EMERGING TECHNOLOGIES AND U.S. FOOD GOVERNANCE SYSTEM

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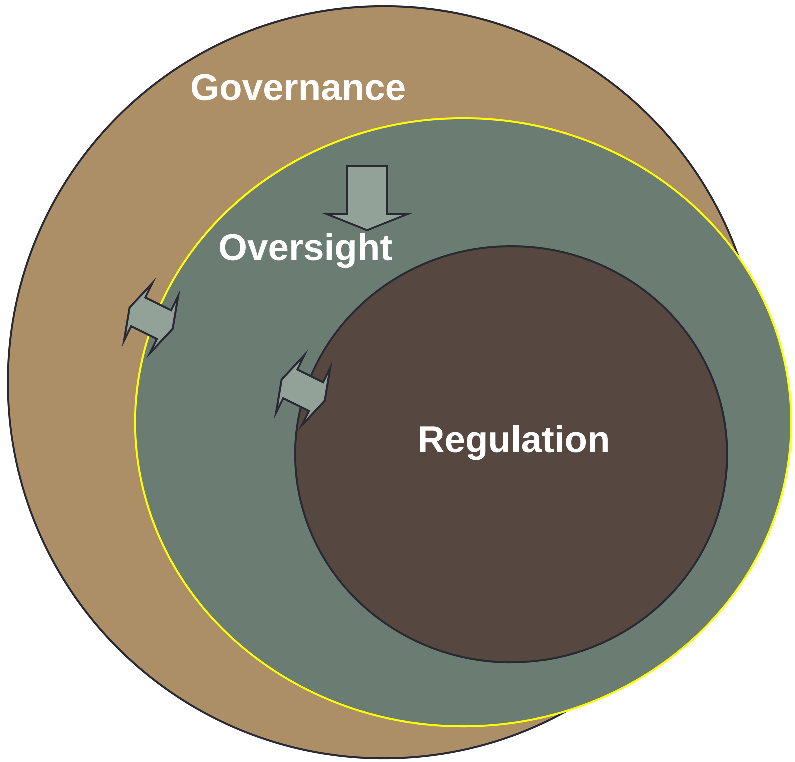
Regulation, oversight, governance

- Governance
  - Complex set of norms, values, processes, and institutions in pattern of rule
- 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

Emerging Technologies and U.S. Food Governance System

- GM foods as a case study
- (Nano foods as a case study)
- General Conclusions From Broader Policy Perspective

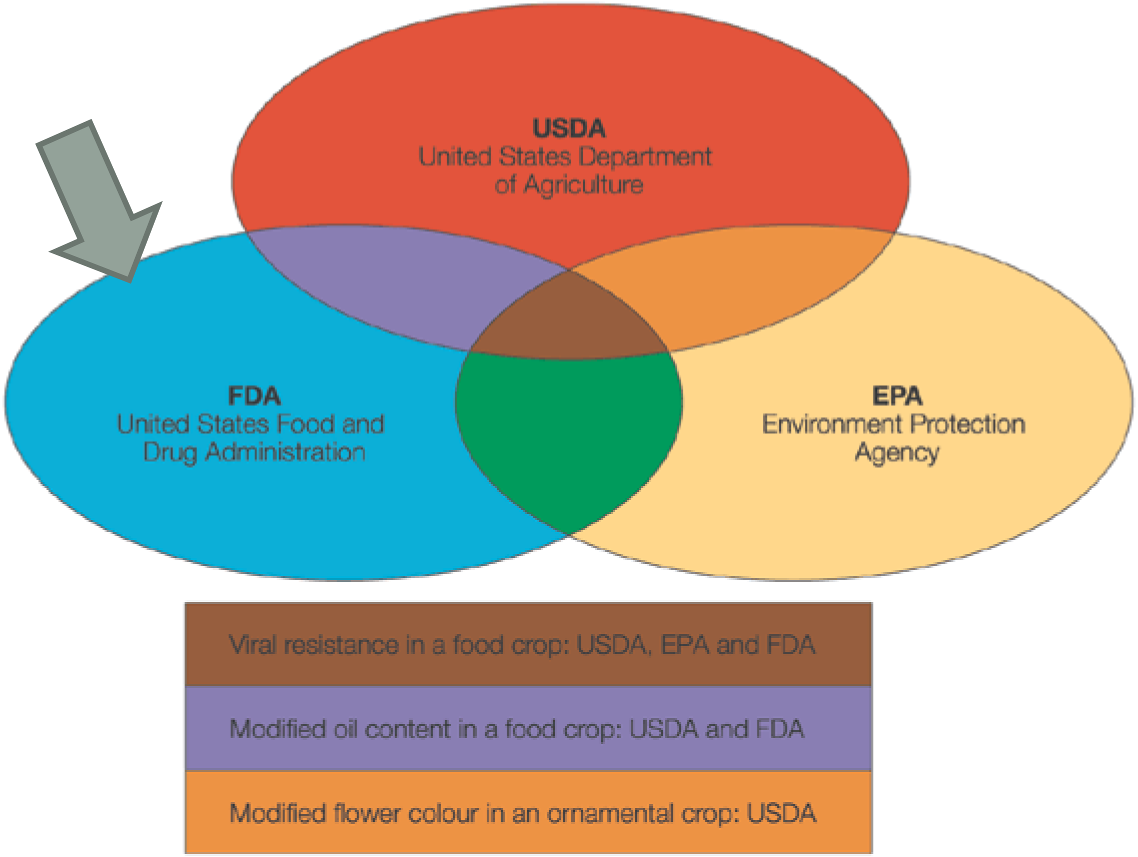
Coordinated Framework for the Regulation of Biotechnology Products (1986-present)

