility and distribution?
ü How are they transformed?
ü What do they become?
ü What 'compartments' do they reside
ü Are they bioavailable?
ü Do they bioaccumulate?

ROS generation
Membrane disruption
DNA Damage
Protein Unfolding….

Difficult Questions

Ü **Where do NP go? What do they become? How long do they stay?**

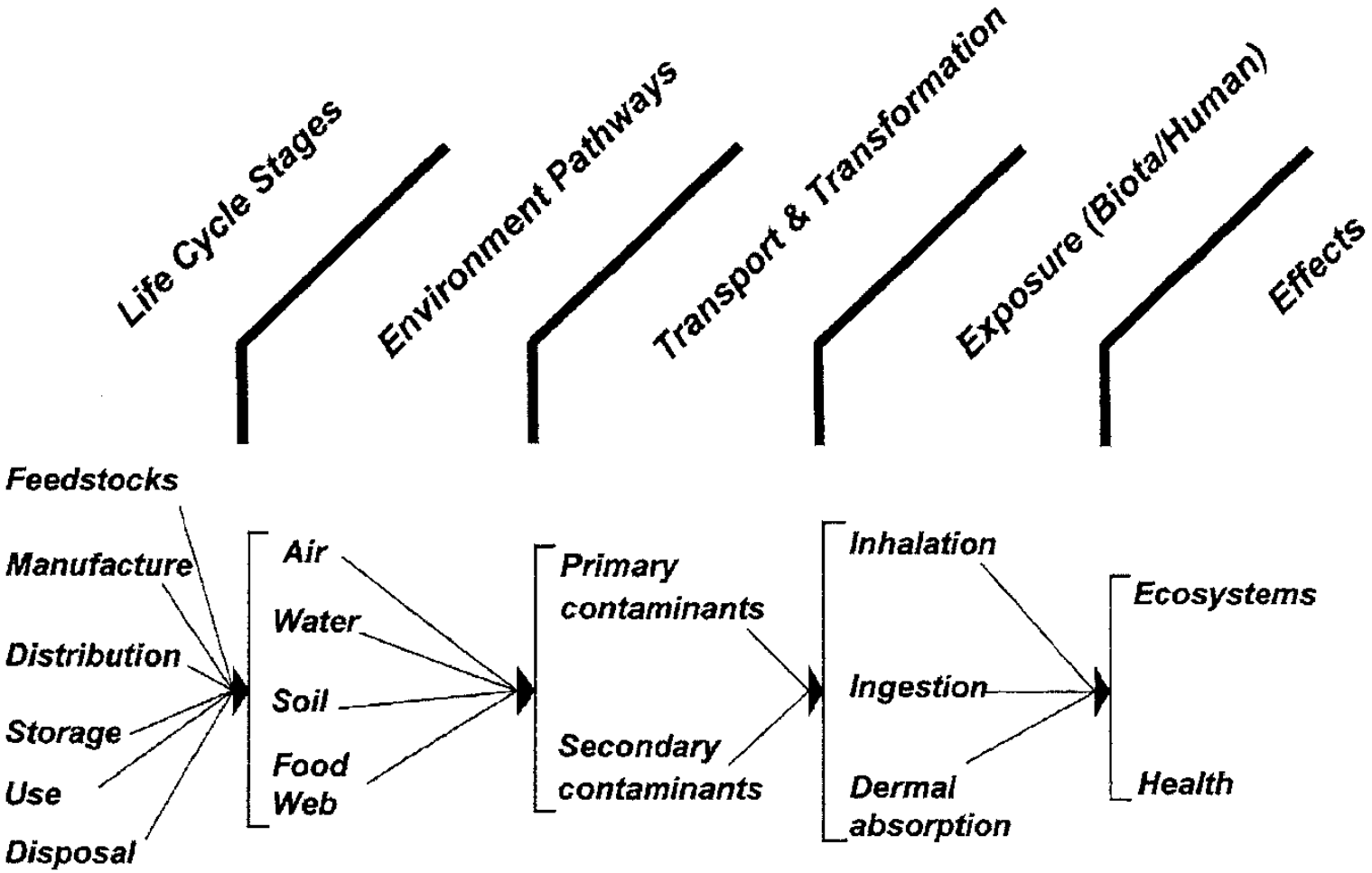


Framework is Fine, BUT…..

