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Innovation in GEOs Governance

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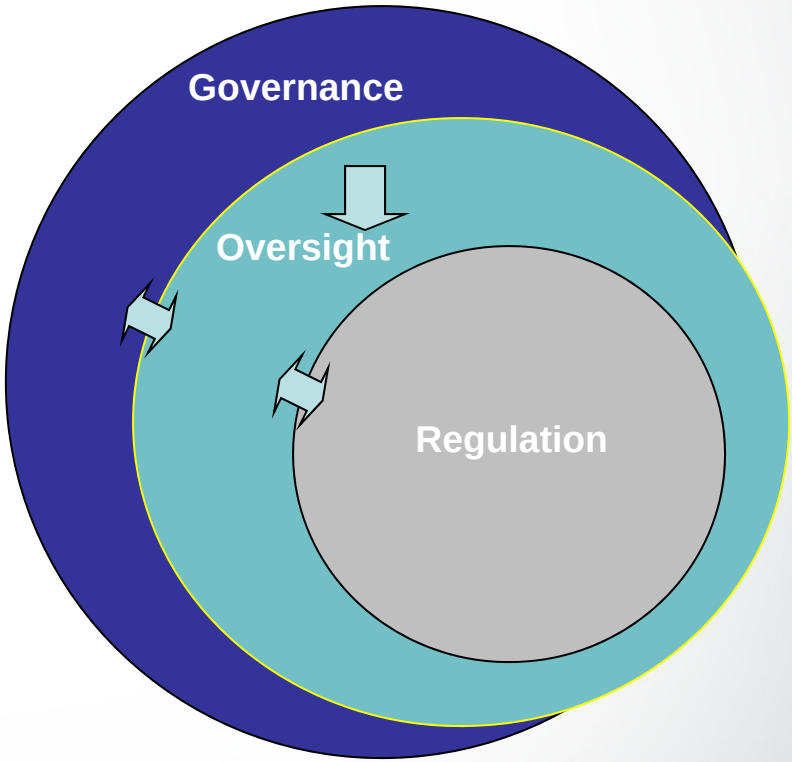
Regulation, oversight, governance

- Governance
  - Complex set of norms, values, and processes, and institutions
- Oversight
  - Watchful and responsible care under governance
- Regulation
  - Authoritative rules dealing with details or procedure having the force of law

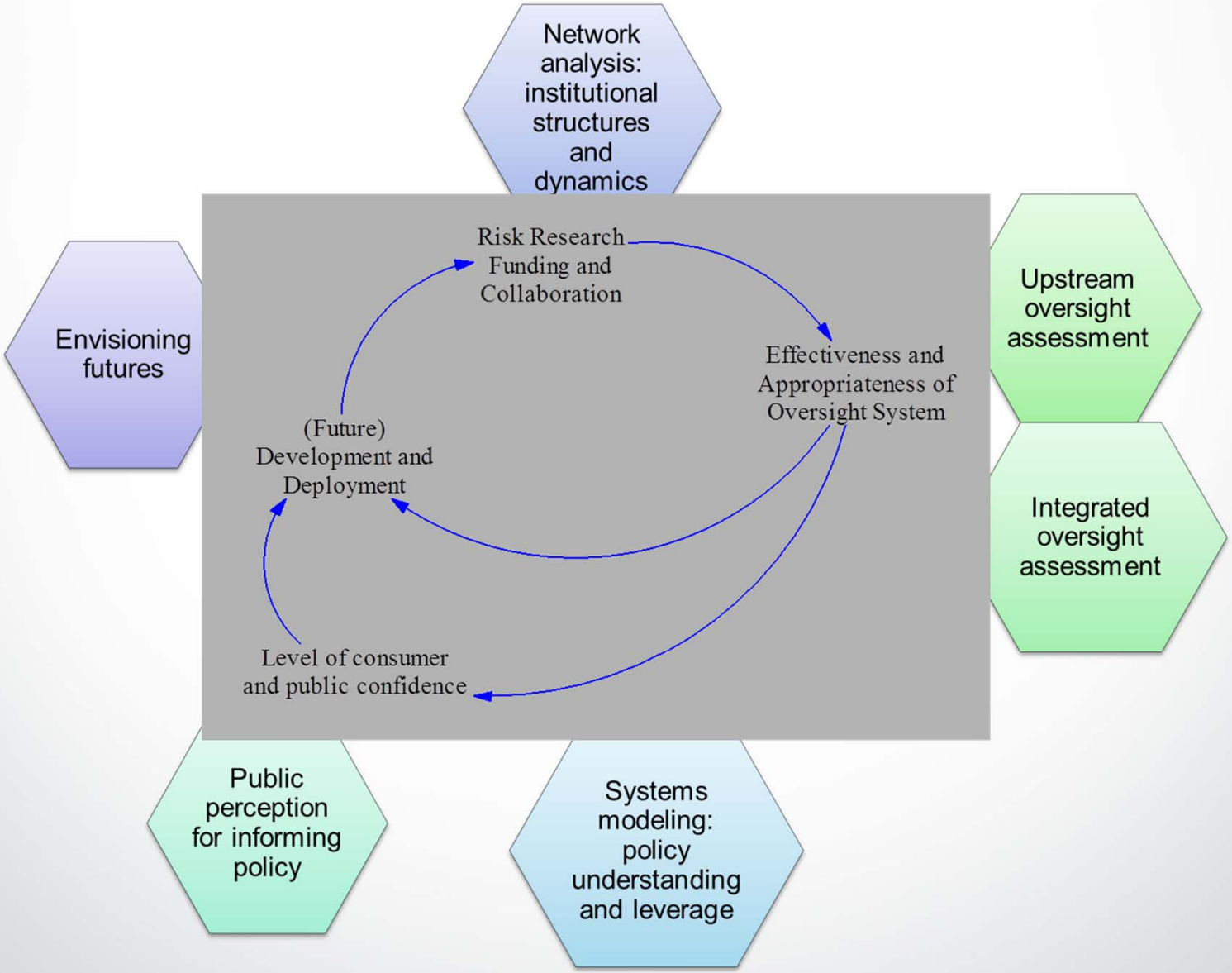


Kuzma, Environmental Law Reporter 2006

Innovation

- Finding a better way of doing something
- Applies not only to the development of existing biotech, but also to policy systems, and other mechanisms of solving global challenges

Governance Systems Research: Evaluation to Innovation



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Evaluation—Historical Pacing

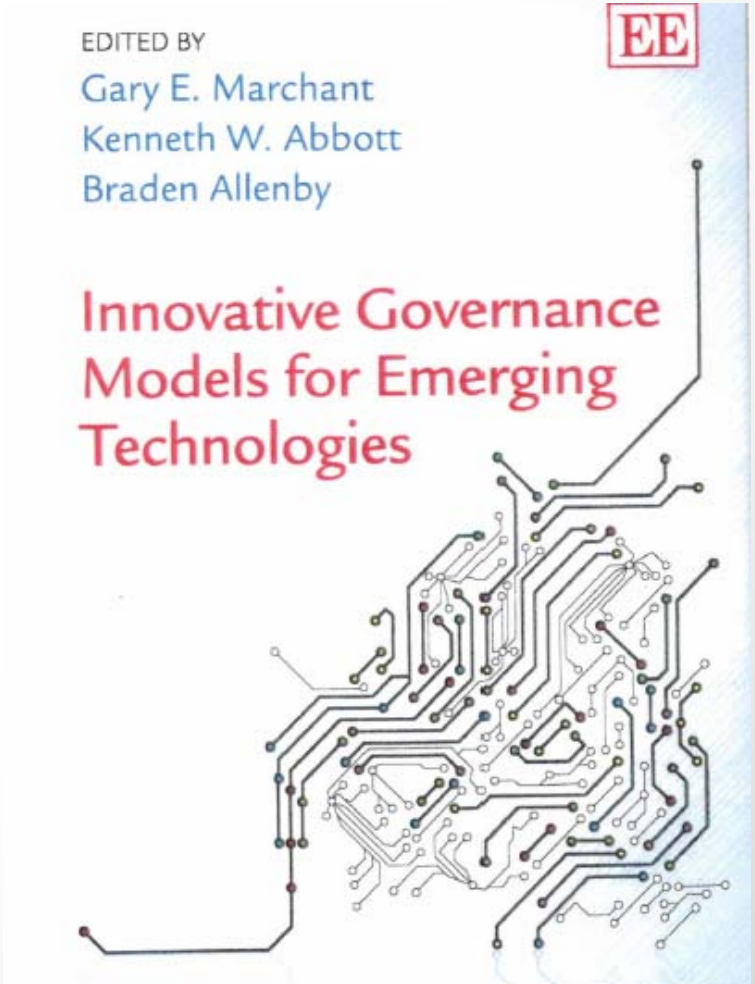
9. Properly paced? Examining the past and present governance of GMOs in the United States

