Preparing for the Future of Emerging Technologies: Upstream and Integrated Oversight Assessment

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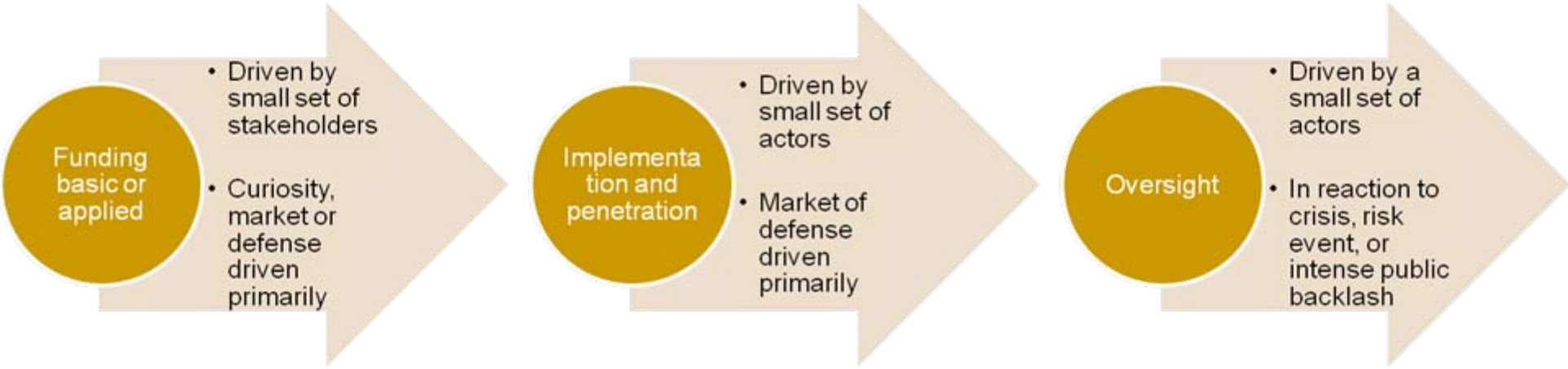
UNIVERSITY OF MINNESOTA

Outline

- Current Emerging Technologies Oversight Policy
- Anticipatory Approaches
  - Integrated Oversight Assessment
  - Upstream Oversight Assessment
- Evolution of ETs and Oversight

Emerging Technologies Current Progression



Problems with Current Model

- Reactionary and Closed Process

- Utilitarian (outcome)
  - Adverse Events (from reactionary, anti-precaution mode)
  - Public Rejection of Beneficial Technologies
- Intrinsic and Procedural:
  - Not democratic
  - Little equity or justice in process
  - Little consideration of values
  - Lack of informed consent
  - Driving force is not S&T for social good

Calls for Anticipation and Participation

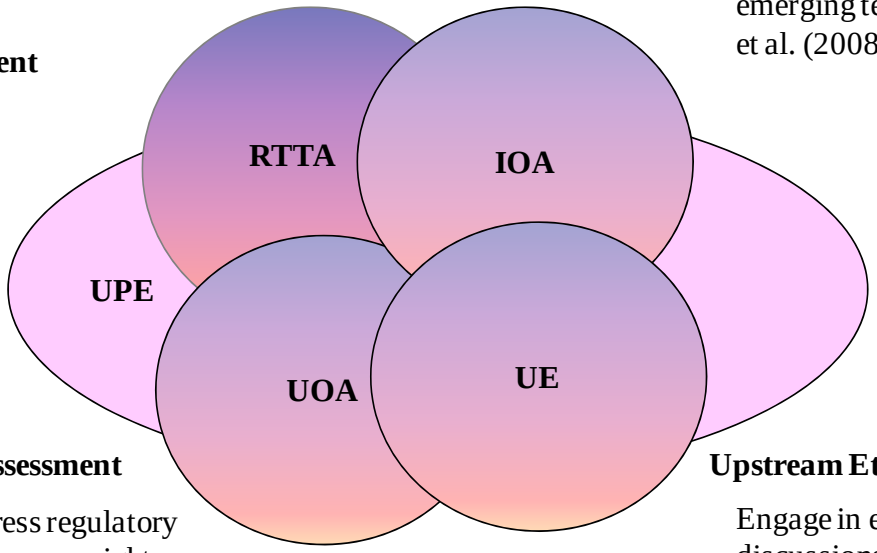
Real Time Technology Assessment

Integrate natural science and engineering investigations with social science and policy research from the outset—Guston and Sarewitz, (2002)

Integrated Oversight Assessment

Multiple-method, interdisciplinary, criteria-based evaluation of oversight by stakeholders and experts to learn from historical experience with previous emerging technologies Kuzma et al. (2008a)

Anticipatory Governance



Upstream Public Engagement

Science-society communication to incorporate new forms of public knowledge in science and technology early in development-Willis and Wilsdon (2004)