Agency	**Jurisdiction**	**Laws**
US Dept. of Agriculture (USDA)	Plant pests, plants, veterinary biologics	Federal Plant Pest Act (FPPA)—1957, Revised to Plant Pest Act 2000
Food and Drug Administration (FDA)	Food, feed, food additives, vet. Drugs, human drugs, medical devices	Federal Food, Drug and Cosmetic Act (FFDCA)--1958
Environmental Protection Agency (EPA)	Microbial and plant pesticides; novel microbes	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)--1947; Toxic Substances Control Act (TSCA) 1976

No “new risks”, no new laws needed, “product not process”

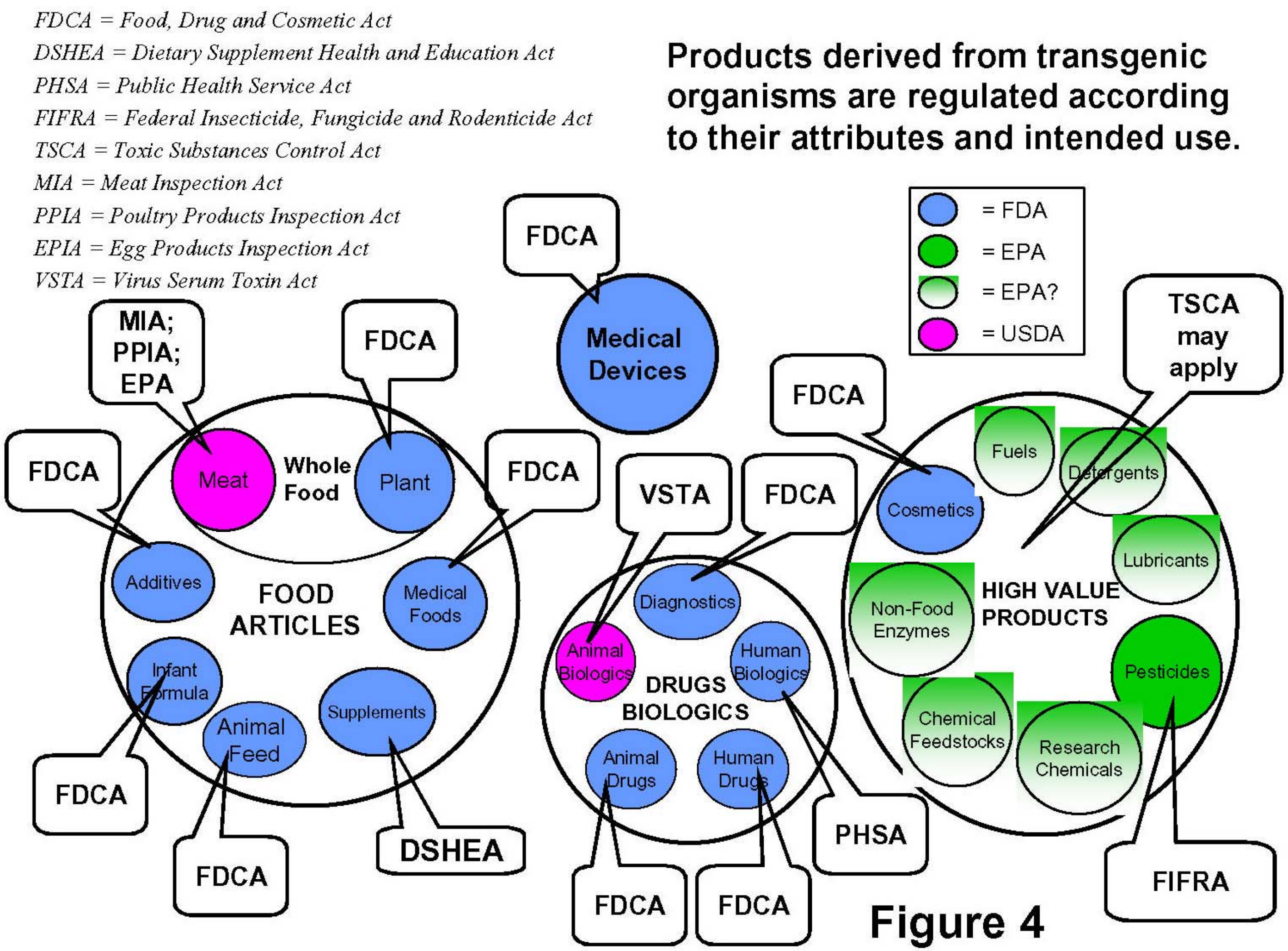
Using GM foods to illustrate

- “Science and risk based process”
- Process is the trigger for taking a regulatory look
- Product then becomes focus
- Based on “process” (GM or not GM) 1st
- Product 2nd (Plant food, feed. Plant pest, Pesticide, Animal, Other)