Jennifer Kuzma

9.1 INTRODUCTION

A case study of genetically modified organisms (GMOs)[1] in US agriculture and the environment illustrates the problem of policy systems to keep up or pace with advances in emerging technologies. This chapter describes the history of GMO governance in four phases, examining the oversight system's ability to pace with technological developments in each phase. In general, government decisions for oversight of GMOs, particularly GM crops, seemed to pace well with technology in a temporal sense. However, they continue to be contested and do not seem appropriate in the longer term for ensuring safety, transparency and public confidence. The GM crop oversight system exhibited temporal pacing through flexible legal frameworks, but not proper pacing. This chapter argues for a broader notion of pacing that incorporates not only elements of timeliness, but also notions of appropriateness in dynamic societal contexts. It will conclude with proposed lessons from the US GMO oversight experience for developing a new prototype model of governance for emerging technologies that properly paces with technological advancements. This model is based upon three pillars: (i) upstream oversight assessment (a subset of anticipatory governance); (ii) dynamic oversight; and (iii) strong objectivity through more extensive public and stakeholder engagement in decision making.

[1] Natural scientists prefer the term genetically engineered; however, we use genetically modified (GM), as it is more in line with international policy discussions. We use GM to indicate any organism modified by recombinant DNA or newer biotechnology methods.

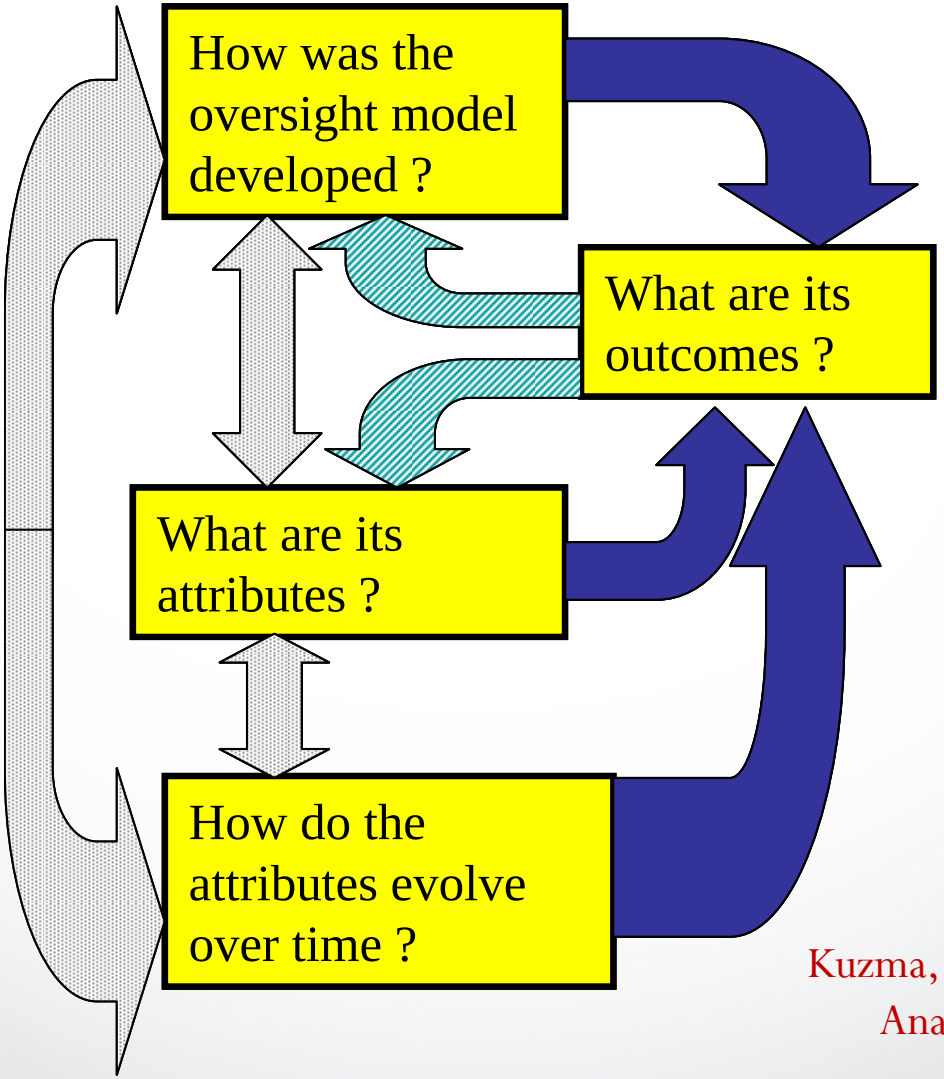


Ways the system "paced" with technology: Phases of CFRB

- Evolution (1950s-1986)
  - Establishment of "pacing through interagency policy-making"
- Implementation (1986-circa 2002)
  - "pacing through rules"
- Adaptation (2002-circa 2009)
  - "pacing through guidance"
- Revolution (circa 2009-present)
  - "pacing through fundamental policy change?"

Criteria-Based Evaluation

Integrated Oversight Assessment: NSF grant 2007-2011



Kuzma,, Paradise, et al Risk Analysis(2008)

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Comparing Oversight Models

Yellow="strength"

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

Gray="weakness"

Paradise, Kuzma, et al. *JLME* (2009)

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.	◪	□	◪	◪

GM Oversight: Proper pacing?

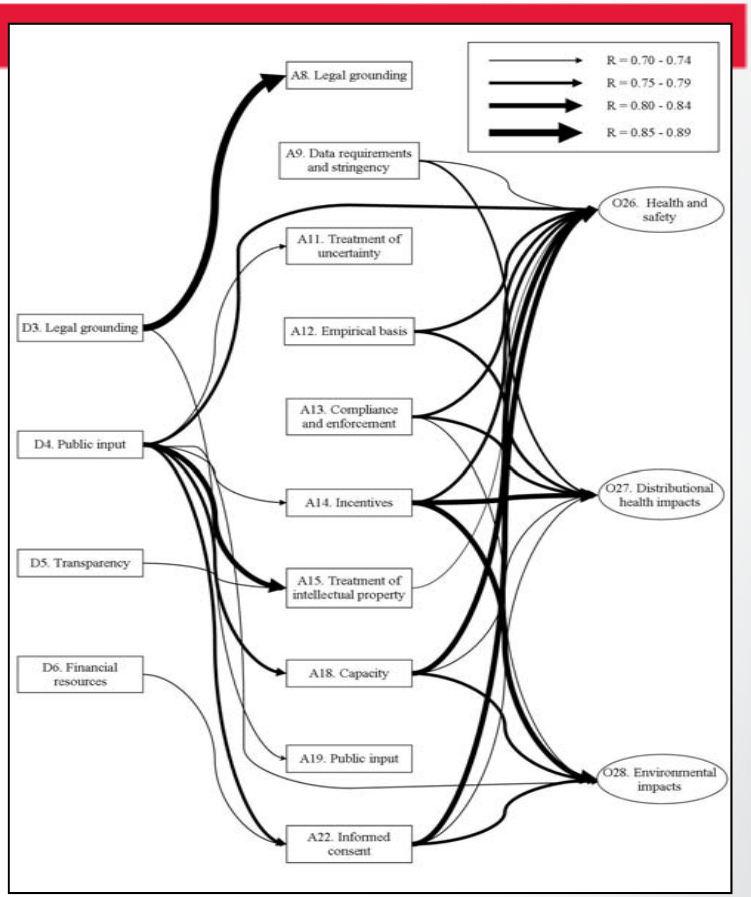
- High flexibility
- Clear subject matter (although changing…)
- Weak legal grounding allowing for multiple interpretations
- Complex institutional structure