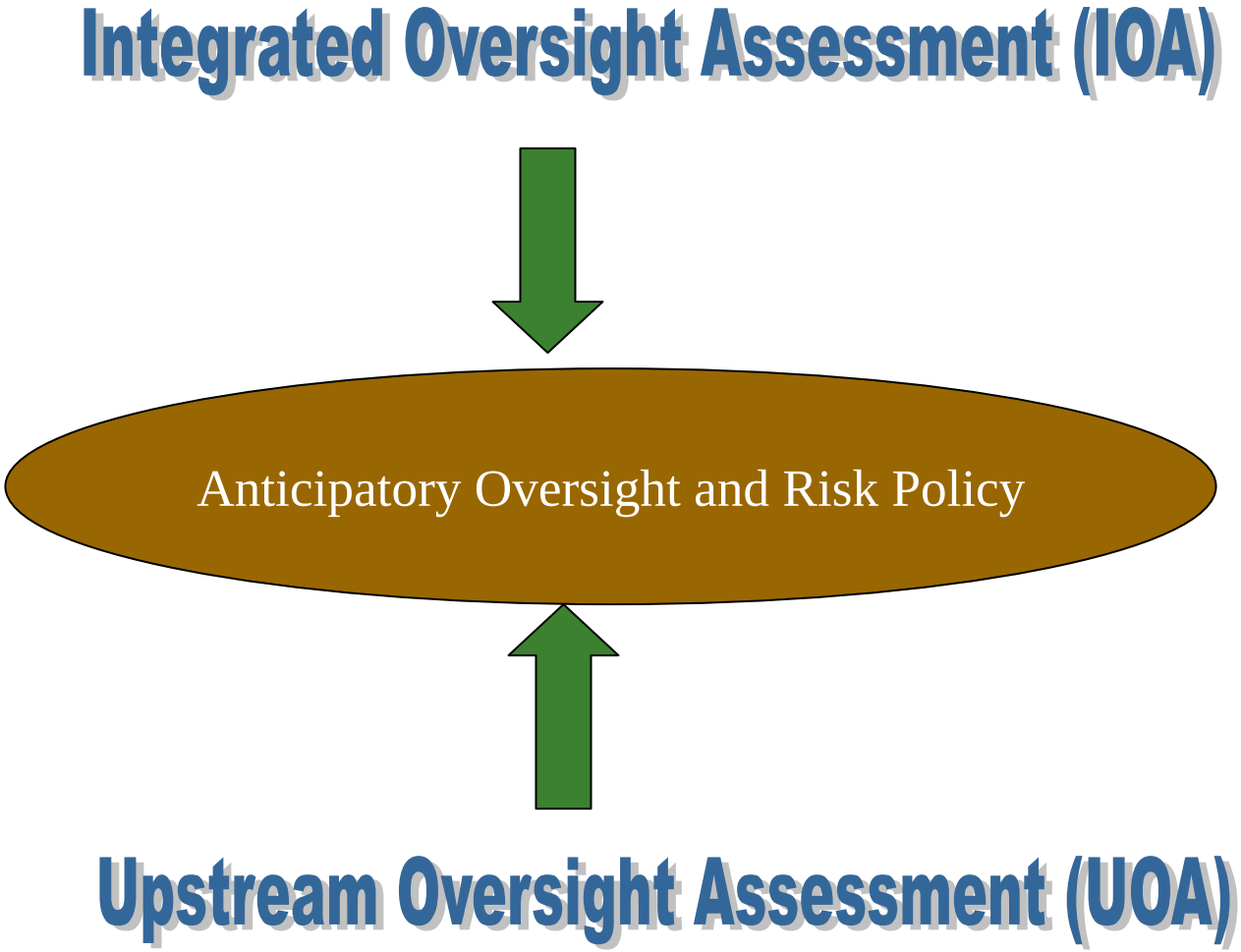
Upstream Oversight Assessment

Identify and address regulatory and non-regulatory oversight issues associated with new technological products long before they are marketed so that system is prepared—Kuzma et al. (2008b)

Upstream Ethics

Engage in ethics discussions and analysis early before and during emerging technologies development—Khushf (2007)

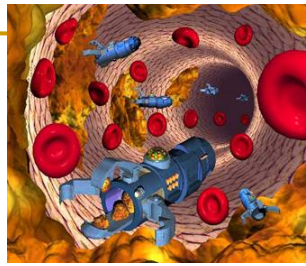
Two Approaches as Subset of Anticipatory Governance

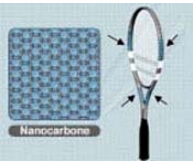


Case Study of Nanotechnology: What is nanotechnology?

- **It's small, it's diverse, conglomerate of existing fields, unified by new tools to manipulate atoms and molecules**
- **The National Nanotechnology Initiative listed the following three criteria for defining nanotechnology:**
  - 1) research and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1 - 100 nanometer range, (1 nm is 80,000th thickness of human hair)
  - 2)creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate size, and
  - 3) ability to control or manipulate on the atomic scale.
- **Creation of nanomaterials by "Top Down" or "Bottom Up" approaches**