Nature Reviews | Genetics

Regulation of Transgenic Organisms By Product



FDA’s Food Biotechnology Approach

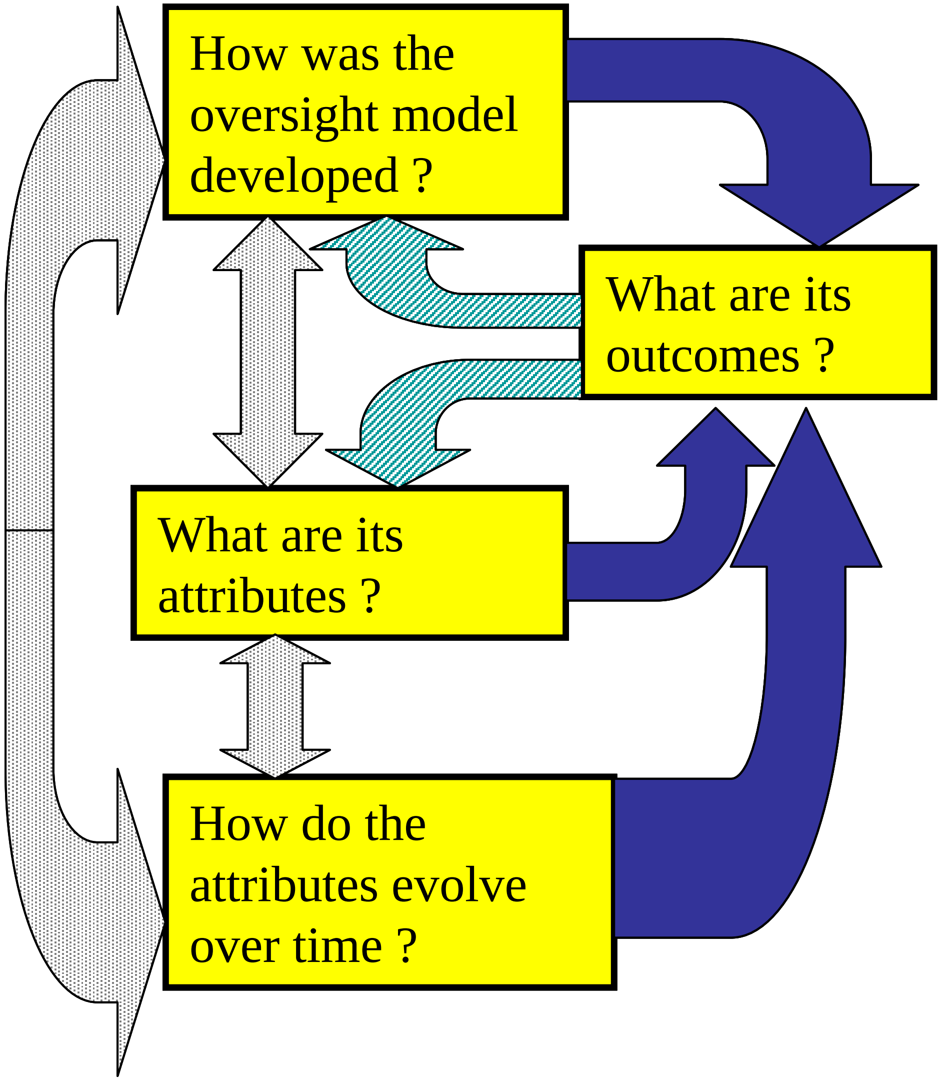
- **1992 FDA issues “Statement of Policy: Foods Derived from New Plant Varieties“**
  - They do not substantially differ from conventional counterparts—”Substanially Equivalent”
  - Voluntary Process, not “regulated” per se—manufacturer consults with FDA (2001 proposed rule to make mandatory, but never passed).
  - However during this consultation, FDA may require “food additive” petition if not “generally regarded as safe” (GRAS)
  - First product, Flavr Savr tomato went through food additive process for antibiotic resistance gene, not the key trait of delayed ripening
  - We assume all other GE foods have gone through the voluntary consultations process.

FDA also does not require labeling of foods derived from genetic engineering

- FDA claims it does not have authority to do so
  - No scientific or risk (material) basis
- EU, China, Japan, Brazil, Australia (and others) have mandatory labeling
- Yet, public surveys and focus groups indicate that an overwhelming majority favors mandatory labeling
  - Rights to know and choose
- Organic market is responsible for negative labeling
  - GE ingredients not allowed in organic certified foods (<1% contamination is OK)

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

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

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

"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?

Cross case comparisor
Strengths and Weaknesse

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.	◪	□	◪	◪

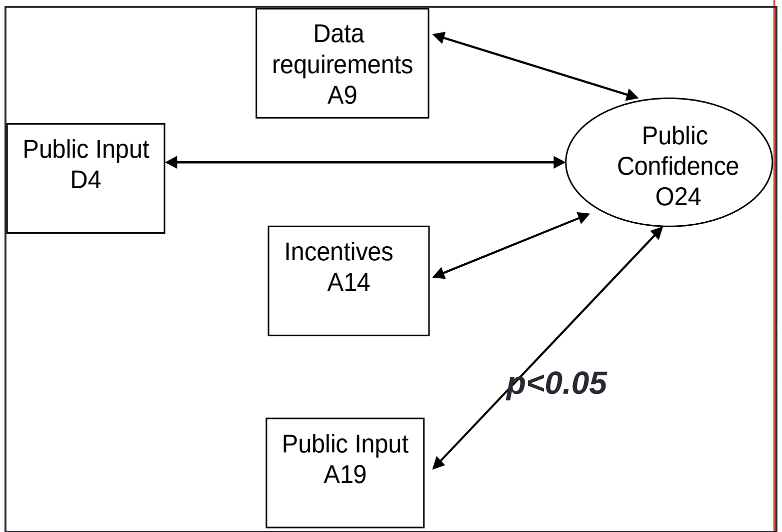
Yellow="strength"