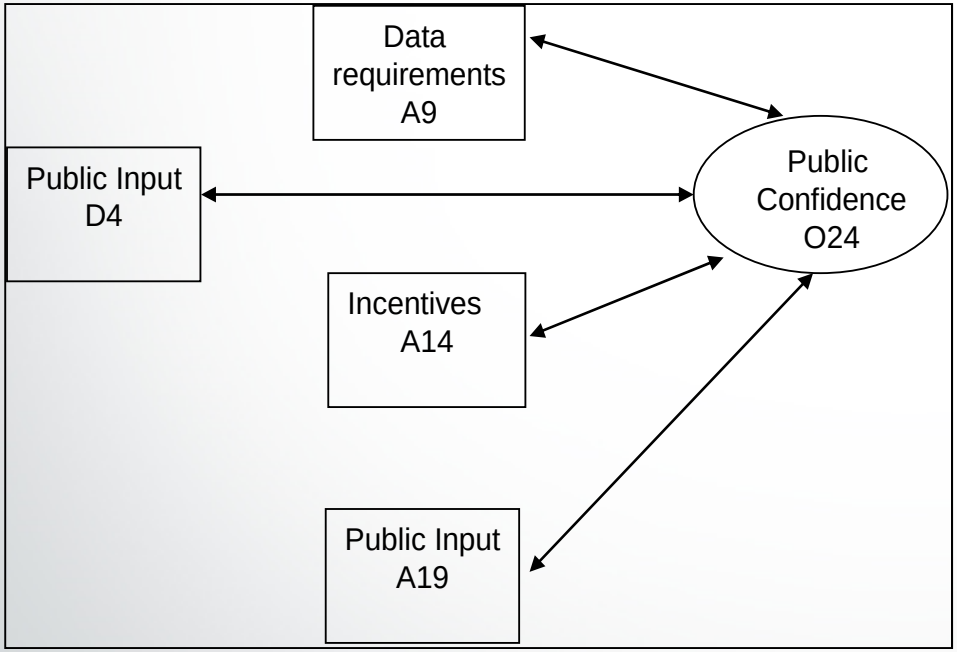
- Little transparency
- Low level of informed consent
- Few opportunities for public input
- Low capacity

More controversy, delay, rejection?

Too much uncertainty for developers of new GM products?

Complex System of GEOs Governance





p<0.05, p<0.002

Imperative for Innovation

Research Implications

- "Science-based" institutional, and normative (ethical) elements of oversight are not separable
- Pay attention to all, not enough for "good science"
- It's a complex system!

Challenges

- Technological Elitism
- "Science Based" mantra in face of uncertainty/ambiguity
- Marginalizes other world views, local and specialized knowledge
- Creates distrust, skepticism

Move from pure “science based” to “science informed, value-attentive, public-respectful ” oversight

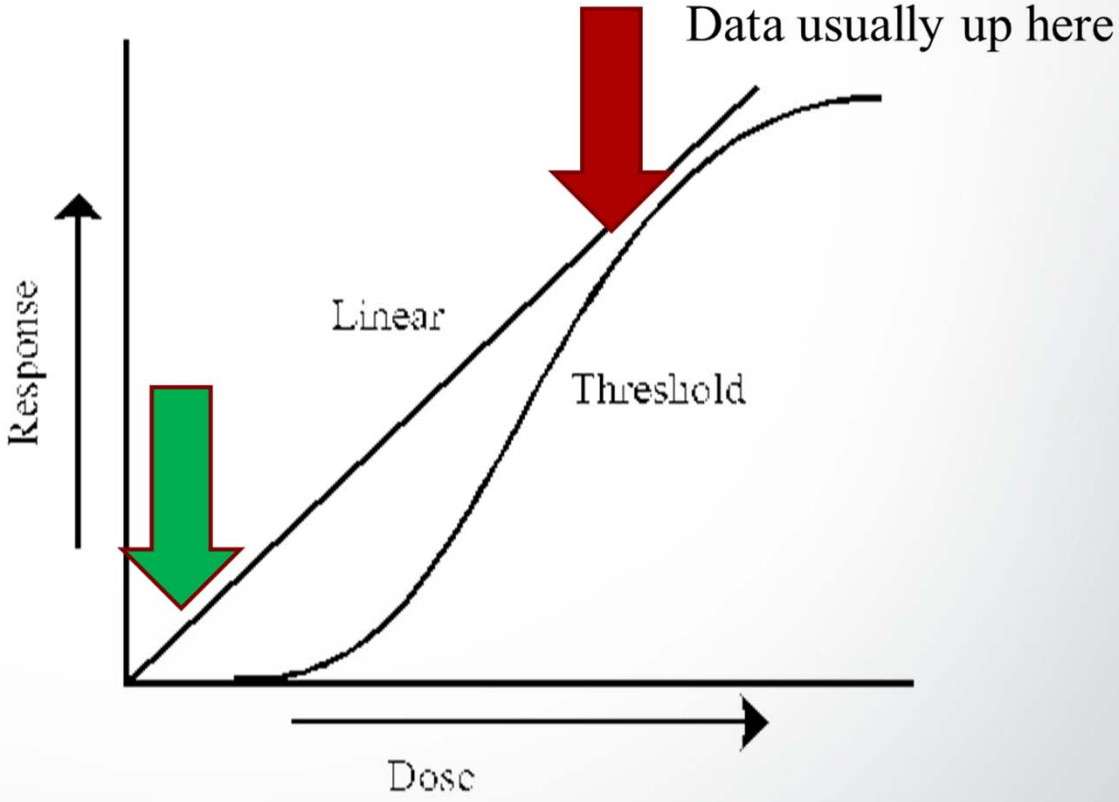
- It’s not all about messaging or understanding your audience
- It’s about listening, dialogue, and mutual social and bidirectional learning
- Analytical-deliberative processes (NRC 1996)

Three more reasons to make this shift:
1) Different Scientific Conceptions of Risk (Renn, et al)

- Different types of harms that need to be considered in risk analysis
- They are “scientific”
- Harms and damages that can occur with “exposure”
  - 1st order physical health and environmental
  - 2nd order physical health and environmental
  - Social structure harm
  - Ethical affronts (without choice, voice, or consent)
  - Psychological well-being
  - Financial impacts (direct)
  - Economic impacts (indirect)
  - Cultural disruption
- Only a wide range of perspectives and voices can “assess” these

2) "Science" alone cannot spur social action
It cannot tell us what to do

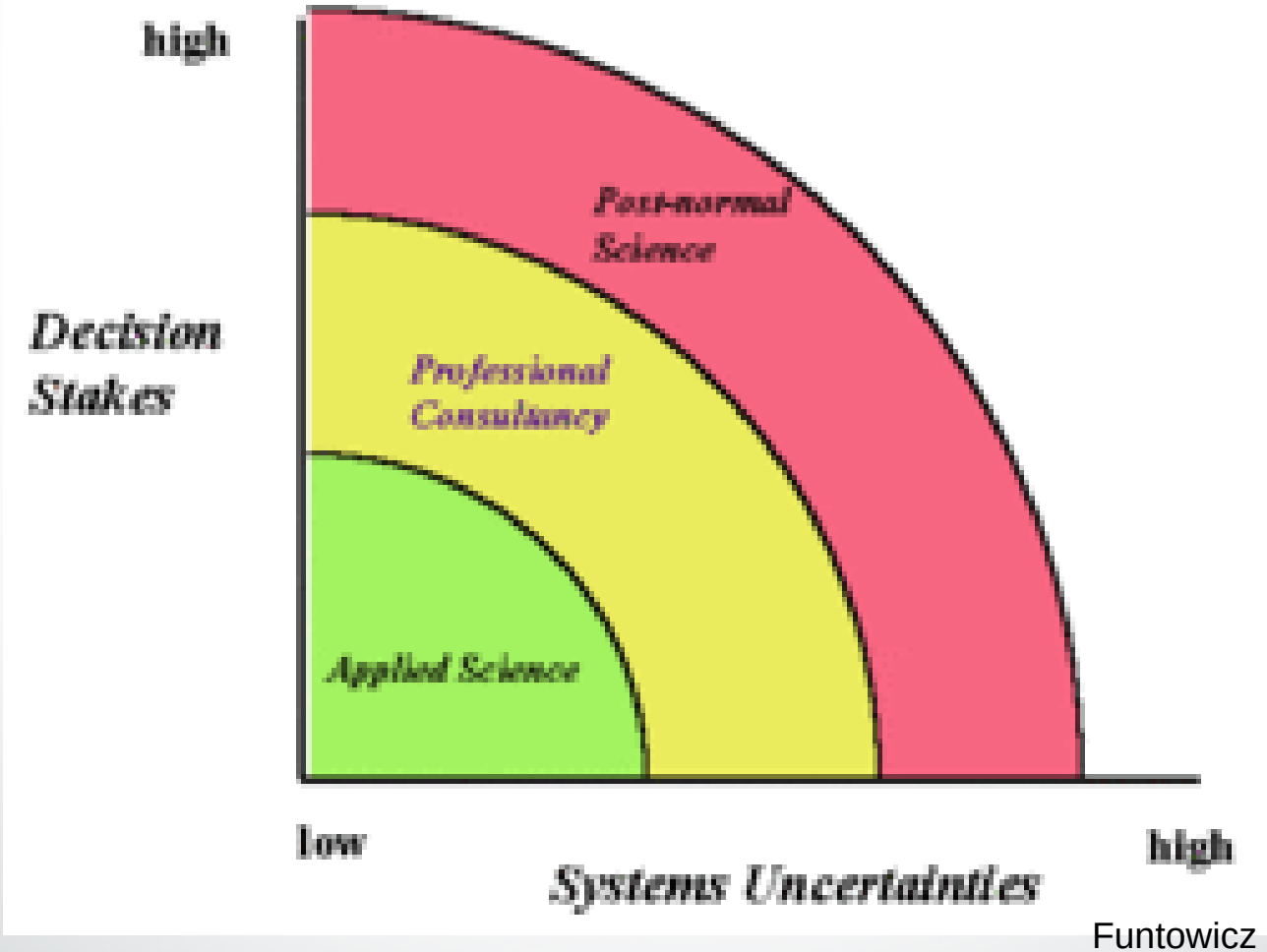
- Places for values
  - Interpretation of data
  - Standards for safety
  - Choice of endpoints