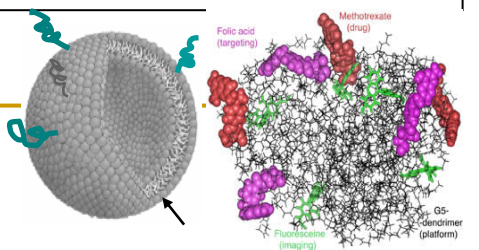
State of Nanotechnology





- **2000 National Nanotechnology Initiative (NNI), $270 M for R&D—**
- **2008 NNI continues, $1.4 B for R&D, including 4% of NNI budget devoted to societal issues, including education (Approx. 1% to ELSI, 1% to EHS)**
- **Over 600 products on market, but just a few medical, agricultural, food, and environmental applications**
- **Congressional hearings on need for more EHS and societal work (2008, 2009)**

- **No specific, coordinated U.S. oversight policy for nanotechnology**
- **"Time" for independent study of oversight models for nanotechnology**
- **More talk and acceptance of the need for public participation and dialogue early and often**



www.nanotechproject.org
Over 600 products on market

Nano-oversight: State of Affairs

- Nanotechnology oversight is based upon existing laws and regulations
  - Multiple agencies, laws, and jurisdictions
  - Some products require pre-market testing, others do not
  - Standards based on mass or volume (not #particles or surface area)
- So far, no concerted efforts for public input and engagement in oversight, although several pilot projects
  - Policy developing after conflicts (e.g. legal petition based, ICTA 2007)
- Argument of “equivalence” as default, unless shown otherwise
- Product, not process arguments
- Similar to experience with GEOs in agricultural or environment in many ways (also similar products—nano in food and ag, nano for GE
- How can we learn from history of ETs in the design of nanotechnology oversight?

Integrated Oversight Assessment Approach

NSF Grant SES-0608791

(Wolf, Kokkoli, Kuzma, Paradise, Ramachandran, Co-PIs).

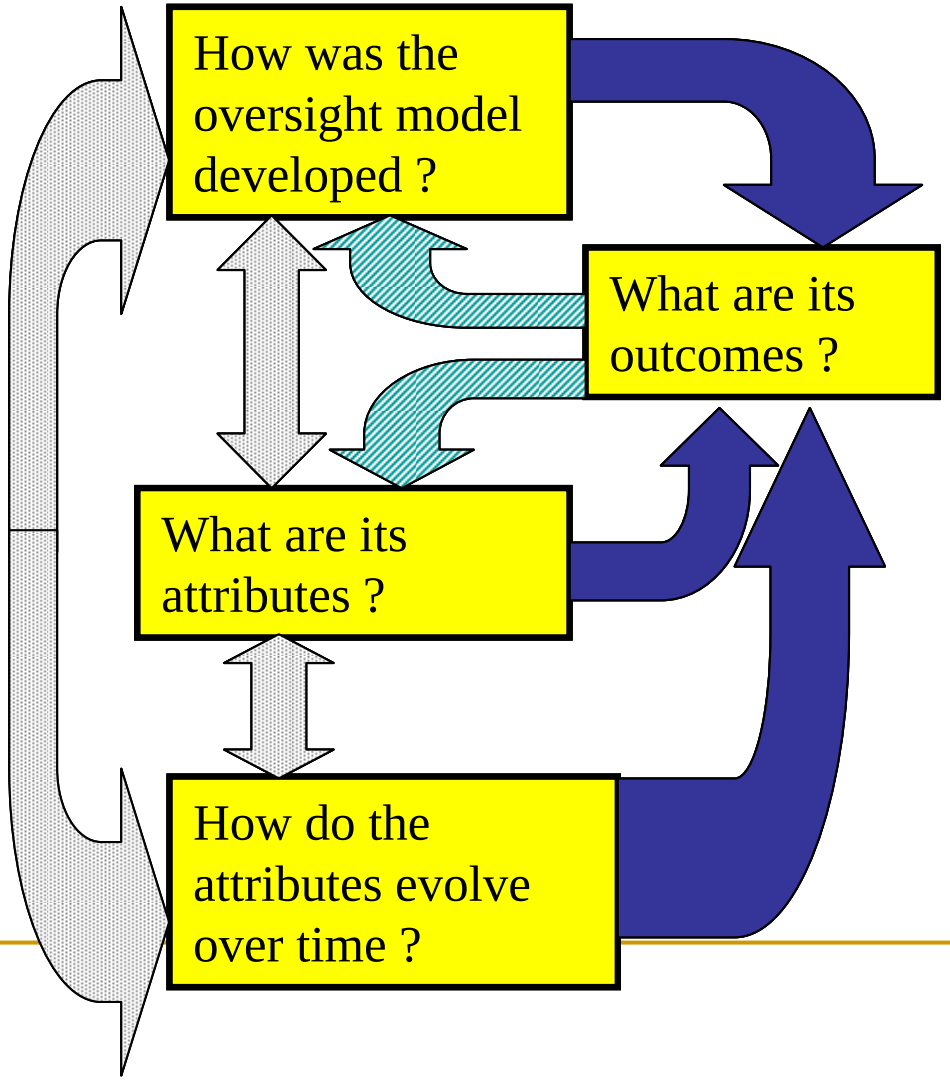
- **Phase 1—Evaluation of 5 historical oversight models, all relevant to nano-bio interface**
  - Drugs, Devices, Gene Therapy, **GEOs in food and agriculture**, Chemicals in the Workplace
- **Phase 2—Mapping lessons to nanotechnology in biological systems**
- **Phase 3—Testing lessons in scenarios for specific nano-bioproducts**

- **Multiple methods criteria, disciplines, stakeholders, and experts involved**
  - Rooted in historical analysis, expert elicitation, stakeholder input, and multi-criteria decision analysis
  - Quantitative & Qualitative, Normative and Empirical

Forthcoming symposium on project, *Journal of Law, Medicine, & Ethics, Winter 2009*

Integrated Oversight Assessment

Kuzma, J., Paradise, J., Ramachandran, G., Kim, J-A., Kokotovich, A. and S. M. Wolf (2008). "An Integrated Approach to Oversight Assessment for Emerging Technologies". *Risk Analysis,* 28(5).



