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

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Outline

- Current Emerging Technologies Oversight Policy

- Anticipatory Approaches
  - Integrated Oversight Assessment
  - Upstream Oversight Assessment

- Evolution of ETs and Oversight
Emerging Technologies
Current Progression

- **Funding basic or applied**
  - Driven by small set of stakeholders
  - Curiosity, market or defense driven primarily

- **Implementation and penetration**
  - Driven by small set of actors
  - Market of defense driven primarily

- **Oversight**
  - Driven by a small set of actors
  - In reaction to crisis, risk event, or intense public backlash
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)

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)

Anticipatory Governance

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)

Upstream Ethics
Engage in ethics discussions and analysis early before and during emerging technologies development—Khushf (2007)
Two Approaches as Subset of Anticipatory Governance

**Integrated Oversight Assessment (IOA)**

Anticipatory Oversight and Risk Policy

**Upstream Oversight Assessment (UOA)**
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

Multi-Criteria & Case Study Approach
Expert and Stakeholder Elicitation

Step 2: Expert and Stakeholder Elicitation
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

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

*****************************************************************************************

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

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

- Ethical, policy, legal, and risk analysis

Methods:
- Expert and Stakeholder Interviews
- Expert Elicitation
- Historical Literature Analysis

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

Dynamism
- D1. Impetus
- D2. Clarity of subject matter
- D3. Legal grounding
- D4. Public input
- D5. Transparency*
- D6. Financial resources
- D7. Empirical basis

Clarity
- D2. Clarity of subject matter
- D3. Legal grounding
- D5. Transparency*

Effectiveness
- D4. Public input
- D6. Financial resources

Dynamism
- A10. Post market monitoring*
- A11. Treatment of Uncertainty*
- A12. Empirical basis
- A14. Incentives
- A15. Treatment of intellectual property
- A16. Institutional structure
- A17. Flexibility*
- A18. Capacity
- A19. Public input
- A20. Transparency
- A21. Conflict of interest
- A22. Informed consent

Elasticity
- A9. Data requirement and stringency
- A13. Compliance and enforcement
- A17. Flexibility*

Legitimacy
- A10. Post market monitoring*
- A11. Treatment of Uncertainty*
- A12. Empirical basis
- A14. Incentives
- A15. Treatment of intellectual property
- A16. Institutional structure
- A17. Flexibility*
- A18. Capacity
- A19. Public input
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- A21. Conflict of interest
- A22. Informed consent

Innovation
- O24. Public confidence
- O25. Research and innovation
- O26. Health and safety
- O27. Distributional health impacts
- O28. Environmental impacts

O23. Extent of change

Uncertainty
"*" indicates uncertain factors.
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**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>GEOs</th>
<th>Drugs</th>
<th>Devices</th>
<th>Workplace Chemicals</th>
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Yellow="strength"

“Science-based” nature of U.S. oversight system

Gray="weakness"

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

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

Kuzma, Romanchek, Kokotovich
Risk Analysis, 2008b

<table>
<thead>
<tr>
<th>Case Study</th>
<th>Risk Data Gaps</th>
<th>Regulatory Unknowns</th>
<th>Transparency Issues</th>
<th>Public Reactions/Attitudes</th>
<th>Potential Benefits</th>
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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

Social and Process Learning

Technology 1

Assessment
Engagement
Values

Decisions: Oversight, Funding, Implementation

Policy Learning

Technology 2

Assessment
Engagement
Values

Decisions: Oversight, Funding, Implementation

IOA

UOA
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