What do you assume down here?

3) We are dealing with Post-normal science in Decision making

"Open dialogue, extended peer communities"
"Research as object of critical scrutiny"



Funtowicz and Ravetz (2006)

And PNS “science” is improved by wider range of knowledge and mental models considered

4) People are not “irrational” They can get it

- Amazed by people’s ability to “get” the science and ask important questions
  - Our nano-food focus group studies
  - My and other’s participation in multiple public engagement events
- They rationally base their views on a variety of factors

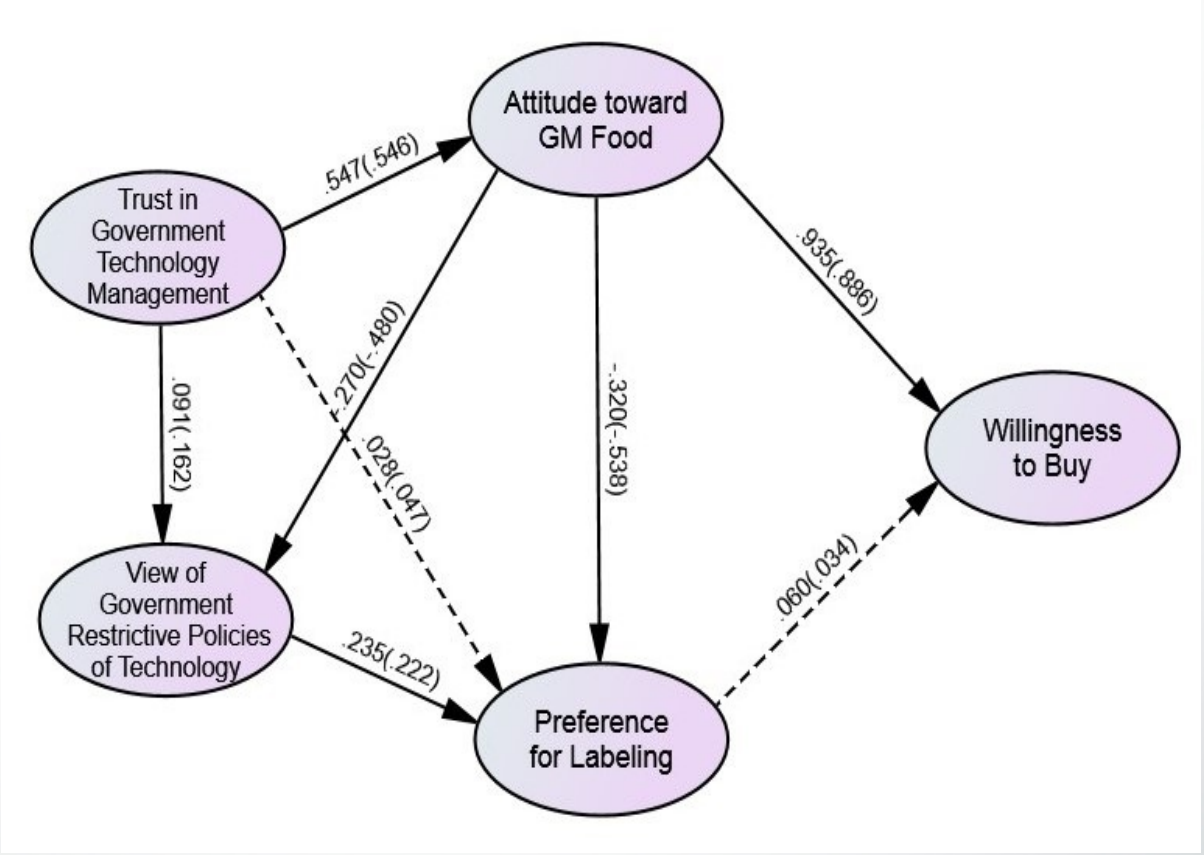
Consumer base decisions on complicated calculus

building on psychometric risk perception paradigm

Yue, Cummings, & Kuzma (in review)

Benefits
Trust
Worldviews
Experience
Familiarity
Control

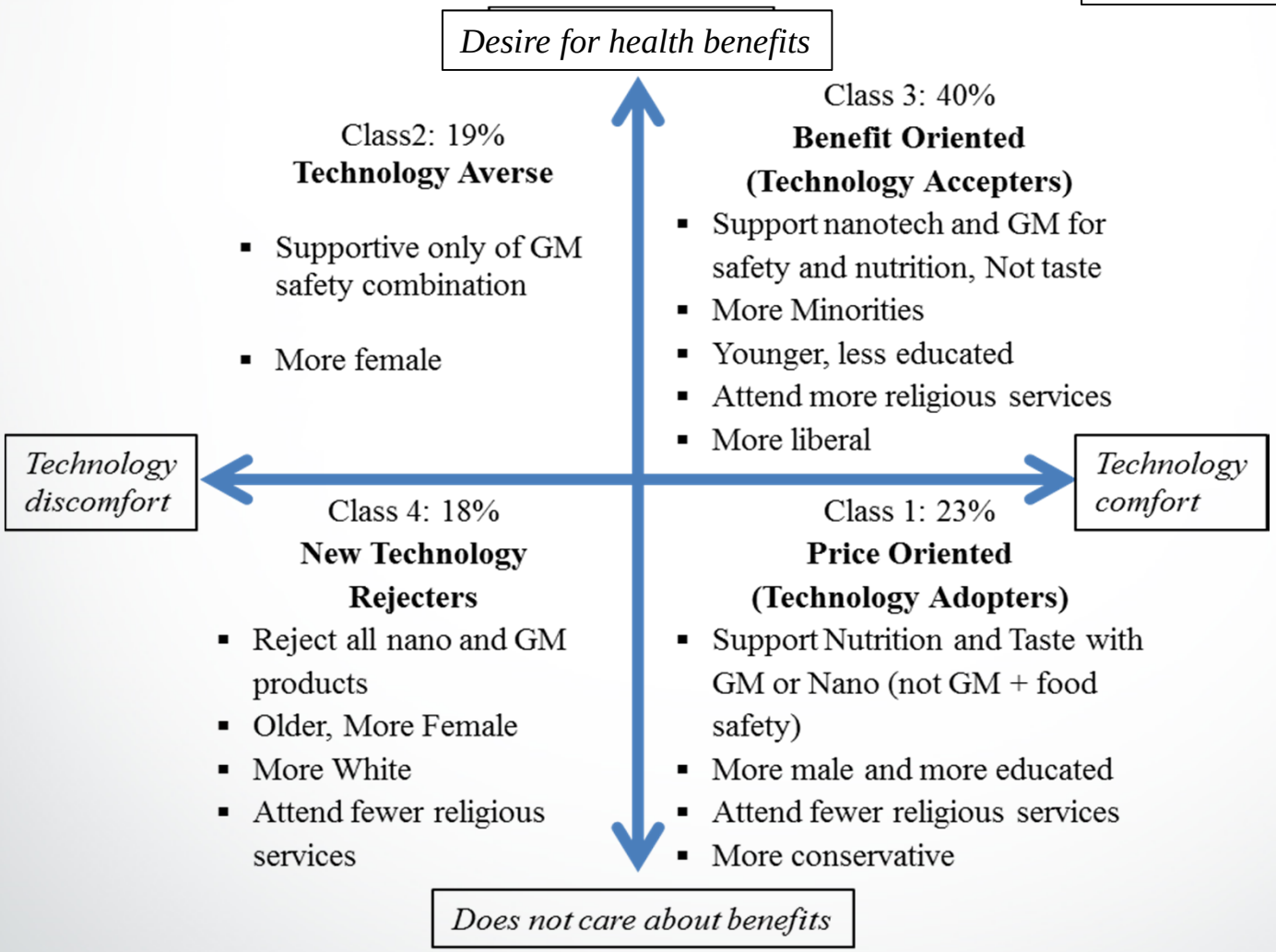
Etc.