- Limited information is available
- Infinite number of variations of NPs-coatings
- NPs change character over time in the environment
- Rate of innovation to rapid for EHS to keep up
- Not enough time and $$$
- No consistent definition of “nano” material

How then do we proceed with Risk Assessment, Governance, and Management

Pretty good consensus on lifecycle



Potential Problems with Current Approaches

- Source Terms Difficult to Predict
  - NanoAg
  - Potential for risk depends on assumptions

- Case study-based approach is narrow
  - TiO_2

    Sunscreens and water treatment (Davis et al. EPA)

Estimating Exposure Concentrations

Environ. Sci. Technol. **2008**, *42*, 4447–4453

Exposure Modeling of Engineered Nanoparticles in the Environment

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Technology and Society Laboratory, Empa - Swiss Federal Laboratories for Materials Testing and Research
Lerchenfeldstrasse 5, CH - 9014 St. Gallen, Switzerland

Received November 27, 2007. Revised manuscript received March 12, 2008. Accepted March 17, 2008.

"The risk quotients (PEC/PNEC) for ... nano-Ag were much smaller than one, therefore comprising no reason to expect adverse effects from those particles."

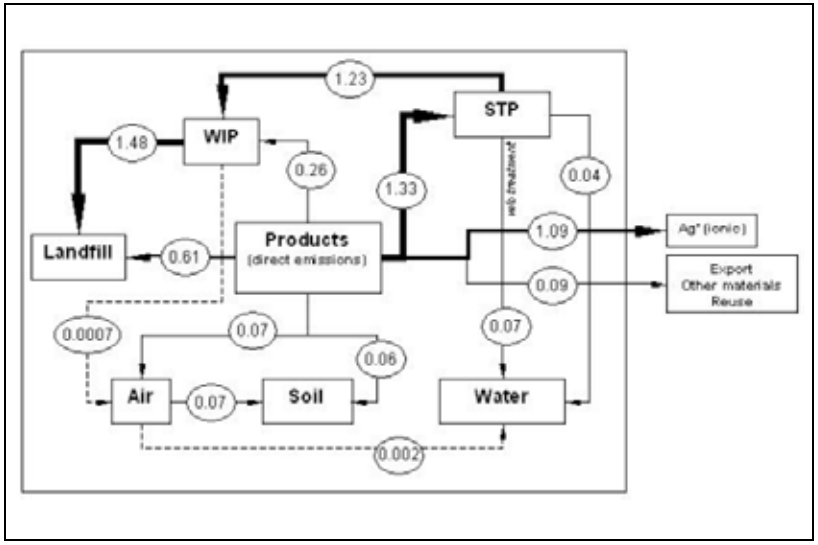
Results for silver ION in 2010

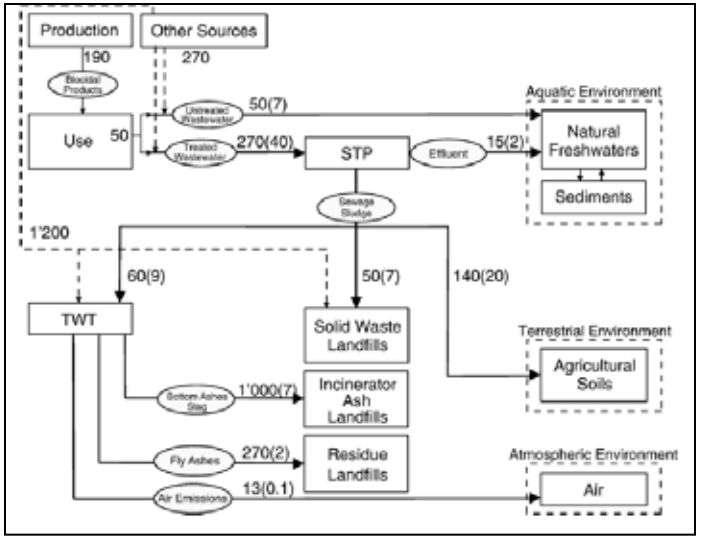
Fresh water RQ≈ 20-160

Sediments RQ ≈ 1.6-6.3

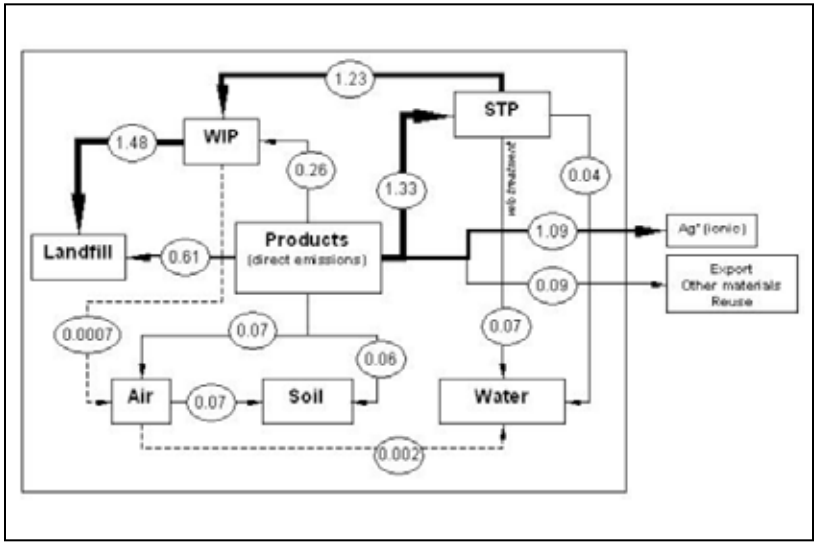
"…our study indicates that **PEC/PNEC ratios greater than 1 cannot be ruled out** for freshwater ecosystems, in particular sediments."

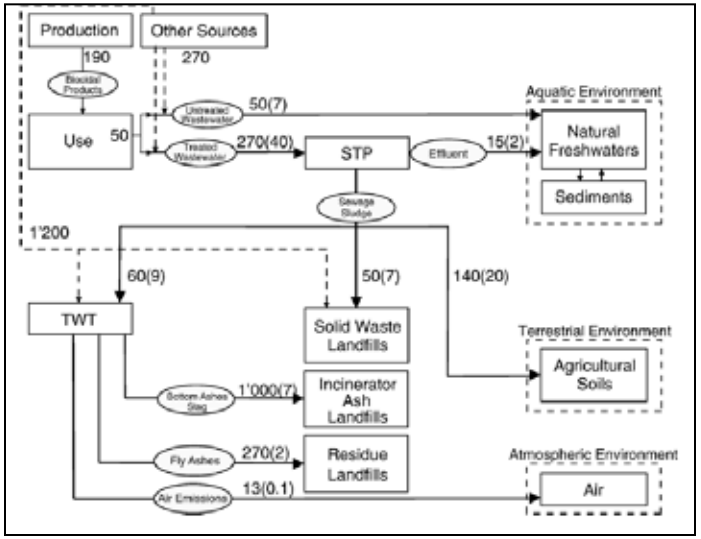
Blaser *et al*. 2008





- Do we believe either model *partitions* Ag NPs correctly?
- Are the simplifying assumptions too drastic?
- Are the properties and transformations of nanoparticles correctly represented?
- Is the large geographic scale suitable for understanding environmental impairment?