Multi-Criteria & Case Study Approach
Expert and Stakeholder Elicitation

Step 2: Expert and Stakeholder Elicitation[3]
Criteria Reduced from 66 to 28

Development: 7 criteria
- D1 Impetus
- D2 Clarity of technological subject matter
- D3 Legal grounding
- D4 Public input
- D5 Transparency
- D6 Financial resources
- D7 Empirical basis

Attributes: 14 criteria
- A8 Legal grounding
- A9 Data requirements;
- A10 Post-market monitoring
- A11 Treatment of uncertainty
- A12 Empirical basis
- A13 Compliance and enforcement
- A14 Incentives
- A15 Treatment of Intellectual Property
- A16 Institutional structure
- A17 Flexibility
- A18 Capacity
- A19 Public input
- A20 Transparency
- A21 Conflicts of interest
- A22 Informed consent

Majority >70% of experts-stakeholders rated the criteria 70 or higher

Outcomes: 5 criteria
- O24 Public confidence
- O25 Research & innovation
- O26 Health and Safety
- O27 Distributional Health Impacts
- O28 Environmental Impacts

"How important is it to consider this criterion in oversight?"
On a scale of 0 (least) to 100 (most),
please rate the importance of each of the criteria to oversight assessment

Case Study Evaluation Using Criteria

How well does the oversight System perform with regard to or reflect the criteria?

GEOs to Nanotechnology: Research Goals

Specific:

- Evaluate oversight for GEOs in food and agriculture in the U.S. from multiple perspectives (social, ethical, legal, technical risk-based, policy)
- Derive hypotheses and evidence-based lessons for nanotechnology broadly and specifically for nano in agriculture, food, or genetic modification

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Broad:

- Develop methodology for more holistic approach to evaluating oversight models for emerging technologies
- Derive more general hypotheses for how features of oversight impact outcomes
- Inform the design of policy options for emerging technologies oversight

GEOs Oversight Assessment as a Case Study for Nanotechnology

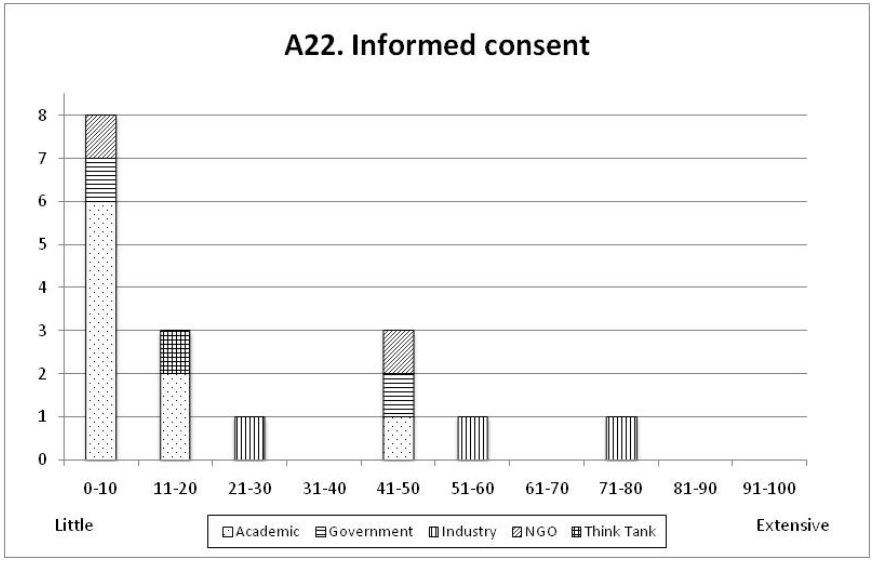
Kuzma, Najmaie, Larson
J. Law, Medicine & Ethics, forthcoming

- Experts/stakeholder asked to rank how GEOs oversight system has performed on scale of 1-100 with regard to 28 criteria