But they are not monolithic: best to appeal to range of groups

***(building on Cultural cognition theory Kahan, Douglas* etc.)**

Yue, Zhao, & Kuzma, *JAE* (forthcoming)



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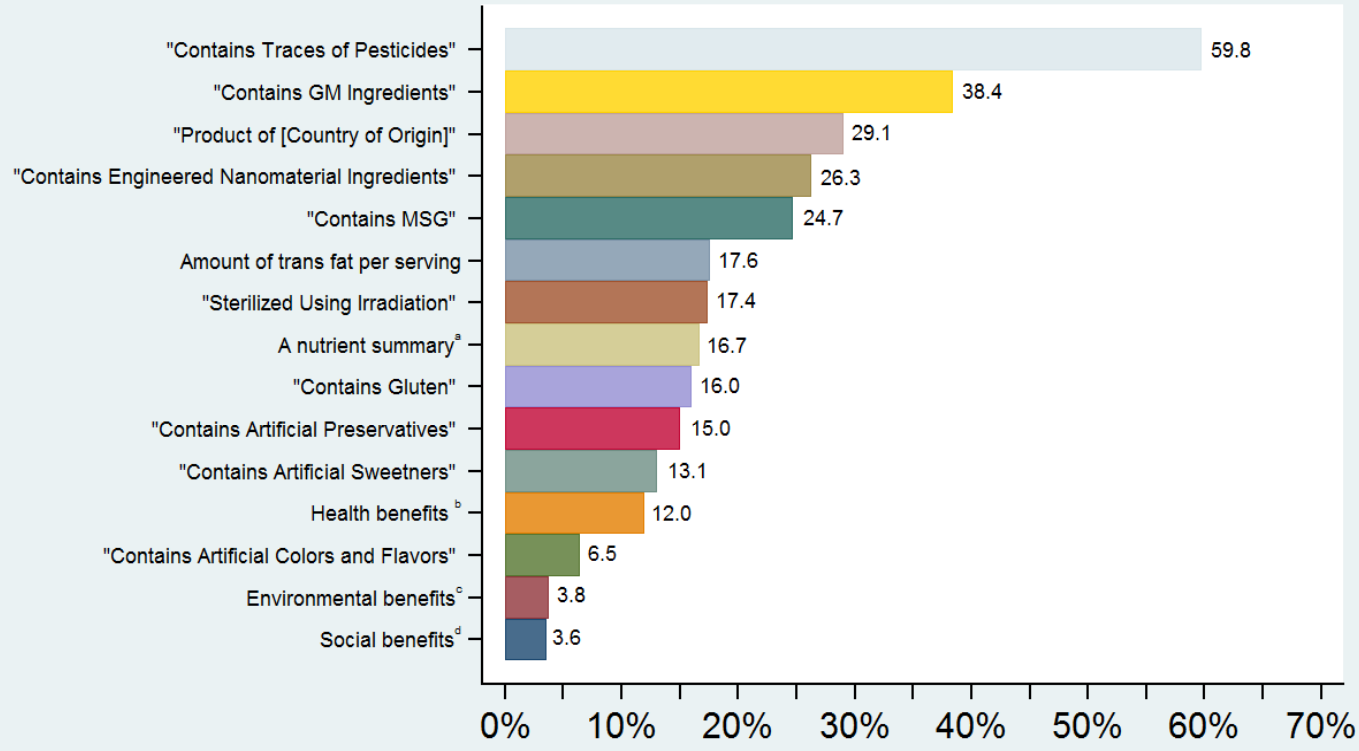
They do want to know…

(Brown & Kuzma in prep)

U.S. consumers place priority on GM labeling



Exact statements: [a]A nutrient summary, such as the amount of calories and fat per serving displayed more obviously than in the Nutrition Facts panel
[b]Health benefits such as "May reduce the risk of heart disease"
[c]Environmental benefits such as "Eco-friendly" or "Minimal Carbon Footprint"
[d]Social benefits such as "Fair Trade"

With those social science observations from the past…

Where are we heading?

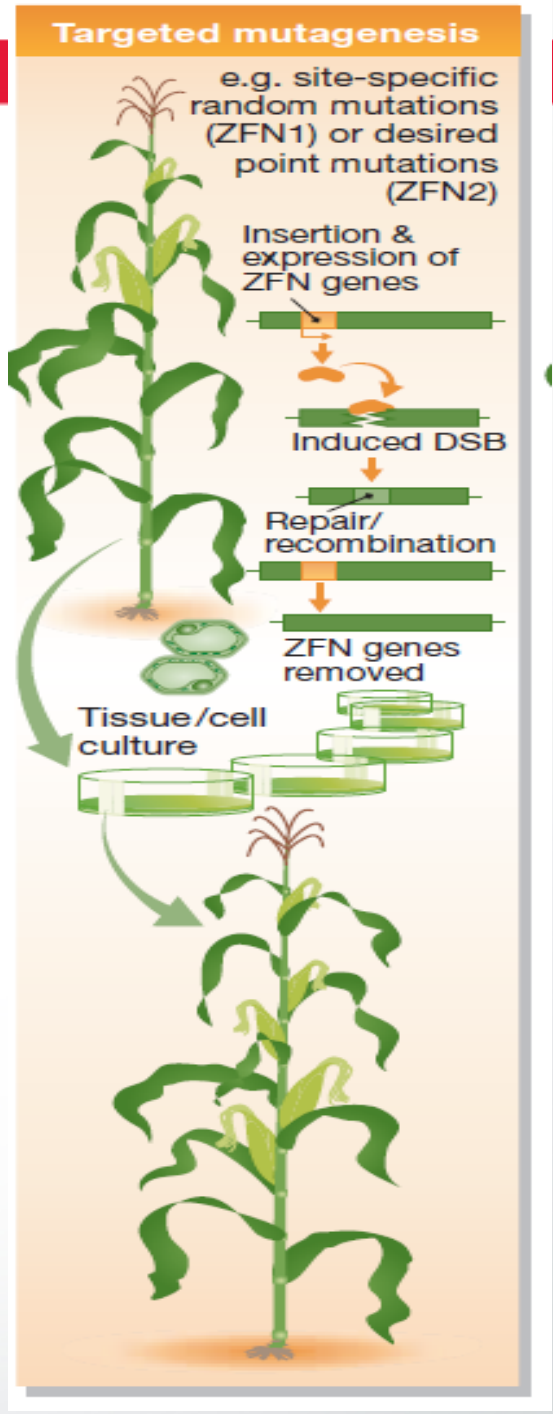
NEW GOVERNANCE ISSUES & THE EXPLOSION OF GENOME EDITING

Genome editing

- Discussions of how current systens will deal with it

- Additional issues:
  - Can Backcross to remove SDN and transgenes
  - In some cases, no rDNA used
  - Nanoparticles or RNA to deliver SDNs

- *Regulatory system is promoting innovation in the science by inspiring engineering to avoid it*



Some common international **questions about SDN regulation**

- Is it based on rDNA, modern biotechnology, etc.?
  - Is the SDN introduced to the host via transgene or rDNA?
  - Is there foreign DNA the plant product?

- How far away is the genetic donor away from host?
  - Is the gene/SDN from same species? (Cisgenic)
  - Is it the gene engineered with promoter and other control sequences?

- What is the extent of genetic change?
  - Deletion—SDN 1
  - Minor modification/sequence replacement—SDN 2
  - Gene replacement or insertion of whole genes---SDN 3

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Our Research Questions

- What is the landscape of the R&D ?
- How do expert-stakeholders understand new targeted modification technologies (genome editing) and risk governance?
- What are their views on current U.S. governance systems as starting points?
- What about future risk governance?