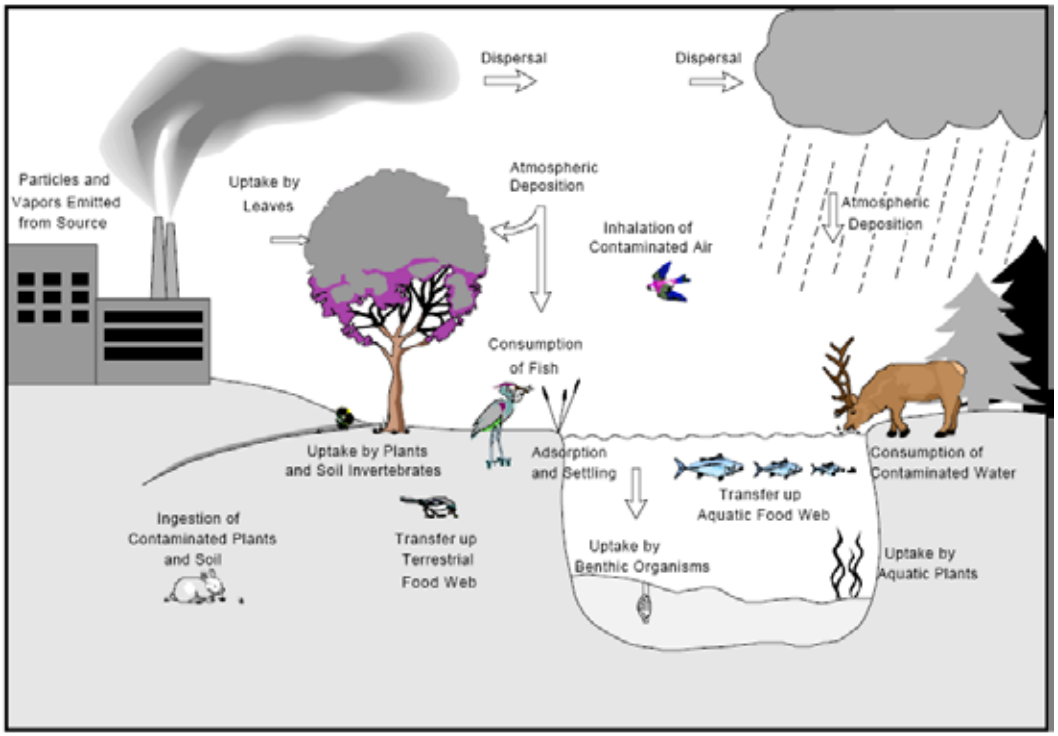
Are we using the right indicators of environmental impact?

Are we getting the environmental concentration correct?

Are worst case scenarios really “worst case”

Is uncertainty underestimated?

Rethinking the *first order* questions for the risk paradigm



EPA's multimedia fate & transport model, TRIM-FaTE

http://www.epa.gov/ttn/fera/data/multi/figure1.pdf

- What is the right level of detail?
- What is a meaningful scale?
- What properties must be represented?
- What processes?
- Are new models of mixing and partitioning needed?
- What transformations are relevant?
- When should co-contaminants be considered.

How should we prioritize the first order questions?