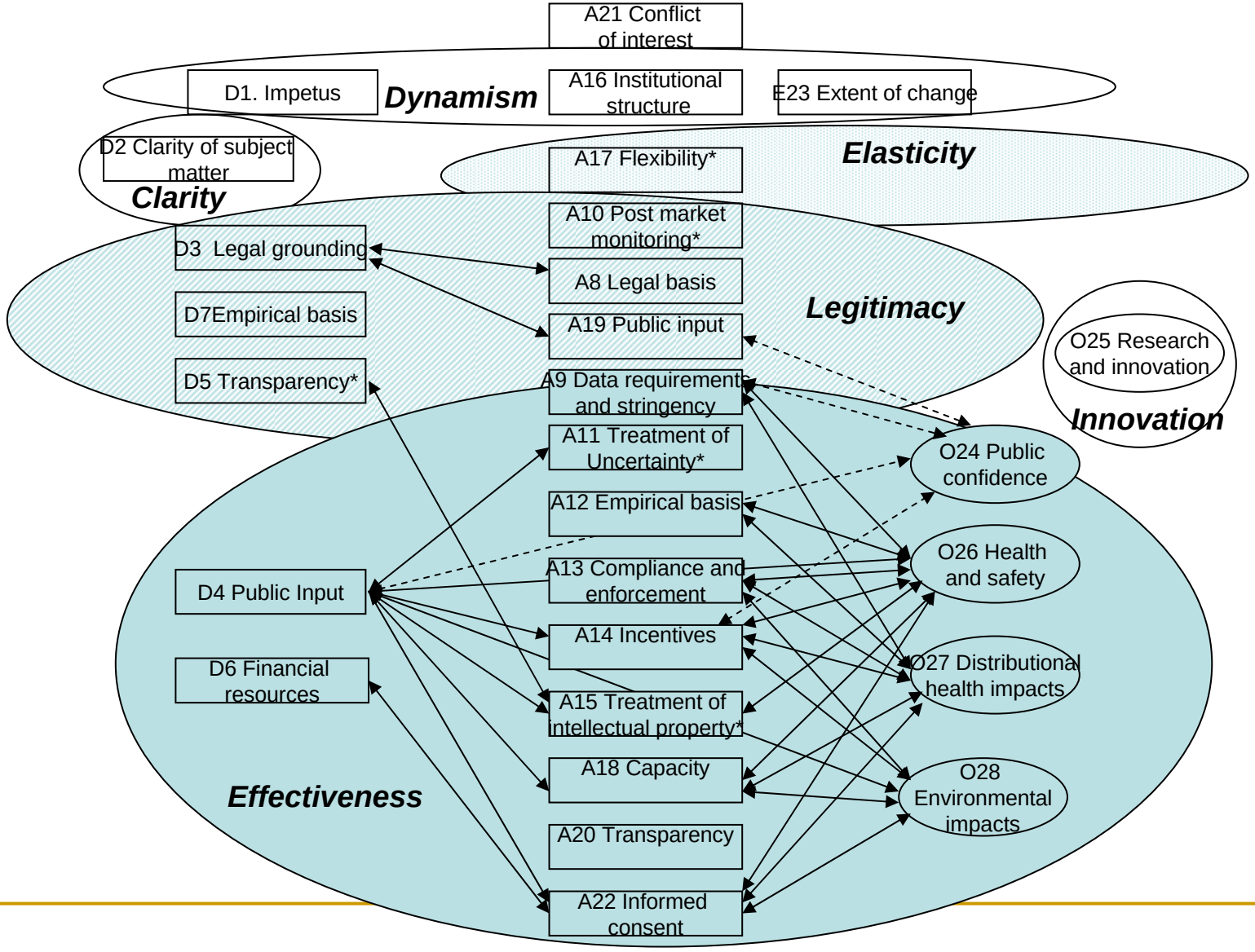
"Strengths" and "Weaknesses" of GEOs Oversight

- **Strengths**
  - Clarity of subject matter (clear)
  - Flexibility (high)

- **Weaknesses**
  - Legal grounding in development (weak)
  - Transparency (low)
  - Financial resources (low)
  - Postmarket monitoring (little)
  - Treatment of intellectual property (closed)
  - Capacity (low)
  - Public input in attributes (little)
  - Conflict of interest (prominent)
  - Informed consent (little)



Correlation and Factor Analysis for GEOs Case Study



Results from Quantitative analysis

- Industry experts scored evaluative criteria more positively than other types of experts (statistically significant difference)
- Highly significant correlations ($p<0.002$) were seen between attributes such as public input and informed consent and outcomes such as health and safety.
- The main factor emphasized health and safety outcomes, but also contained criteria associated with
  - democratic and ethical principles (informed consent, public confidence, public input to system development, just distribution of health outcomes, and transparency);
  - evidentiary foundations (data requirements, specific empirical basis, and treatment of uncertainty);
  - institutional foundations (incentives, compliance and enforcement, capacity, proprietary information provisions, and financial resources).

Public Attitudes & Oversight:
Most Prominent Coding Theme in Interviews

- *"Because the system was cobbled together for GEOs it alienated a significant chunk of the population. This affected public confidence."*
- *"No people who were thoughtfully critical were at the table."*
- *"The process was no help to public confidence because it is complicated, decentralized, and confusing (who is responsible for what?). Agencies end up passing the buck which led to regulatory gaps."*
- *"People didn't know what was going on in the initial development of GEOs oversight; it only appeared in the Federal Register which is generally not observed by the public."*
- *"Confidence in regulation is not high and public also has low confidence in regulations. This is because the process is not transparent."*

"There should be early and broad stakeholder engagement…This will allow regulators to identify areas of major concerns presented."