NSF grant: Voytas, Dobbs, Kuzma, Wang

Technology Analysis & Strategic Management, 2013
http://dx.doi.org/10.1080/09537325.2013.850657

Routledge
Taylor & Francis Group

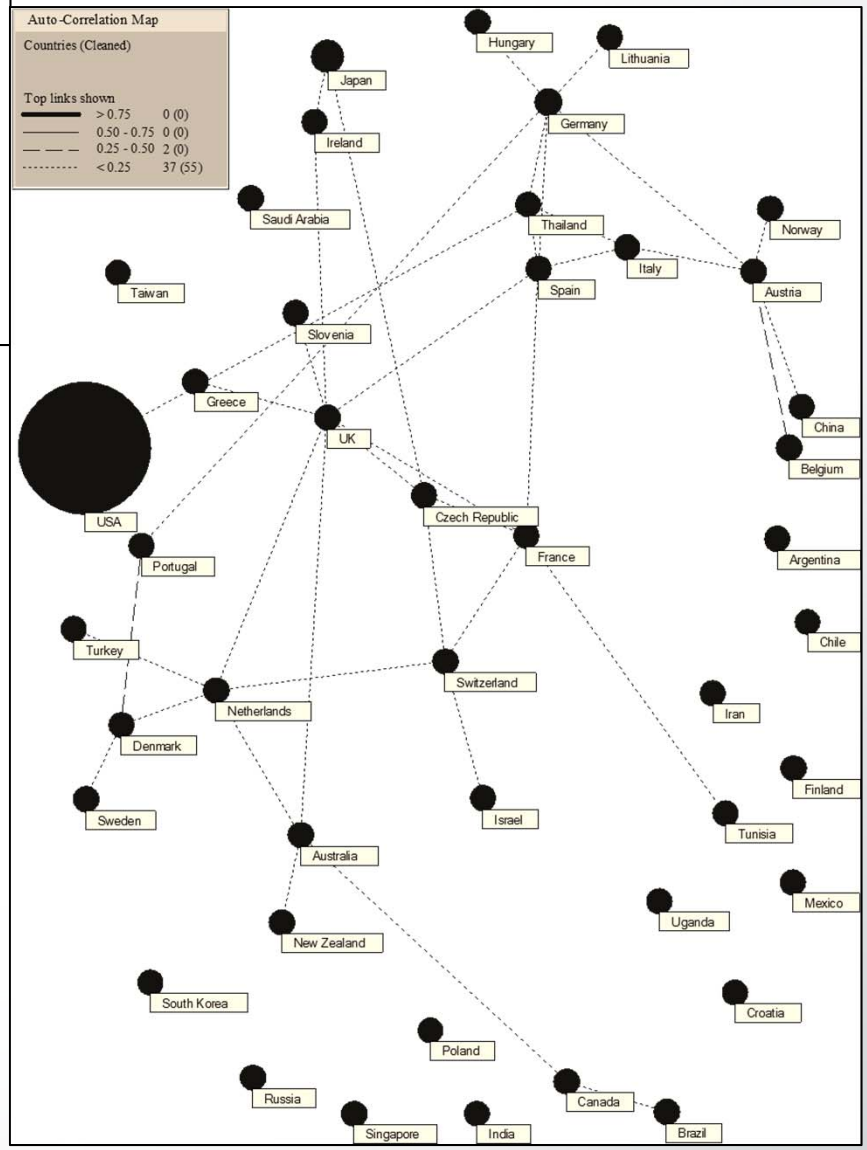
Mapping the emerging field of genome editing

Aliya Kuzhabekova[a] and Jennifer Kuzma[b]*

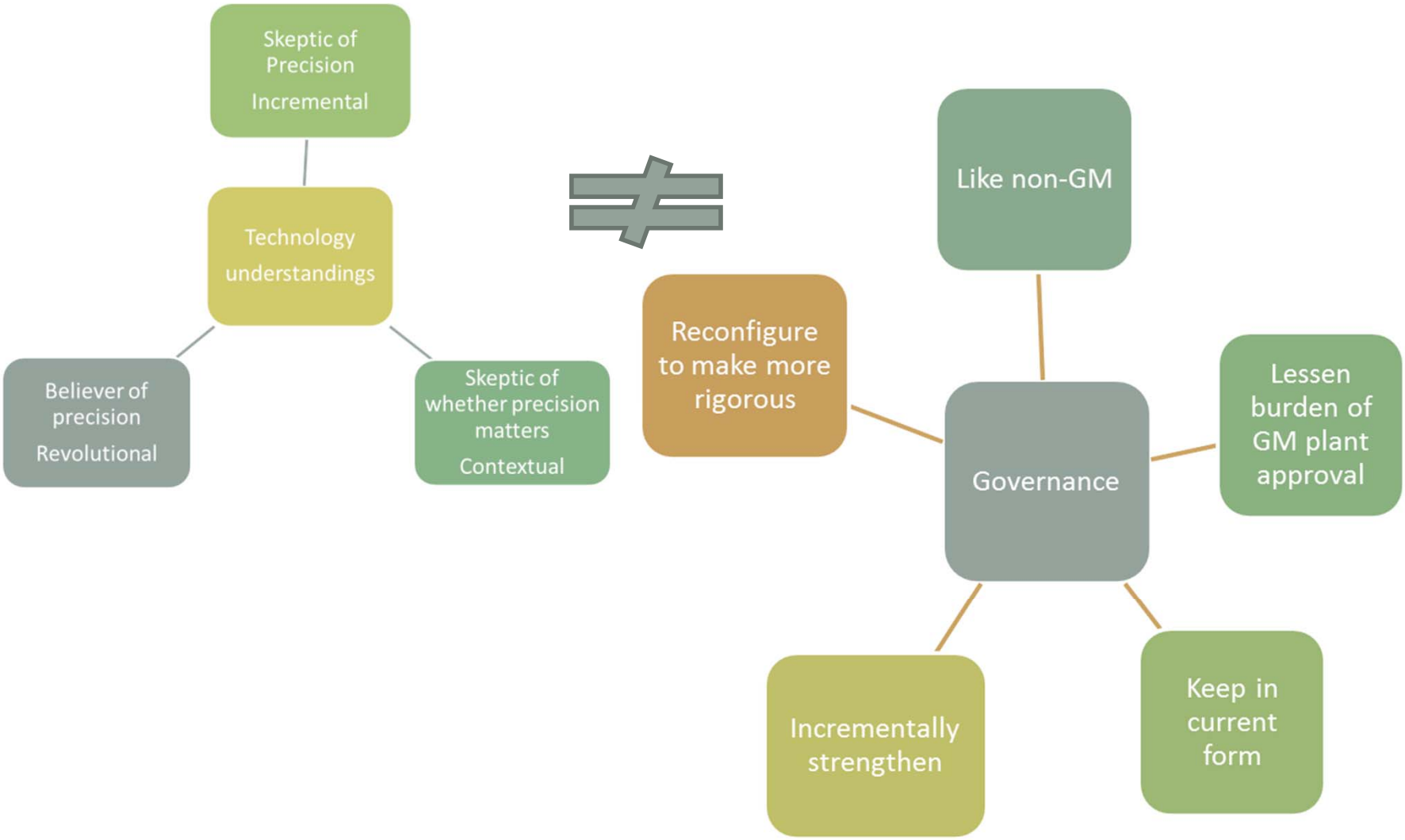
[a]*School of Education, Nazarbayev University, Astana, Kazakhstan;* [b]*School of Public Affairs, North Carolina State University, Raleigh, NC, USA*

- Concentrated
- Focusing on biomedical problems
- Few partnerships between DCs & LDCs
- Different subject matter foci in DCs and LDCs
- Little Collaboration among U.S. funders

- Related to History of problems of agricultural biotechnology



Surveys and Interviews of Expert-Stakeholder Group:: Technology understandings & oversight policy preferences



Narratives of governance change

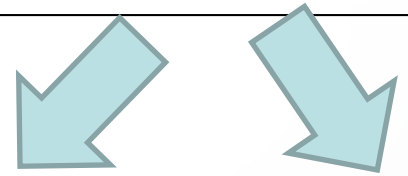
TagMo is an Incremental Technology --

- Maybe TagMo doesn't change technology concerns dramatically
- It doesn't FORCE a governance change, but gives us OPPORTUNITY to re-examine and change governance.
- Diversity of changes suggested from **more relaxed to more rigorous**

Pragmatist/Opportunist

TagMo is Revolutionary Technology

- TagMo is a dramatically different technology that forces a change in governance: How?