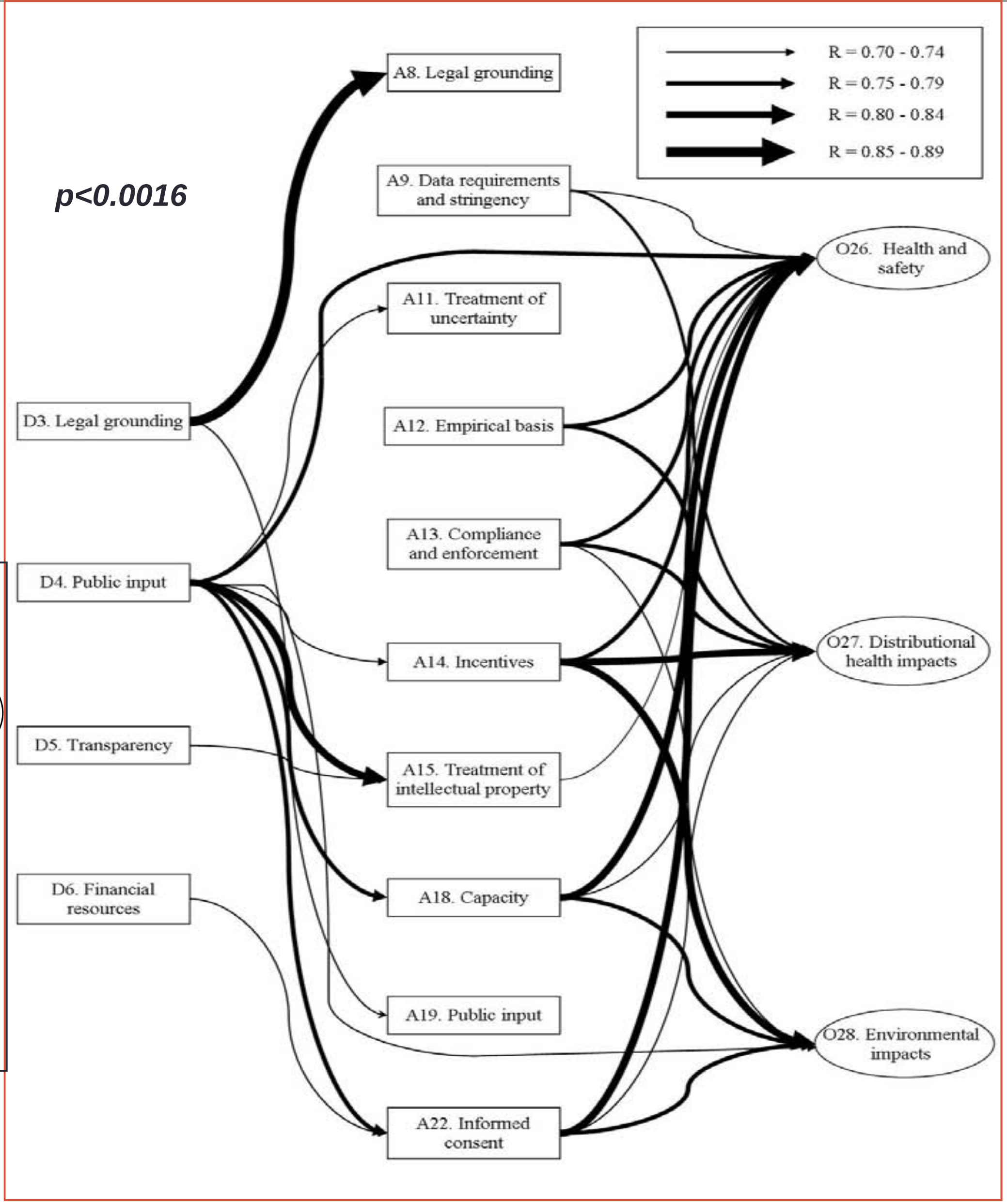
"Science-based" nature of U.S. oversight system

Gray="weakness"

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

Correlation Analysis: Relationships of "normative" and "empirical" Criteria





GM Oversight: Proper pacing?

• High flexibility • Clear subject matter • 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 new GM products?

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.

Kuzma, J. in ***Innovative Governance Models for Emerging Technologies*** Eds. Marchant, Abbott, & Allenby. Edward Elgar (2013) (in press).

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?”