"Development of system should be more inclusive."

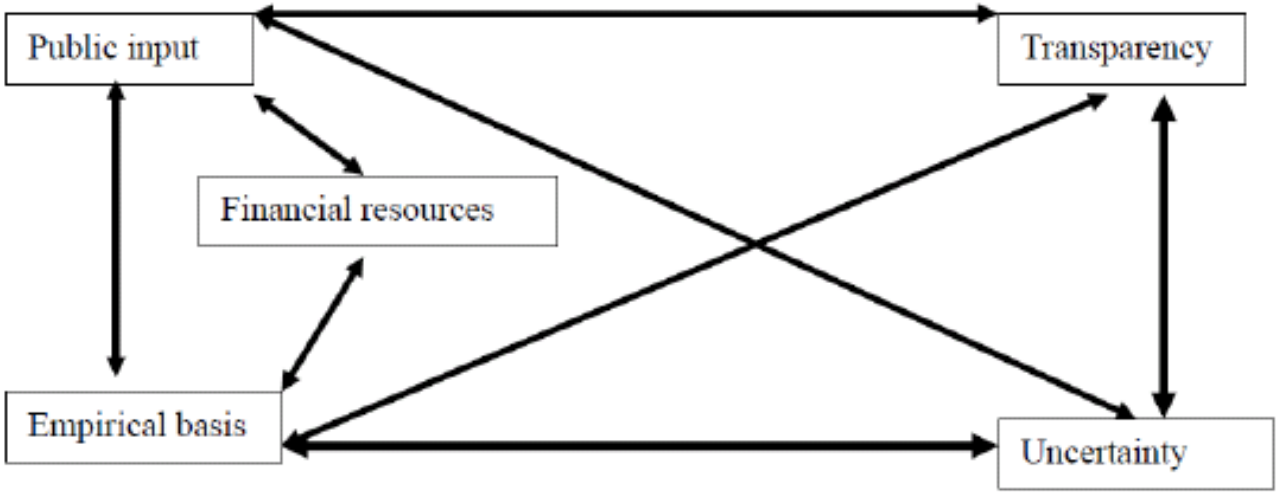
"They won't understand it" excuse is bogus as environmental risk is understandable. People can understand the likely impacts of release new technology x, y, and z into environment. Those types of public discussions have to take place. They need to be consistent."

Conclusions from GEO case study

- Public input, informed consent, and transparency in oversight for ETs are important for normative reasons and are hypothesized to positively influence outcomes of oversight, such as public confidence and environmental health and safety.
- Not a distinct separation of ethics-, institution- and “science-based” elements of oversight—
  - E.g. choice of endpoints, interpretation of “safety”, how system deals with uncertainty
- Multiple lines of evidence, cases, and arguments supporting the above
- Do they apply across other historical models of oversight?

Common Correlations Across Four Case Studies

Human drugs, medical devices, GEOs, and workplace chemicals



General conclusion:

"Science-based", institutional, and normative elements of oversight are intertwined, and all should be considered and strengthened for effective oversight of ETs.

Cross case comparison:
Strengths and Weaknesses

Criteria	GEOs	Drugs	Devices	Workplace Chemicals
Development				
D1. Impetus	◪	□	□	□
D2. Clarity TS	■	■	◪	◪
D3. Legal grounding	□	◪	◪	◪
D4. Public input	□	◪	■	◪
D5. Transpar-cy	□	◪	■	◪
D6.Fin.resources	□	□	□	□
D7. Emp basis	◪	◪	◪	◪
Attributes				
A8. Legal basis	◪	◪	◪	◪
A9. Data requir.	◪	■	■	□
A10. Postmarket	□	◪	□	□
A11. Treat.uncert	◪	◪	◪	◪
A12. Emp basis	◪	■	■	◪
A13. Compliance	◪	■	■	□
A14. Incentives	◪	◪	■	□
A15. Int.property	□	◪	◪	◪
A16. Ins.struct.	■	◪	◪	-
A17.Flexibility	■	□	◪	□
A18. Capacity	□	□	□	□
A19. Public inp	□	□	□	◪
A20. Transpar-cy	□	□	◪	□
A21. Conflict	□	◪	◪	◪
A22. Inf.consent	□	◪	◪	□
Extent of change				
E23. Change	◪	◪	◪	-
Outcomes				
O24. Pub.conf.	◪	□	□	◪
O25.Research	◪	◪	◪	◪
O26.Health	◪	■	■	◪
O27. Distr.health	◪	◪	◪	-
O28. Environm.	◪	□	◪	◪

Yellow="strength"

"Science-based" nature of U.S. oversight system

Gray="weakness"

Paradise, Kuzma, Wolf, Kuzhabekova, Kokkoli, Hall, Ramachandran, *JLME* Winter 2009.