Relaxes need for oversight

Intensifies need for oversight

Techno Hype-Hypo Reg

Systems View

The (risk governance systems) FOREST View

- "As we're able to…have more and more **powerful techniques** to modify these plants, we will be able to **modify these plants more and more from their standard configurations**. Especially with gene addition, we can **completely rewire a number of these plants… The one concern I have is that if we're creating plants before we really know what the sorts of products are."**
  - *- TagMo researcher*

Points of agreement—written survey

- **Majority** of the subject matter experts (SMEs) agree that mistakes in governance were made with 1st generation GMOs
- **Majority** would prefer some level of premarket review by government
- **Majority** acknowledge that stakeholders and citizens need to be informed/engaged

SO WHAT ARE WE DOING IN U.S.?

Governance of Gene Editing

USDA can exert broad authority for GEOs under CFRB

- " under the provisions of these regulations (7 CFR part 340), a GE organism is deemed a regulated article if it has been genetically engineered from a donor organism, recipient organism, or vector or vector agent listed in 340.2 and the listed organism meets the definition of "plant pest" or is an unclassified organism and/or an organism whose classification is unknown, or ***if the Administrator determines that the GE organism is a plant pest or has reason to believe it is a plant pest"***

- ***USDA circa 2000 indicated it would use this authority not only for plant pest sequences to cover all GE plants.***

“Pacing through Policy Shift”

Revolution (2010-present)

- (2010) USDA decides not to exert authority for Zinc Finger Nuclease low phytate corn
- (2011) In January, Congress has hearing about GE alfalfa case. Several members of Congress question USDA’s authority under the PPA to regulate GM crops at all.
- (2011) After completing the HT alfalfa EIS, USDA decides to fully deregulate HT alfalfa allowing for its unrestricted use.
- (2011) While in the process of completing the EIS for HT sugar beets, USDA partially deregulates them allowing for their restricted commercial use
- (2011) USDA approves amylase corn without EIS
- (2011-2012) USDA deregulates several GE crops without EIS

USDA decides several GE crops,
including Ht bentgrass do not fall under their plant pest authority

Revolution Phase:
Crops recently exempted from any premarket review
(Ledford 2013)

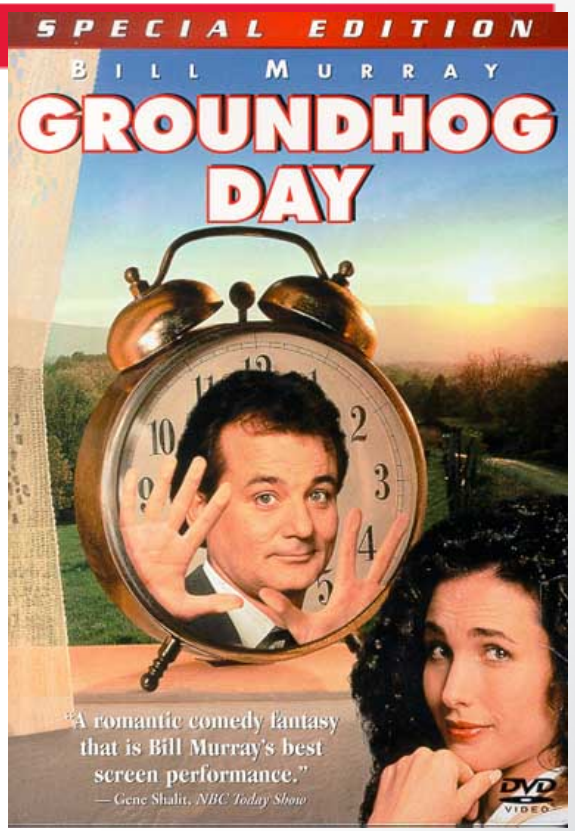
CROPPING OUT REGULATION

Since 2010, the US Department of Agriculture has told at least 10 groups that their genetically modified (GM) crops would not be regulated because a plant pest was not used to do the engineering.

Crop	Trait	Developer	Technique
Switchgrass	Easier conversion to biofuels	Ceres	Gene gun
Grapes	Red colour	University of Florida	Gene gun
Turf grasses	Herbicide tolerant	Scotts Miracle-Gro	Gene gun
Maize (corn)	Improved nutrition	Dow AgroSciences	Zinc-finger nuclease
Plums	Faster breeding	Appalachian Fruit Research Station	Non-transgenic offspring of GM parents
Tobacco	Faster breeding	North Carolina State University	Non-transgenic offspring of GM parents
Sorghum grass	Higher yields	University of Nebraska–Lincoln	Epigenetics
Not disclosed	Faster breeding	New Zealand Institute for Plant and Food Research	Non-transgenic offspring of GM parents
Ornamental plants	Not disclosed	BioGlow	Not disclosed
Not disclosed	Not disclosed	Cellectis	Meganuclease-targeted gene deletions

SOURCE: APHIS

Déjà vu



- U.S. go alone approach
  - Not participating in international workshops on SDN
  - Focusing R&D on problems with markets (not necessarily feeding the world, environment, etc.)
- Making oversight “mistakes” (of past)
  - No external advisory group input
  - Slipping products into market without public discussion
  - No premarket review (at all)
  - This is not “Science based”

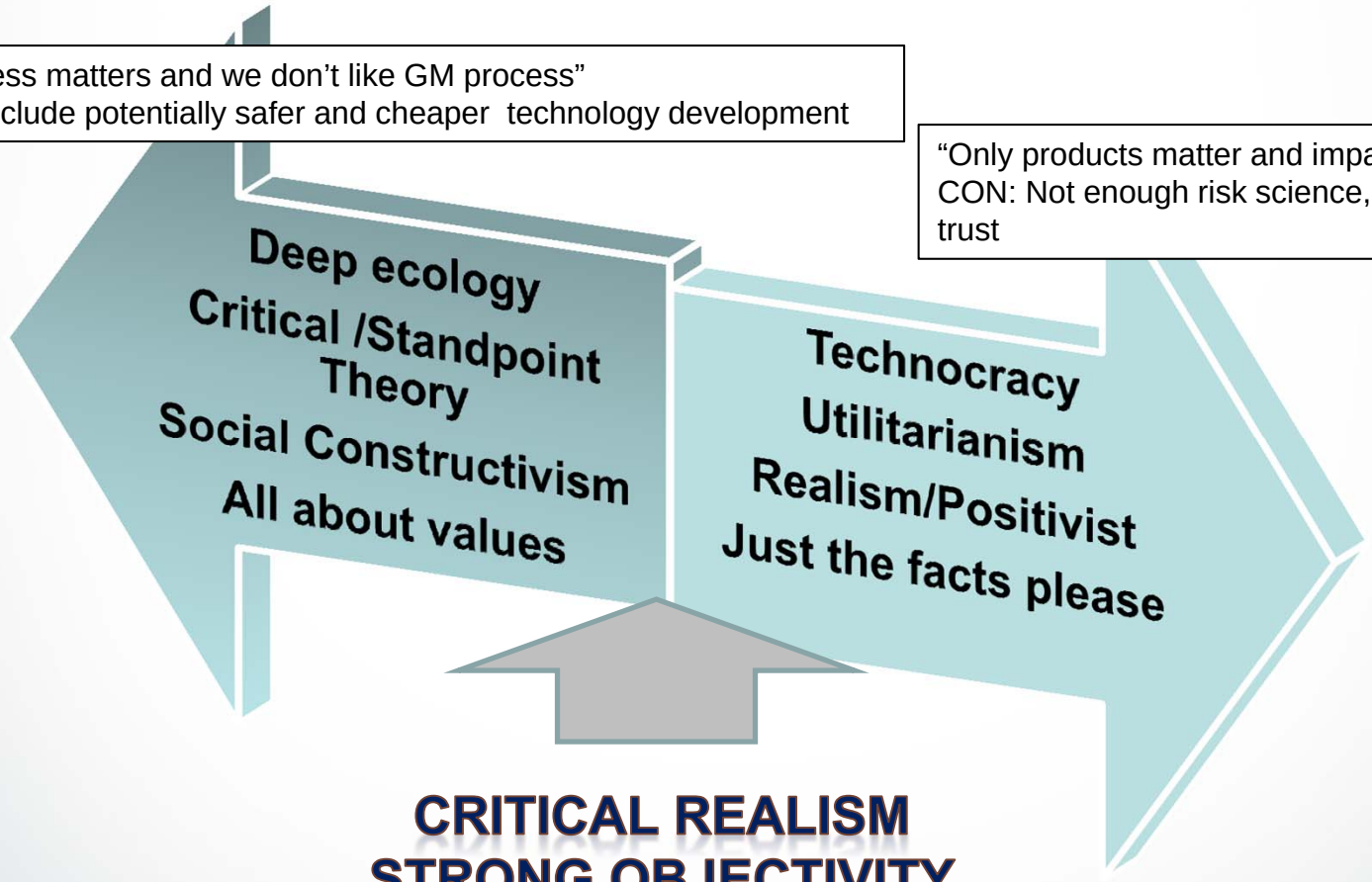
- Animal Biotechnology community can do it better!
- It is early enough…
- Take a bold approach, whether “voluntary” or formal…