Pacing through Policy Shift Revolution (2009-present)

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

Closed system--contested

- There is growing knowledge and reaction in the U.S. (and abroad)

- Policy processes are contested in key ways:
  - Buying of natural, local, organic foods
  - NGO legal suits concerning GM crops (and nanofoods)
  - Recent labeling propositions on state ballots
  - Transgenic salmon bans in a few states

- Delays in technology deployment
  - Monsanto backs off pursuing EU GM crop approval
  - LONG (over decade) approval for GM salmon (1st animal-derived food)

- Companies are starting to use GM methods that stretch definition of "genetic engineering or rDNA"…. (Kuzma and Kokotovich 2011)
  - Active Regulatory Avoidance
  - USDA deciding outside of regulatory scope

A closed hierarchical networked system

- Consumer “precaution versus promotion” views, value-based concerns, labeling desires, are dealt with by contesting the system (shocking it) through NGOs & courts, ballots, and purchasing. (CLOSED)

- The policy decision making is networked between to elite few technology developers, industries and regulatory agencies (NETWORK at top)

- These networks make decisions that are top-down with little bottom-up input (HIERARCHICAL)

What about U.S. consumers? Choice Experiments

(Zhao, Yue, Brown, Cummings, Kuzma, in review, 2013)

Table 1. Choice Experiment Attribute and the Corresponding Attribute Levels

Attribute	Level
The **Production Technology** used to produce the rice	Nanotechnology Genetic Modification Conventional
The type of **Benefit** that could be attained by using the given technology	Enhanced nutrition Improved product taste Improved food safety of the rice Less harmful impact on the environment during production No additional benefit
Product **Price** for a 32 oz (2 lb) bag of long grain white rice	\$3.75 \$5.00

Results (Zhao, Yue, Brown, Cummings, Kuzma, in review 2013)

Table 5. Simulated Maximum Likelihood Estimates from Mixed Logit Model

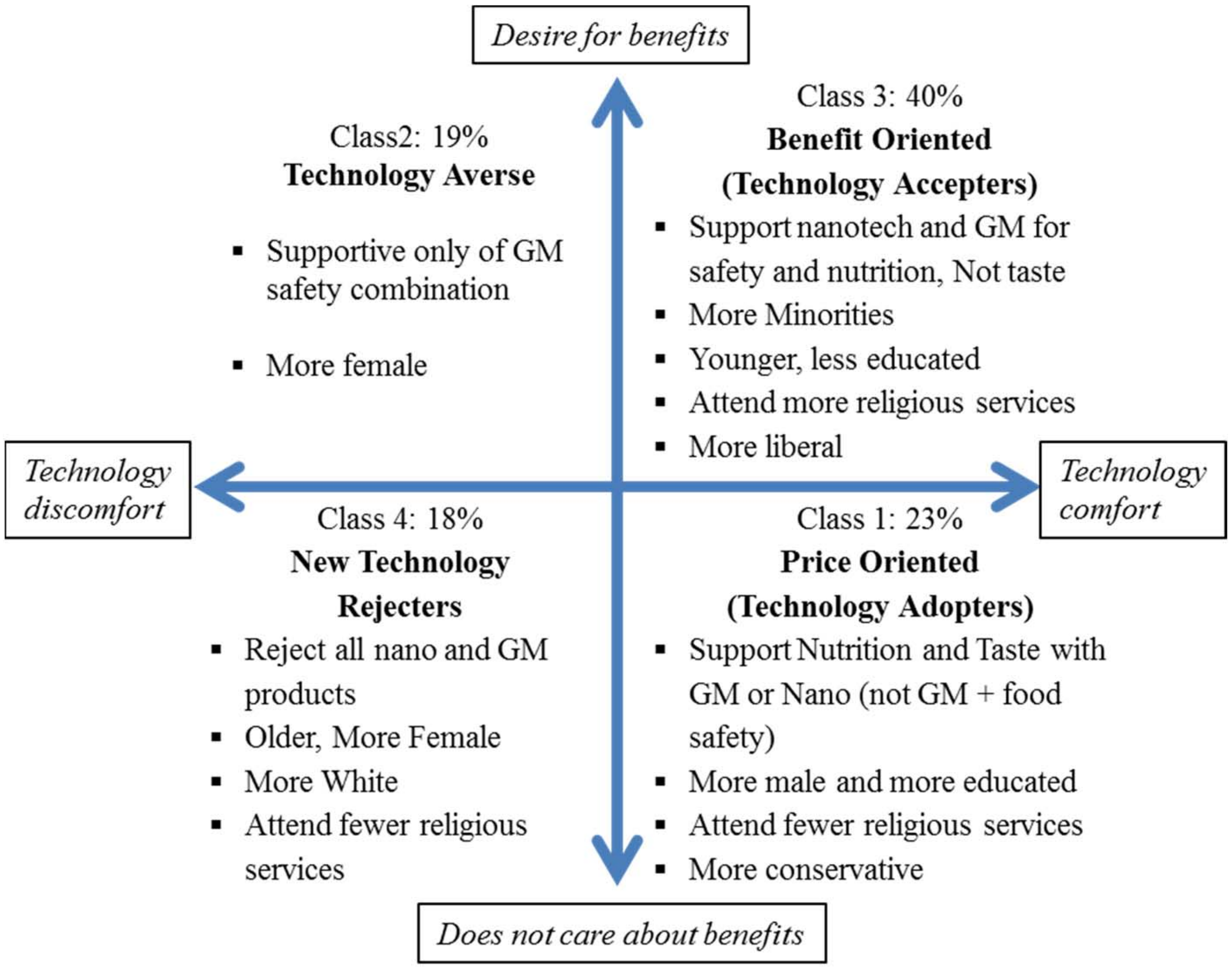
Traits	Willingness-to-pay($/lb)
Nanotechnology	-0.87
GM	-0.96
Nutrition	0.92
Safety	0.98
Environment	0.57
Taste	0.56

Table 4. Simulated Maximum Likelihood Estimates from Mixed Logit Model

Traits	Mean Coefficient	Derived Std. Dev. Coefficient
Price	-0.74***	1.16***
	(0.04)	(0.04)
Nanotechnology	-1.29***	1.50***
	(0.06)	(0.06)
GM	-1.43***	1.74***
	(0.07)	(0.07)
Nutrition	1.37***	0.41***
	(0.07)	(0.09)
Safety	1.46***	0.89***
	(0.08)	(0.08)
Environment	0.85***	0.92***
	(0.07)	(0.07)
Taste	0.83***	0.55***
	(0.07)	(0.08)

A single asterisk (*), double asterisks (**), and triple asterisks (***) denote significance at the a =0.05, 0.01 and 0.001 levels, respectively.