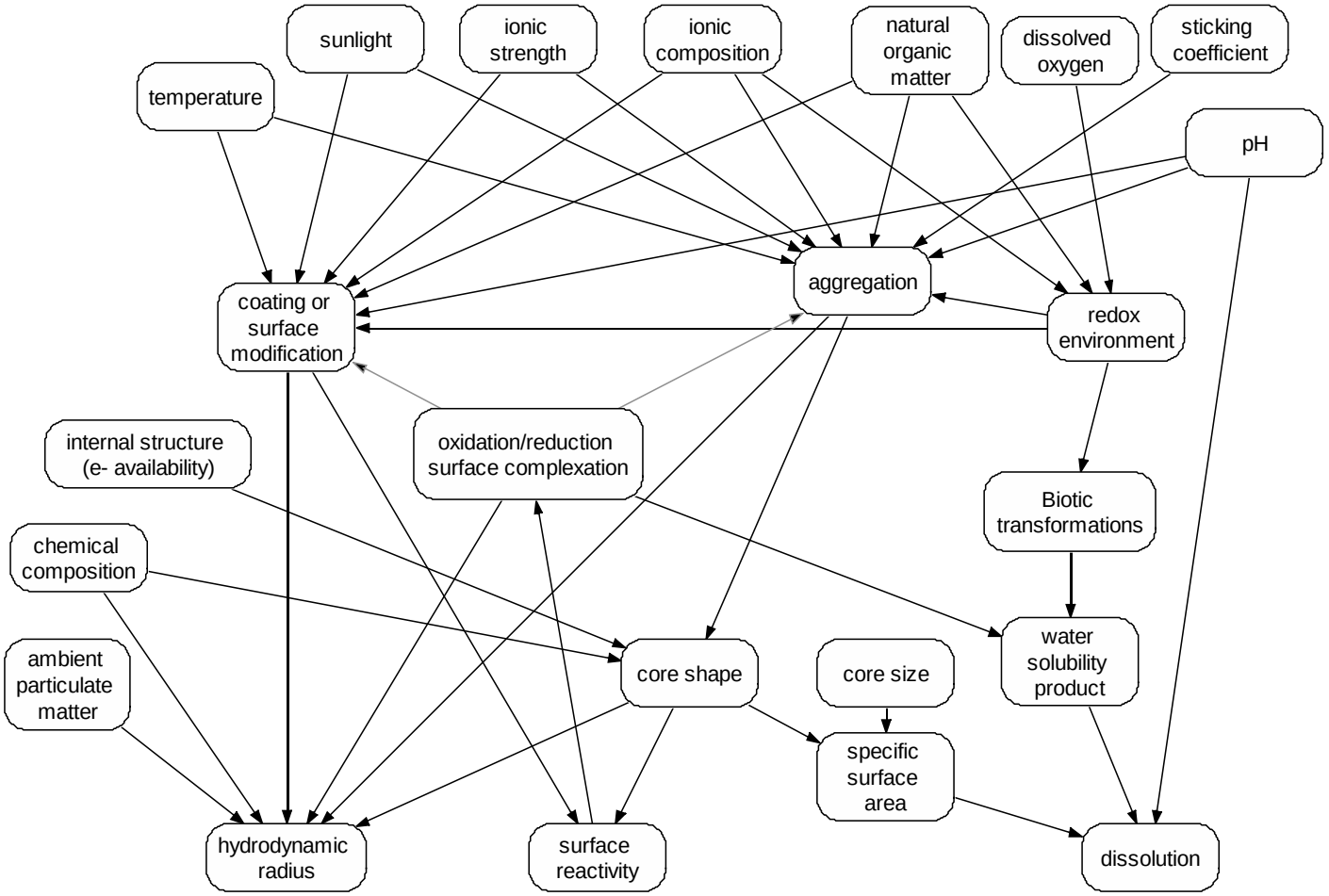
A proper prioritization:

- Has an explicit objective
- Incorporates interconnectedness of research
- Is unbiased