NEW GOVERNANCE PARADIGMS & INNOVATION

A Theoretical "Middle Ground" Forward

"Only process matters and we don't like GM process"
CONS: Precludes potentially safer and cheaper technology development

"Only products matter and impacts"
CON: Not enough risk science, hypocrisy, lack of trust



CRITICAL REALISM
STRONG OBJECTIVITY
ANALYTICAL DELIBERATIVE RISK ANALYSIS
RESPONSIBLE INNOVATION

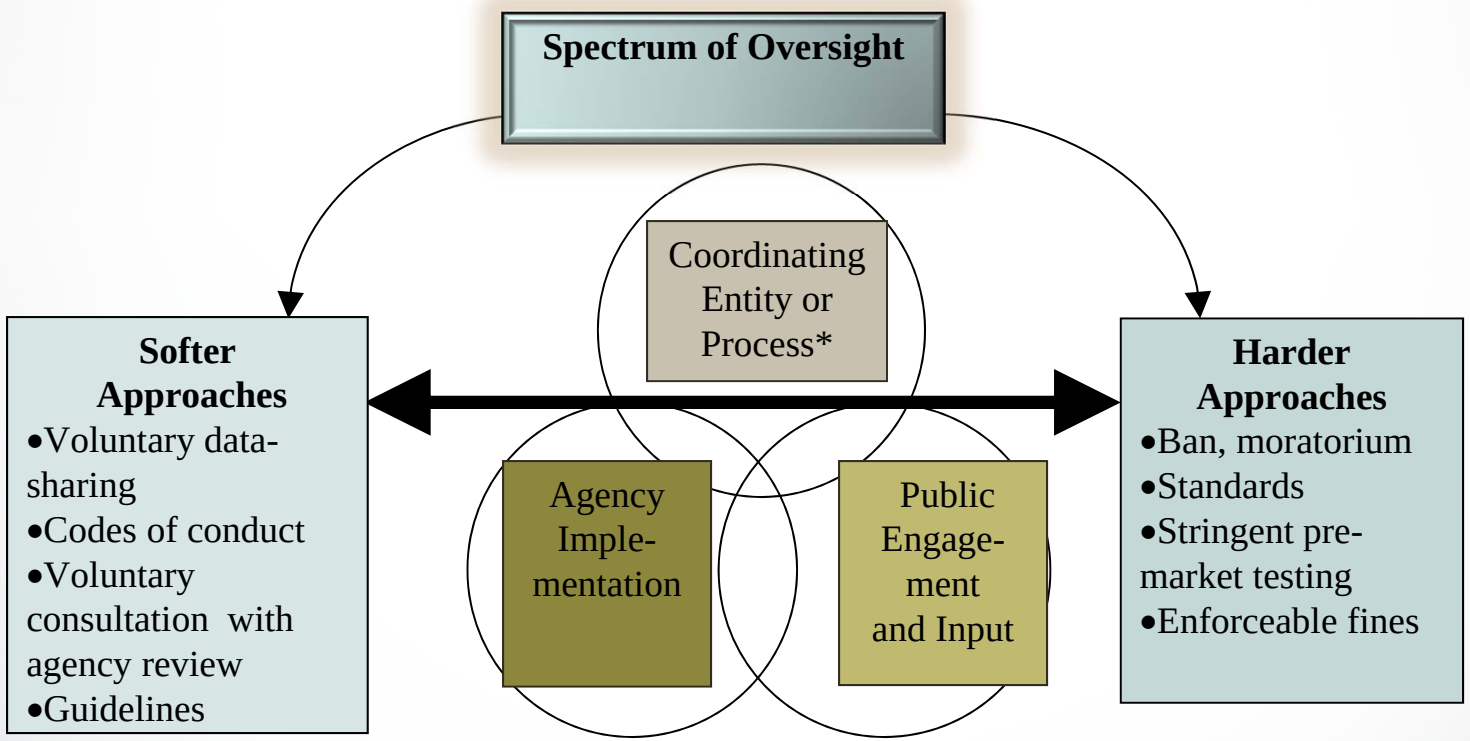
Responsible Research & Innovation

- *Owen & Von Schomberg (2013).*

- "I categorise here four types of irresponsible innovation: Technology push, Neglectance of fundamental ethical principles, Policy Pull, and Lack of precautionary measures and technology foresight."

- *"Responsible Research and Innovation is a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products(in order to allow a proper embedding of scientific and technological advances in our society)."*

Dynamic Oversight:
An example "practical" way forward



Ramachandran, et al. 2011

* with citizen, governmental, academic, industry, tribal, and NGO representation

Principles

- Anticipates convergence
- Inclusive
- Public empowerment
- Learning among groups
- Respectful
- Multiple iterations
- Preparedness at all stages
  - (including post-market)
- Transparent
- Adequate resources
- Continuous
- Evolving
- Information-generating
- Information- and value-based

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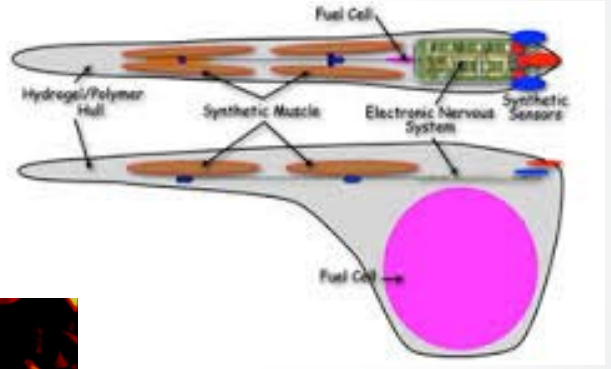
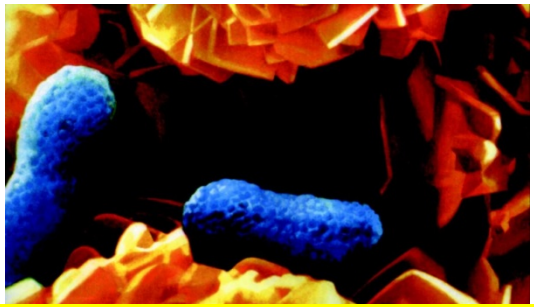
Upstream Oversight Assessment: Case Studies for Syn Bio

- Cases of medium to longer term development
- Mental models of diverse stakeholder-SMEs
- Policy Delphi process in 4 rounds

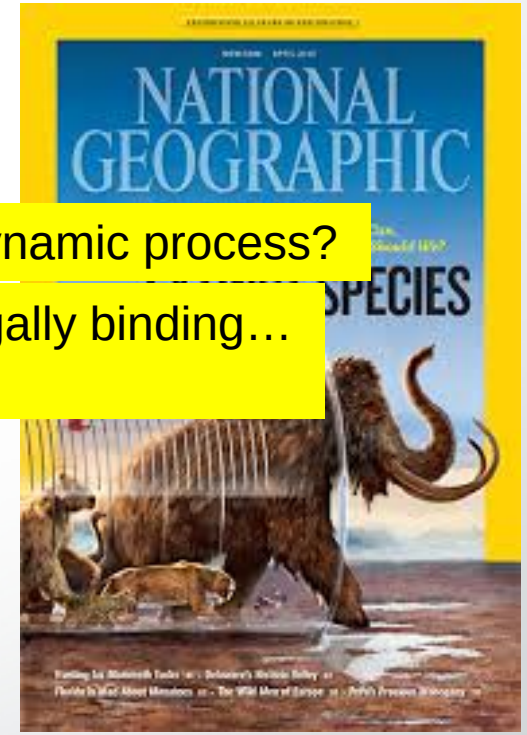


Kuzma PI, Cummings co-PI 2013-2014
Sloan Foundation SB Program



Run some Animal Biotech cases through a Dynamic process?

Does not have to be regulatory based or legally binding…
Proof of concept.



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GES center Website: ***go.ncsu.edu/ges***