Problem

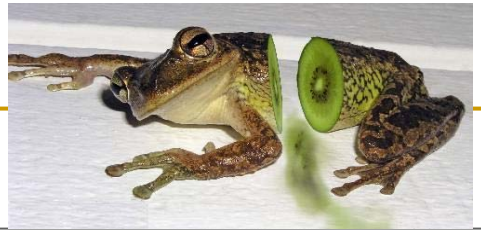
- "Sound science" basis of U.S. oversight approach
  - marginalizes public and stakeholder input
  - does not acknowledge value-laden process that risk assessment and management are

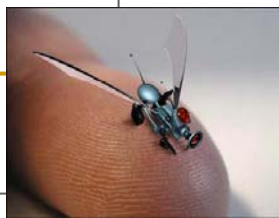
- How can we evolve from purely "science-based" oversight to "legitimate and effective" oversight? or "science-enhanced, public-sensitive, and value-respected" oversight?

Future of ETs Oversight: Public Participation Challenges

- Need to identify appropriate participation and engagement methodologies and resources for them
  - Will people welcome the opportunity or be apathetic? (e.g. NISE-net)
- Need to address government authority & scope for making decisions based on public input and criteria outside of "science-based" ones
  - Counter argument that these elements lie outside of jurisdictions. If so, where does engagement occur and how does it feed into DM?
- Need to address cultural barriers and biases among scientists, regulators, decision makers, stakeholders and public
- **Need to figure out ways to overcome HUGE problem:**

intellectual property protection ⟷ transparency and public engagement

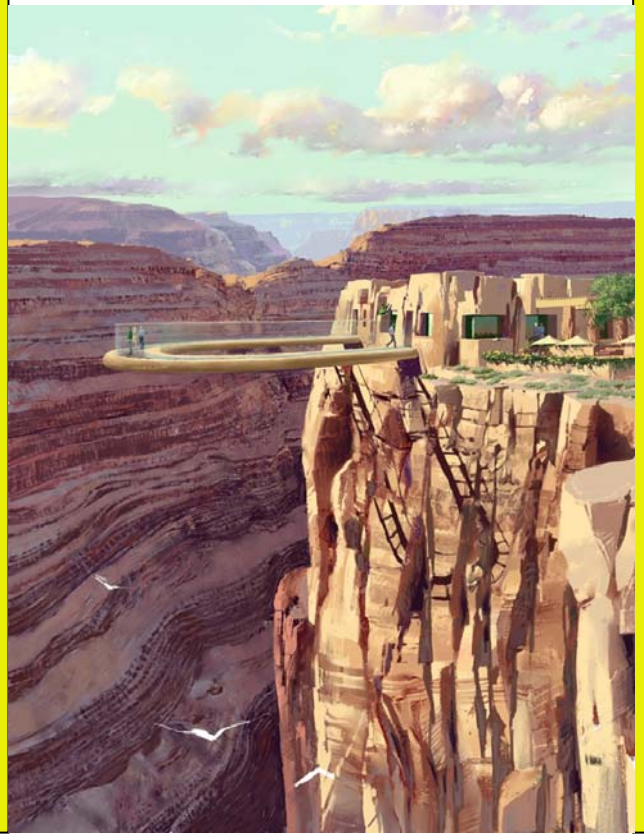




Problem

What public perception studies
and engagement
tell us about oversight
(what the public cares about)

Transparency
Mandatory systems
Opportunities for Input
Knowledge
Choice



How emerging
technology
oversight systems
(non-medical products)
develop
and operate

Little Transparency (CBI)
Voluntary labeling
Few opportunities for input
(Fed Reg, and
Public Meetings)

Upstream Oversight Assessment

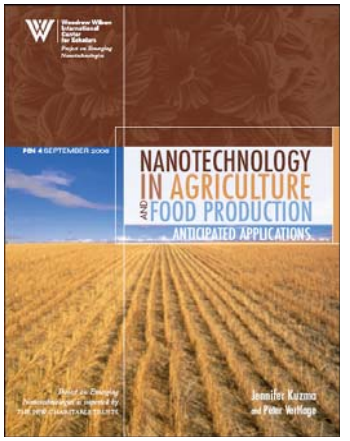
- Not to predict but to prepare
- Select projects in R&D (or earlier)
- Ask questions related to data, risk, values, oversight systems
- Priorities for
  - Public Engagement
  - Risk-relevant data
  - Organizational and/or legislative readiness for oversight

UOA Applied to Agrifood Nanotechnology

Phase 1*: Database of R&D Projects—Potential Applications

Phase 2:* Selection of Case Studies—Cover Diverse Categories and Suspected Issues

Phase 3: Assess cases and priority attention areas



Sample Questions:

- What are the potential impacts on human health and the environment associated with the agrifood nanotechnology application?
- What are the types of data and information needed to address the uncertainties surrounding risks and benefits of the application?
- What are the statutes and agencies that might be involved in oversight for the potential product? What are the uncertainties in the system?
- Is there a micro- or macro-scale version of the product on the market? If so, does the nano-scale application warrant additional or new oversight approaches?
- What might be the broader social issues surrounding oversight of the potential product or application? What are the research, policy, or engagement needs for addressing these issues?