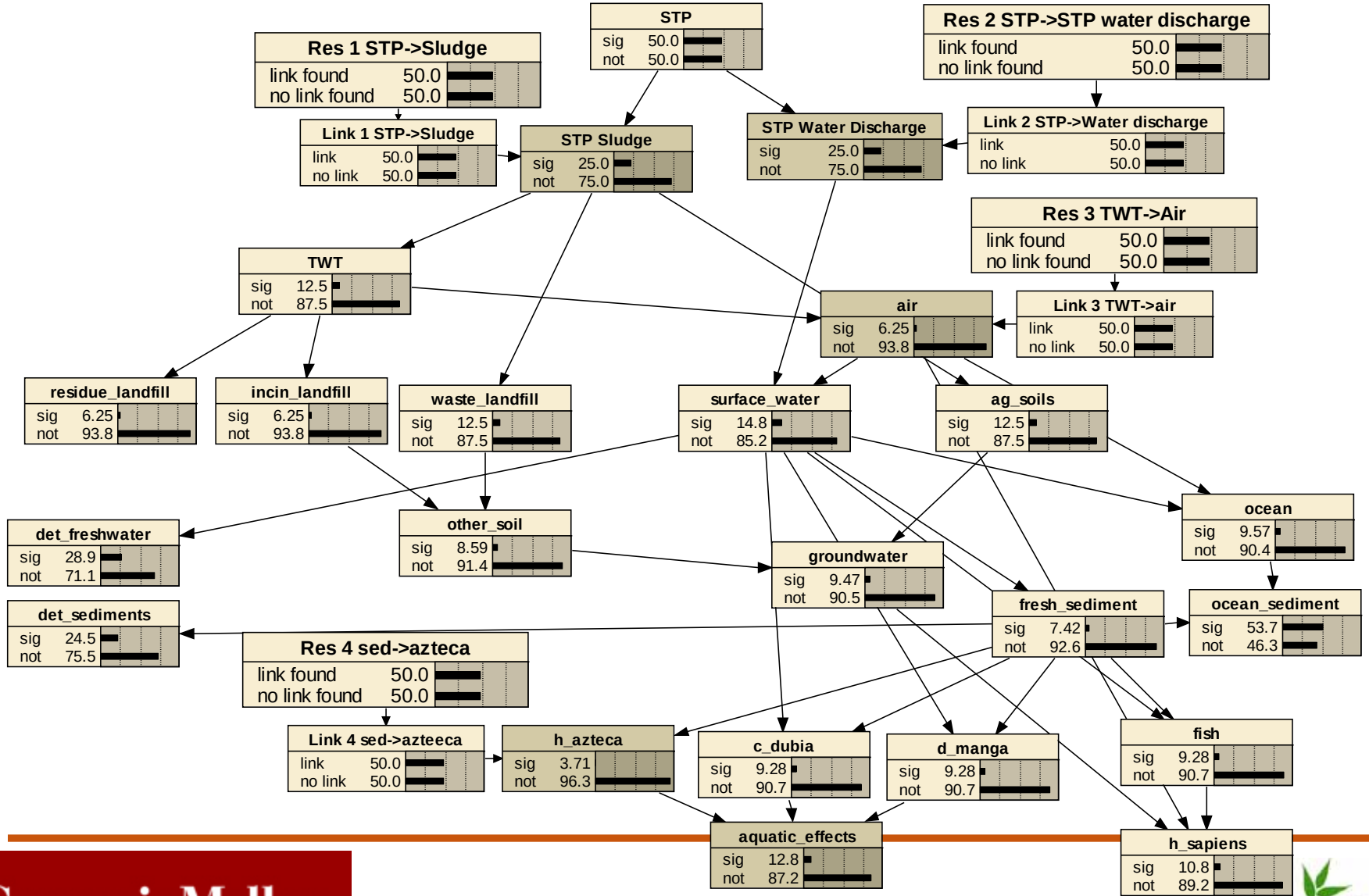
Perhaps a model could do this better. The model must be

- Causal, to incorporate how information flows between areas of knowledge
- Probabilistic, to reflect uncertainty in such knowledge.

Bayesian Belief Network Model of Nanosilver Transformations in the Environment



Bayesian Belief Network of Nanosilver Environmental Flows



Risk Management

- Two schools of thought
  - ž Eliminate Hazard (Green Chemistry)
    - Not always possible (e.g. TiO_2 for H_2 from Sunlight)
  - ž Eliminate Exposure
    - Encapsulation (TiO_2 in sunscreens)
    - Protective equipment for workers
    - Minimize release to environment
    - Public education/labeling

What Should Regulation Address/Prioritize?