Consumers are not homogeneous



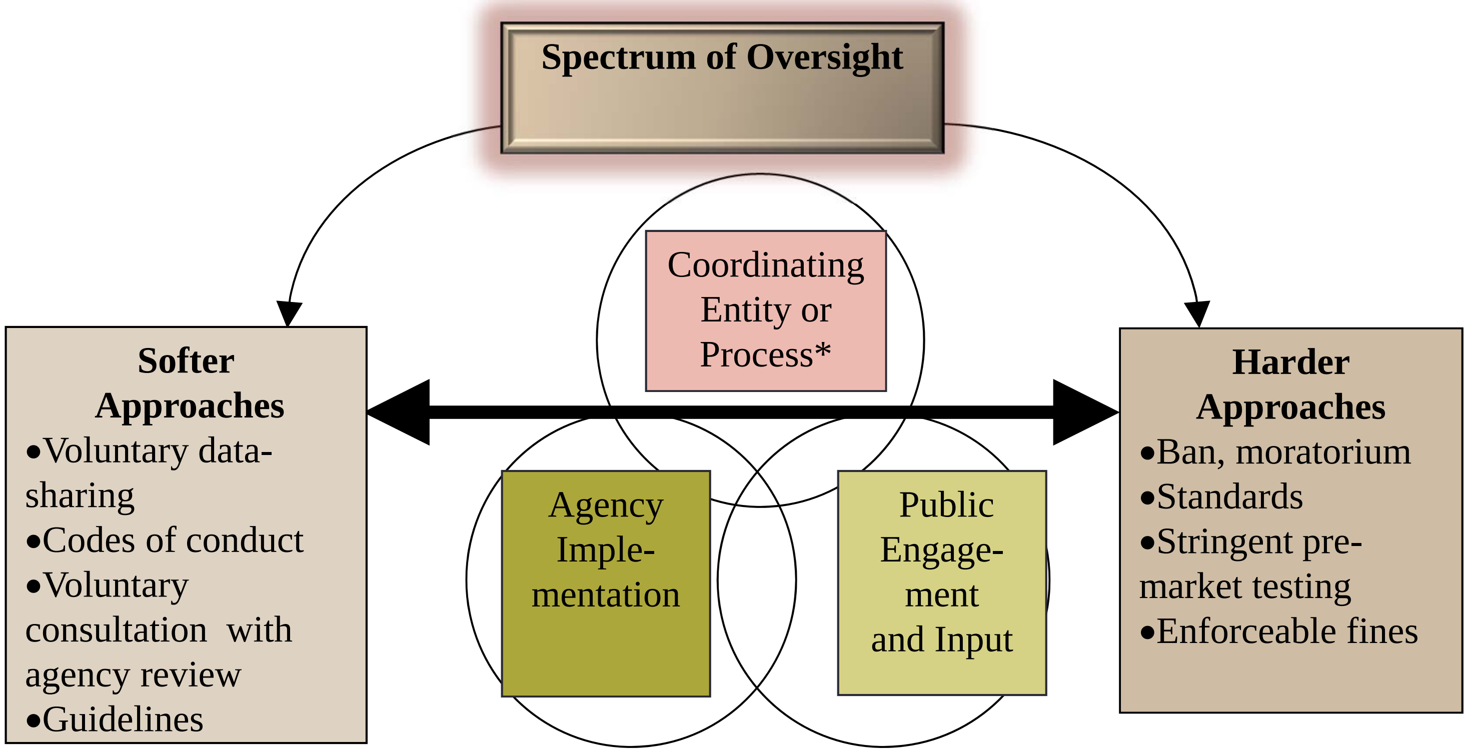
U.S. Food Governance

- Neoliberal governance VALUEs have predominated, although purported to be “science based “ with exclusion of values
- In absence of evidence, safety or substantial equivalence is assumed so as not to stifle industry and needed economic development.
- It is not transparent with regard to ET food products nor is labeling of these products required.
- At times, contradicts multi-national food policies (e.g. labeling and traceback of GM foods, Japan ban on U.S. wheat)
- U.S. has influence in WTO-WHO-FAO Codex process, but still may be definitional collisions for new products (e.g. GM vs. not GM)

U.S. Food Governance: Conclusions

- Relies heavily on industry producers and processors
- System split among three key agencies that have differing mission, goals, and approaches.
- Key agencies have significant deficiencies in emerging technologies (ETs)and food oversight.
- Based on laws over 100 years old, and outdated regulations.
- Very flexible system with room for wide interpretations by political philosophies
- Highly closed network that does not seek to incorporate bottom-up input (hierarchical, industry-regulatory-tech developer network)

Vision of Dynamic Oversight



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

Additional 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

Thank you for this kind invitation!
& Acknowledgments

- National Science Foundation Award for “Intuitive Toxicology: the Case of Nanotechnology”
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Food and Nanotechnology