Upstream Oversight Assessment: Agrifood Nanotechnology

Database of 160 Emerging R&D Applications of Agrifood Nanotechnology[1]

Selection of Case Studies
Case Study Analysis Approach
Identification of Risk and Oversight Policy Issues

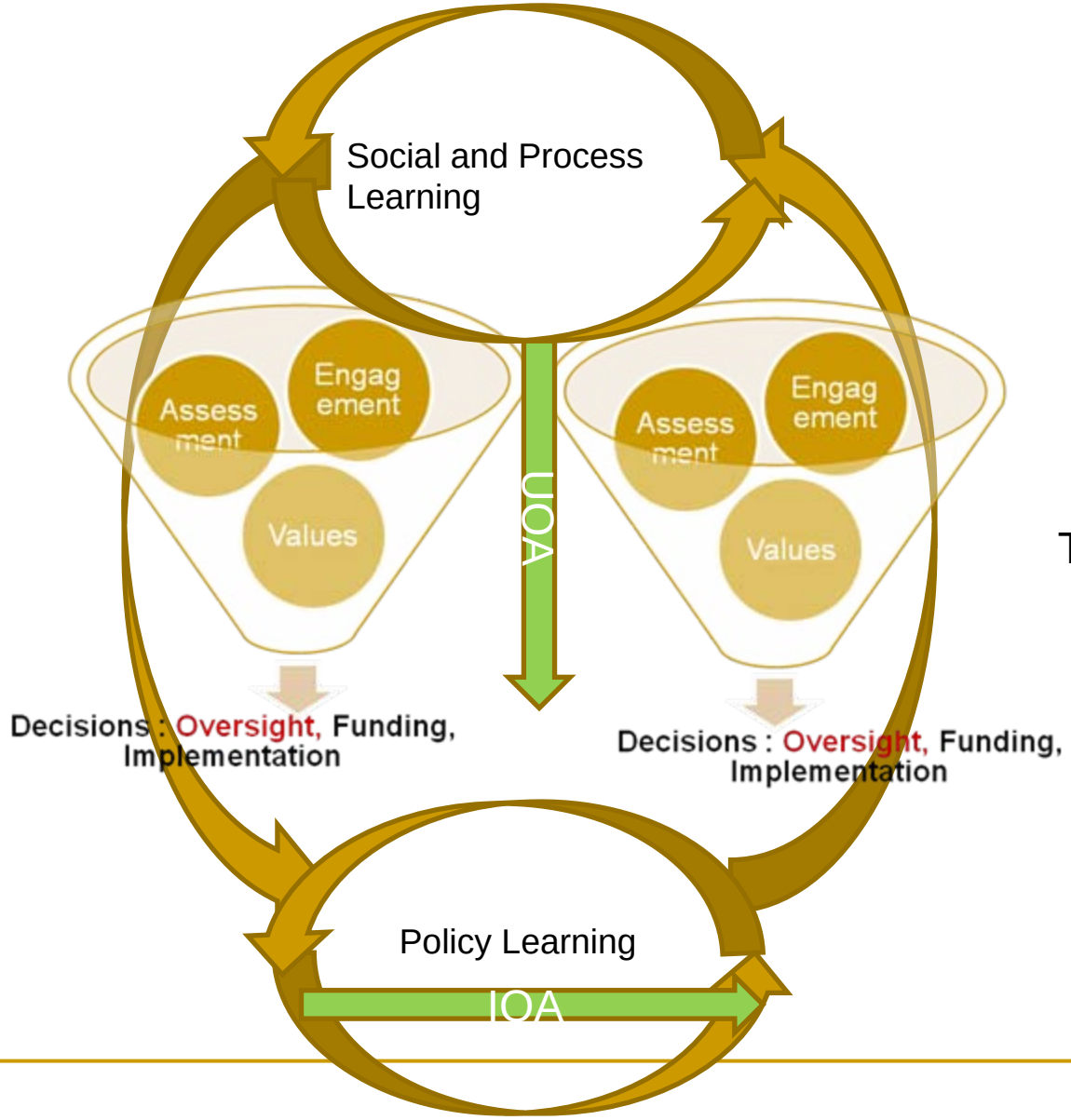
Case Study	Risk-Data Gaps	Regulatory Unknowns	Transparency Issues	Public Reactions/ Attitudes	Potential Benefits
(1) Agroecosystem particles	H	VH	L	VH	H
(2) Plant production particles	VH	H (nano)	H	VH – H	H
(3) Food enhancement particles	VH	H (nano)	H	H	M
(4) Composites for nonfood product (e.g., medical)	H	H (nano)	H	L	H
(5) Animal husbandry particles	H	VH	VH	VH – H	VH
(6) Composites for food packaging	H	M	VH	M	H - M

Kuzma, Romanchek, Kokotovich
Risk Analysis, 2008b

Conclusions

- Move from “Science-based” to “Science-enhanced, public-sensitive, and value-respected” oversight
- Anticipatory Governance as a framework for a multitude of complementary activities to achieve this goal
  - IOA and UOA as two with a focus on oversight policy
- Iterative and adaptive learning
  - Do not need to wait for good risk info or perfect AG methodologies
  - Goal to prepare, not predict
- Revised approach will almost certainly improve success of ETs by multiple measures (not just market measures)
  - Democratic and ethical foundations will improve immediately
  - Theory and evidence that indicates that utilitarian outcomes will improve (NRC 1996, 2008; this project; etc.)

Preparation for the Future of Emerging Technologies



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