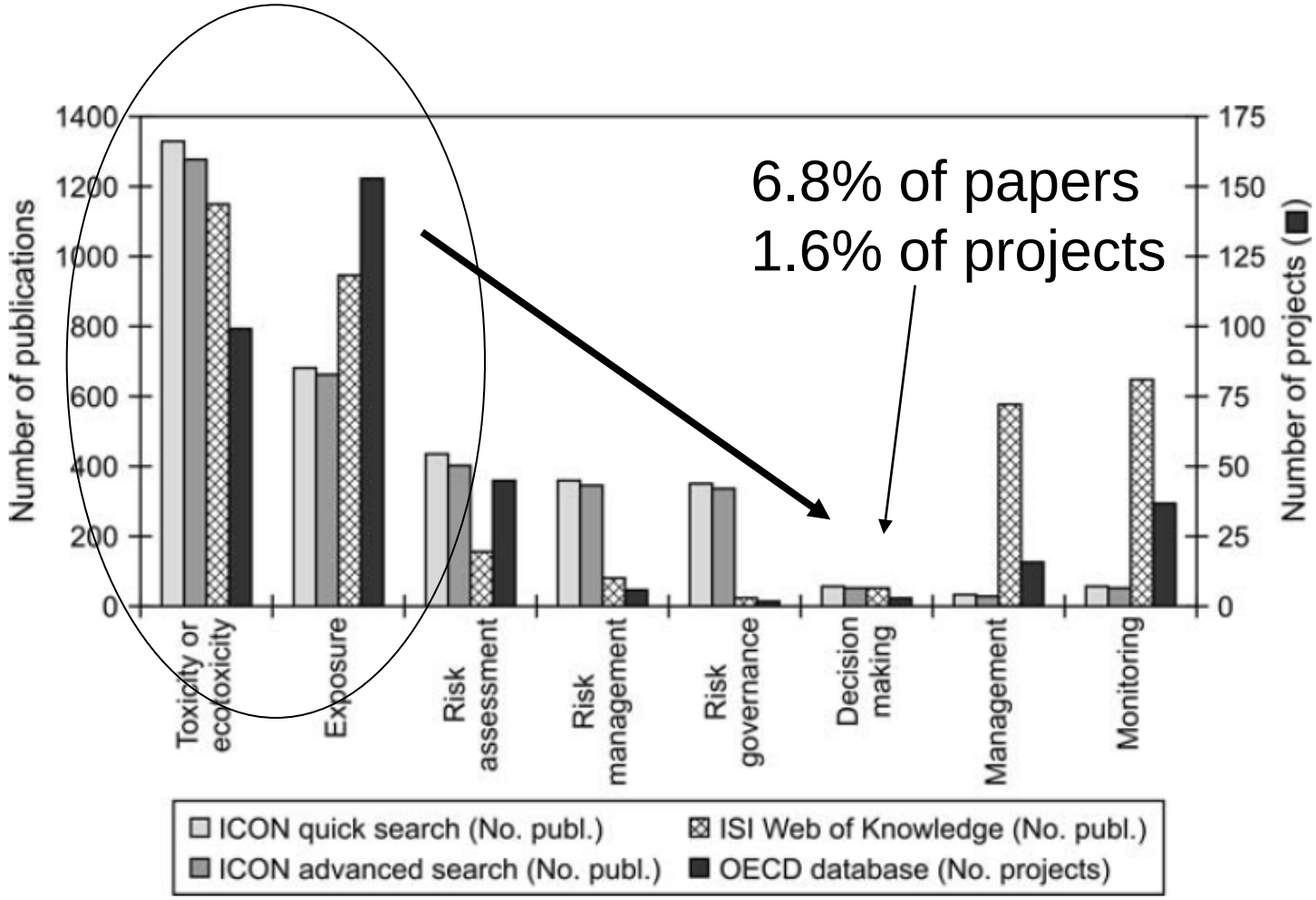
- Hazard or exposure or both?
- Which material or materials?
  - Greatest use
  - Most potential for release
  - Highest toxicity potential
  - What “bins” do we use to classify nanomaterials?
- How do we prioritize research to best reduce uncertainty to these questions?
  - Value of information

How do we Move from this "Approach" to Making Real Decisions?

- What decisions must be made?
  - ž Regulate Silver NPs
  - ž Nanomaterials need their own MSDS
  - ž EPA should use TSCA to manage Nanomaterials
  - ž NPs with different coatings should be treated as individual NPs
  - ž Agencies should get a 10% increase in funding for nano EHS