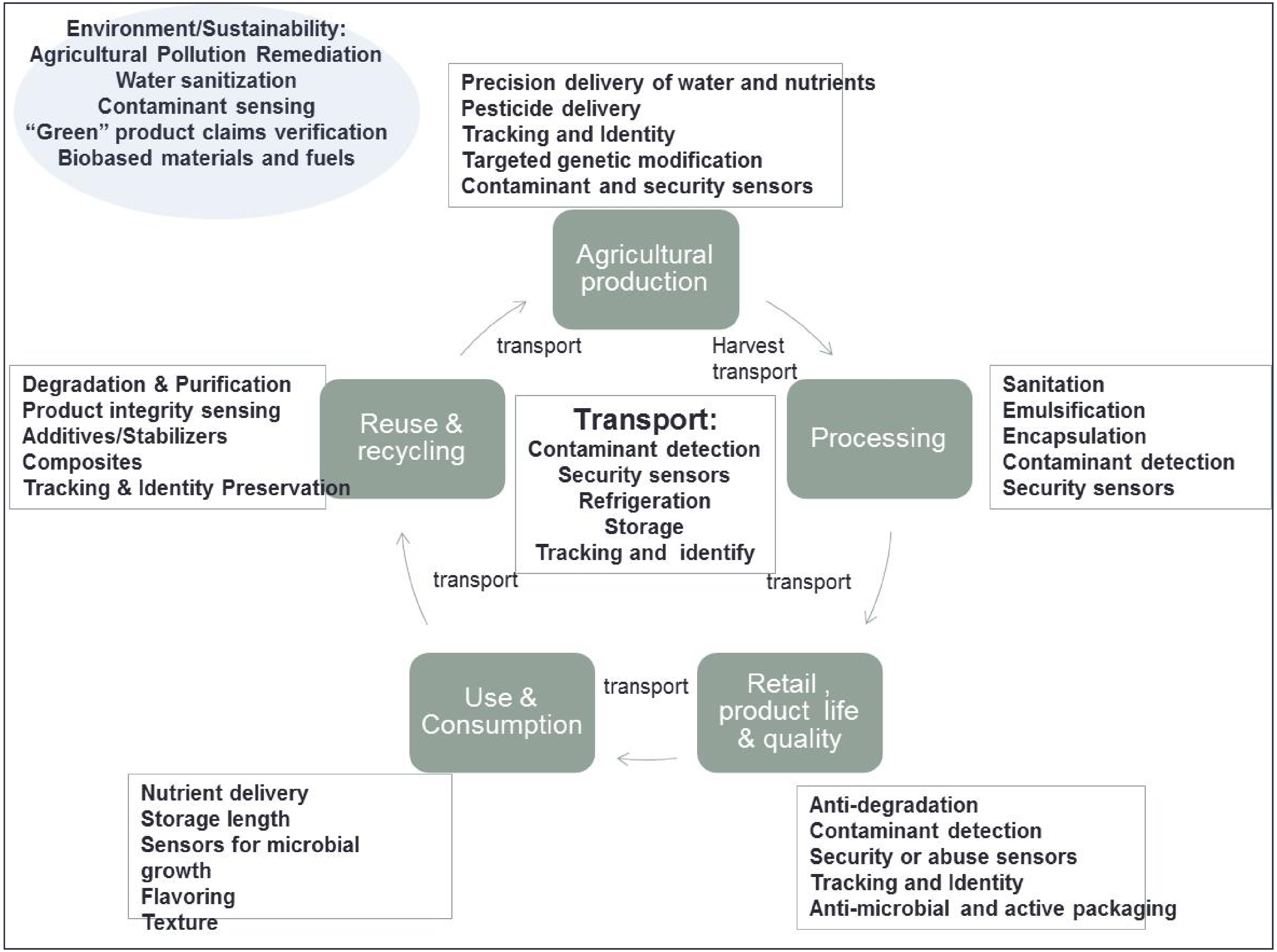
Pros:

- potential enhancement of the security, abundance, safety, and sustainability of food in the face of a growing population
- decreasing resources such as land, fuel, and water.

Cons:

- uncertainties associated with the risks and benefits,
- previous negative experiences with other emerging technologies in food,
- increases in socioeconomic disparities given access to the technologies,
- further distance from “natural” foods, and j
- job loss from traditional commodity displacement

Kuzma in prep



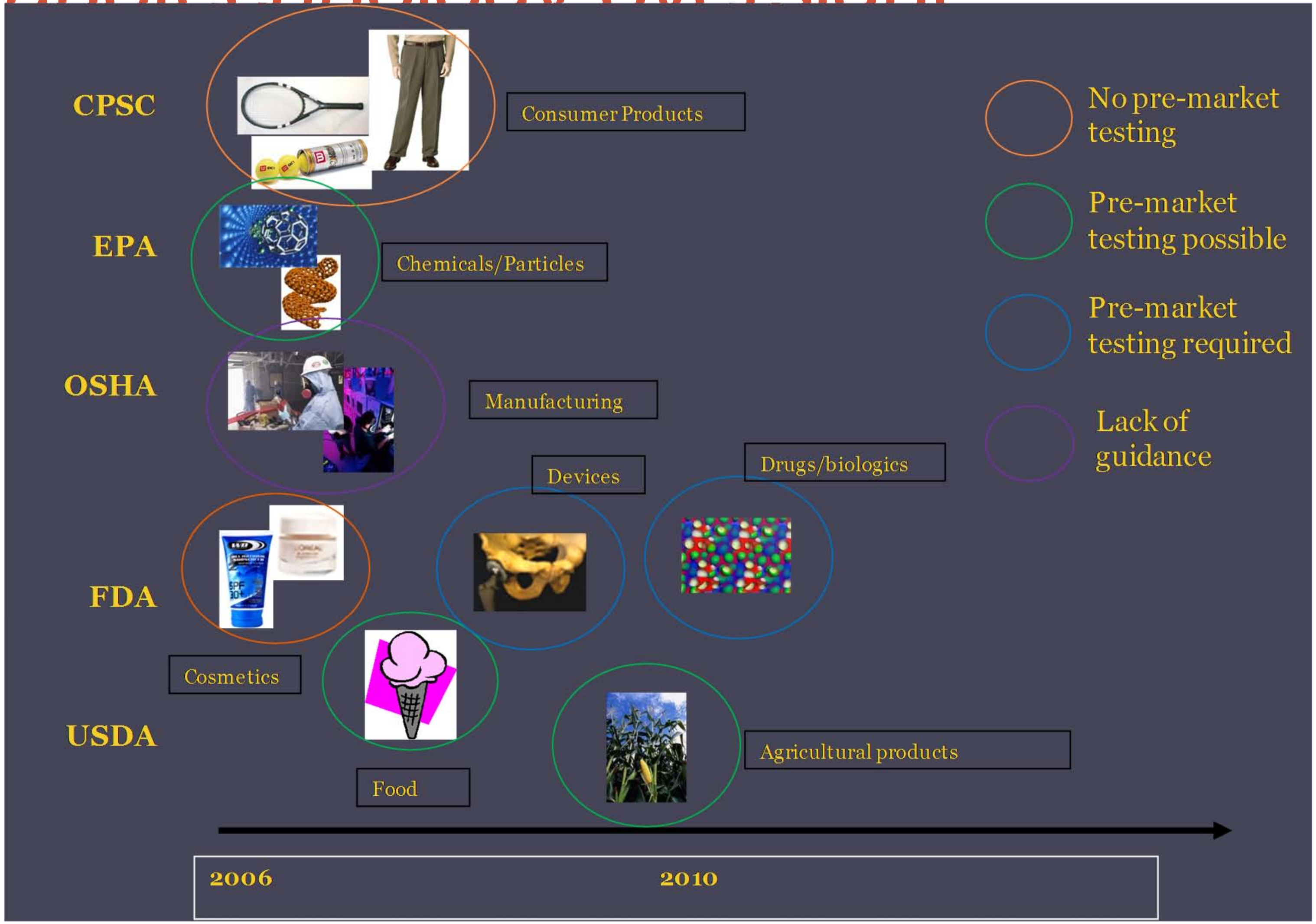
Special Features of Nanoparticles
Benefit and Risk Context

Promise	Pitfalls	
Increased surface area	Increased reactivity?	
Increased bioavailability and targeted to certain tissues	Increased toxicity?	
Lower doses effective	Lower doses toxic?	
Skin, membrane penetration may speed onset of action	Toxicity through nontraditional routes of administration?	

Selected Nanomaterial and Food Safety studies (Kuzma in prep)

Nanomaterial	Description	Select Effects	Study
Fullerenes and single walled nanotubes	These ENMs may be used in food processing or packaging materials.	Oxidative damage in distant organs in rats	Folkman et al (2009)
Ferric oxide	ENMs designed to improve bioavailability of iron	No histological or hypoxic damage in livers in rats	Rohner et al (2007)
Sliver	Sliver ENMs used in food packaging and food processing materials.	Increased brain weight, liver weight, elevated red blood cells, infiltration of inflammatory cells around central hepatic veins in rats. Sex-specific effects.	Kim et al. (2008)
Polymers of N-isopropylacrylamide methylmethacrylate acrylic acid (NMA)	Mucoadhesive polymers to increase GI transit time. Potential carrier for water insoluble food components.	No apparent signs of toxicity in rats	Bisht et al. (2008)
Copper	Dietary supplements	Renal tube necrosis, enlarged stomachs in mice	Meng et al. (2007)
Chitosan	Anti-microbial agent in food	No effects or toxicity observed in rats.	Yoksan and Chirachanchai (2008)
Zinc	Dietary supplement	Anorexia, vomiting, diarrhea, lethargy, death, elevated blood enzymes, decreased hemoglobin, renal tubular dialation in mice	Wang et al. (2006)
Titanium dioxide	Approved color additive & whitening agent.	Elevated heart enzymes, possible damage to heart function, liver inflammation, brain inflammation, renal tubules filled with proteinic liquid in mice. Differences in 25 and 80 nm particles observed in accumulation and effects.	Wang et al. (2007)
Aluminum oxide	Cookware	Chromosomal abnormalities, genotoxic effects in rats	Balasubramanyam et al. (2009)

Nanotechnology oversight



Adapted from Evan Michelson, Woodrow Wilson International Center, Project on Emerging Technologies, 2006

Nanofoods through FDA

- Difficult to find about what products are nano-sized, whether GRAS, or food additives (or contact substances)
- 2009 Guidance suggests that industry not call nanoparticles GRAS, but not binding.