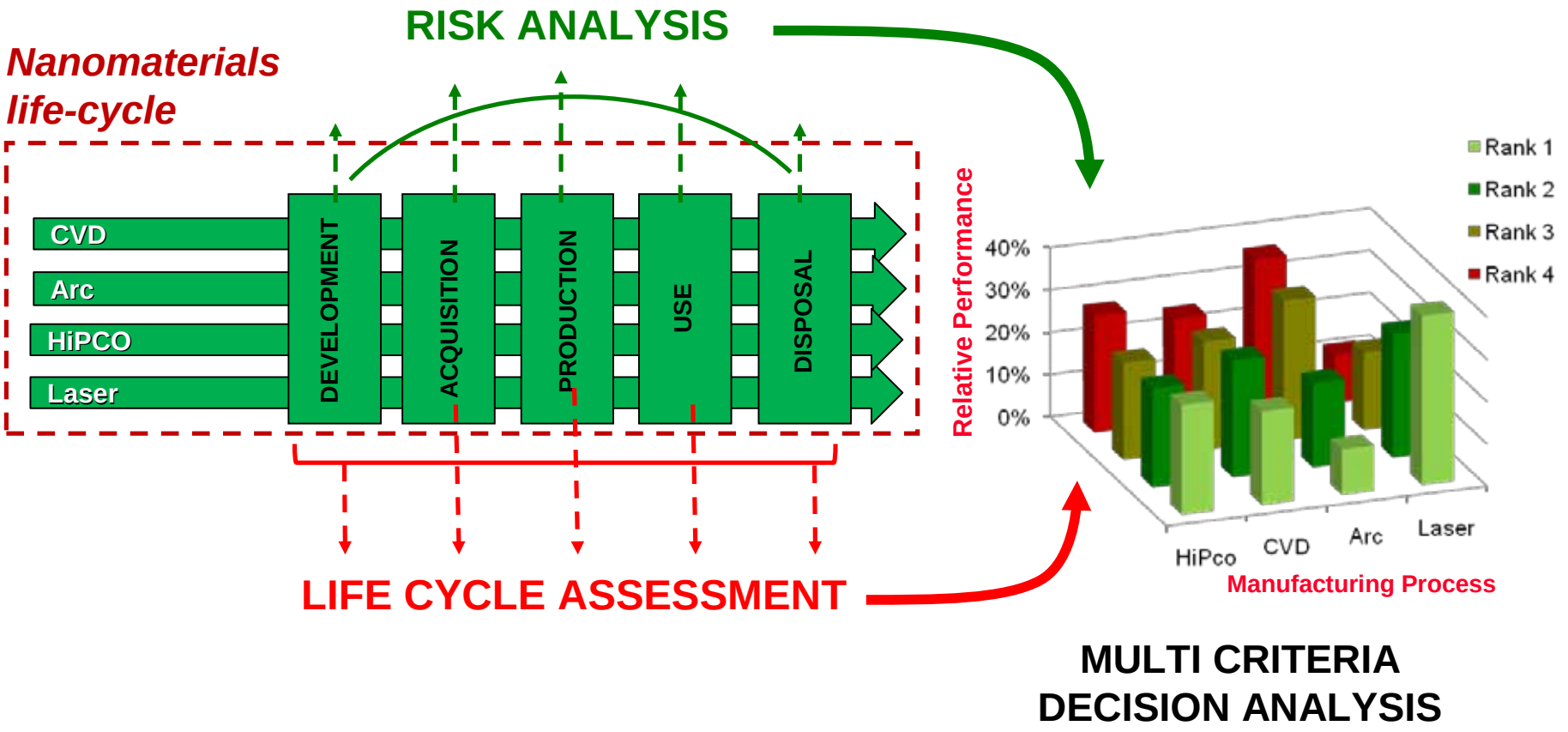
    "To maximize knowledge of aquatic ecosystem impacts of nanoscale silver, 40% of the effort should be devoted to fate & transport, 30% to developing detection methods…"

How do we Bridge the Gap?



Grieger et al. **(2010)**. *JNR* 12 383-392

MCDA and Risk Management Under Uncertainty



Based on Canis, Seager & Linkov (2010)

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Final Thoughts

- Develop risk governance frameworks that promote timely decision making
  - ž Streamline risk assessment
  - ž Adaptive, flexible, innovative framework
  - ž Focus on near and mid-term decision making (e.g. MCDA)
    - Incorporate as much information as is known today and revise/adapt as new information available
- Use explicitly-stated, quantifiable objectives to develop research strategies
  - ž Bayesian (Statistical) Approaches

Final Thoughts

- Dealing with uncertainty
  - ž Managing uncertainty
  - ž Make decisions in spite of uncertainties
  - ž Focus research on reducing key uncertainties