
Justification for/Consequences of GMO Regulation

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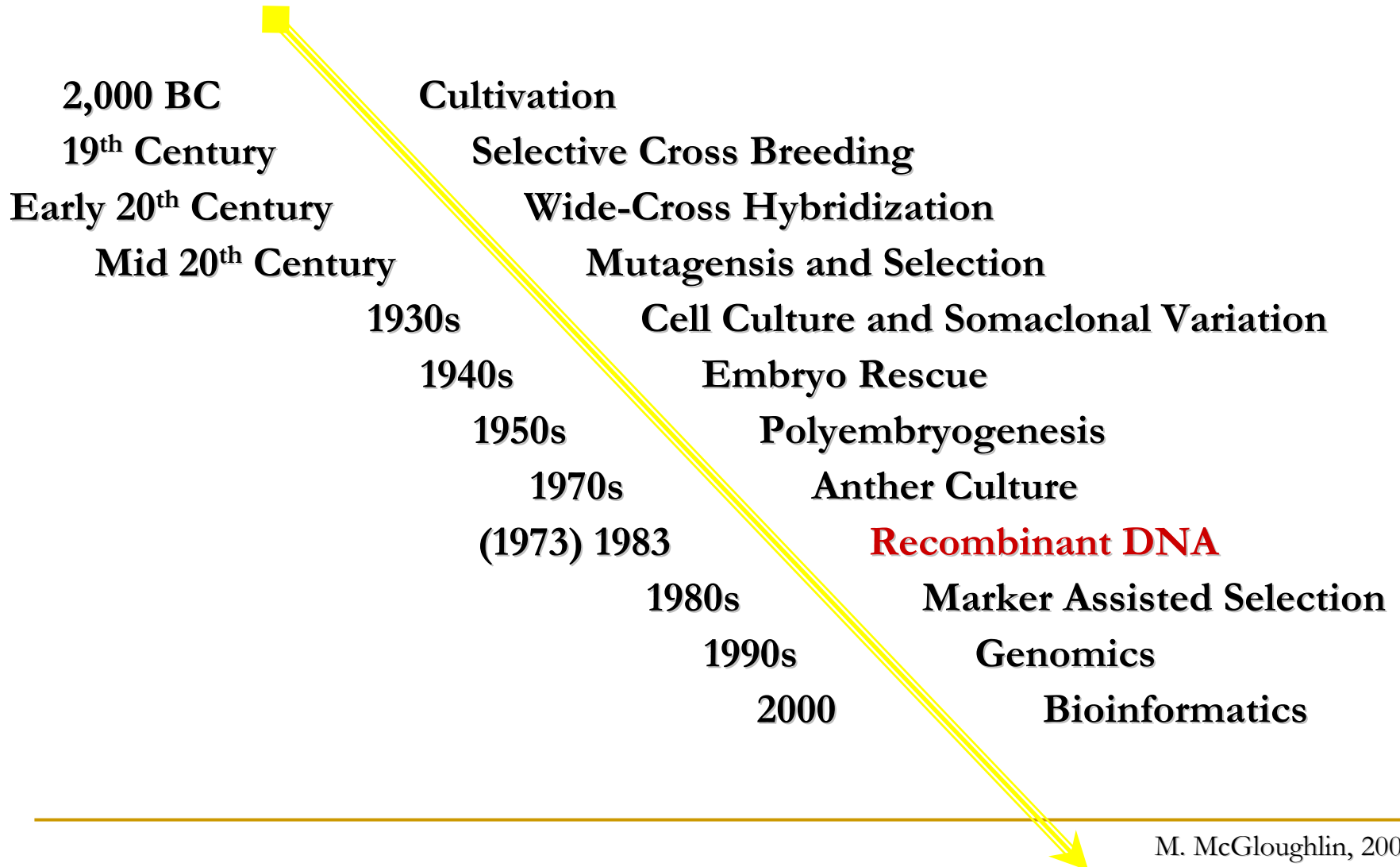
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Overview

- Continuum of Genetic Improvement
 - Principles of Regulation
 - Principles of Regulation, Ignored
 - Consequences of Flawed Regulation
 - Science Shows A Better Way
 - Conclusions
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Genetic Improvement Continuum



Benefits of R-DNA-Modified Plants

- ↑ Yields
 - ↓ Chemical pesticides
 - Less runoff
 - Fewer poisonings
 - ↓ Water requirements
 - Shifts in herbicide usage
 - Environmentally friendly herbicides
 - ↑ No-till farming
 - ↓ soil erosion
 - ↓ runoff
 - ↓ CO₂ released
 - ↓ fungal toxins
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However...

- “Pseudo-crises”
 - Fear-mongering by NGOs
 - Bad Press
 - Over-Regulation
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Consensus on Old vs New Biotech

- Genetic modification is not new.
 - WHO Regional Office for Europe, 1982

 - Risks can be assessed and managed with current risk assessment strategies and control methods.
 - WHO Regional Office for Europe, 1982
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Consensus on Old vs New Biotech

- Crops modified by molecular and cellular methods should pose risks no different from those modified by classical genetic methods.
 - U.S. National Research Council, 1989
 - As the molecular methods are more specific, users of these methods will be more certain about the traits they introduce into the plants.
 - U.S. National Research Council, 1989
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Principles of Regulation

- Degree of regulatory scrutiny should be commensurate with risk
 - Similar things should be regulated in a similar way
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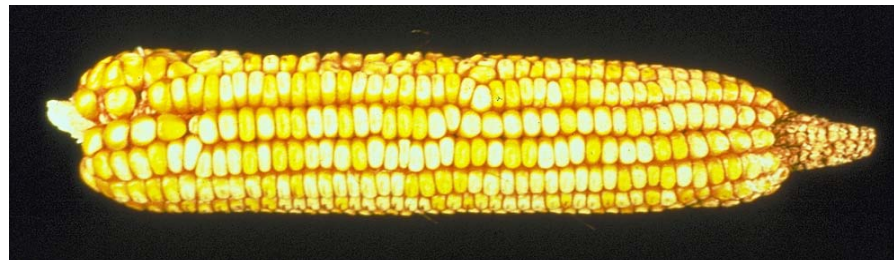
Principles of Regulation

- The *product* of genetic modification and selection should be the primary focus for making [regulatory] decisions . . . and not the *process* by which the products were obtained.
 - U.S. National Research Council, 1989
 - If the *scope* of regulation is unscientific, the entire approach is unscientific
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Principles of Regulation, Ignored

- Unscientific
 - Process-based
 - Case by case review
-

New versus Old Biotech



New versus Old Biotech

- *Triticum agropyrotriticum*
 - *Pluot/aprium*
-

Consequences of Flawed Regulation

- ↑ R&D Costs
 - Interminable delays
 - Dithering over “coexistence,” “asymmetrical authorisations,” tolerances, labeling, etc.
 - Fewer products in the pipeline (↓ benefits to farmers and consumers)
 - Mischief
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Compliance Costs: Insect-Resistant Corn

(*Kalaitzandonakes et al*)

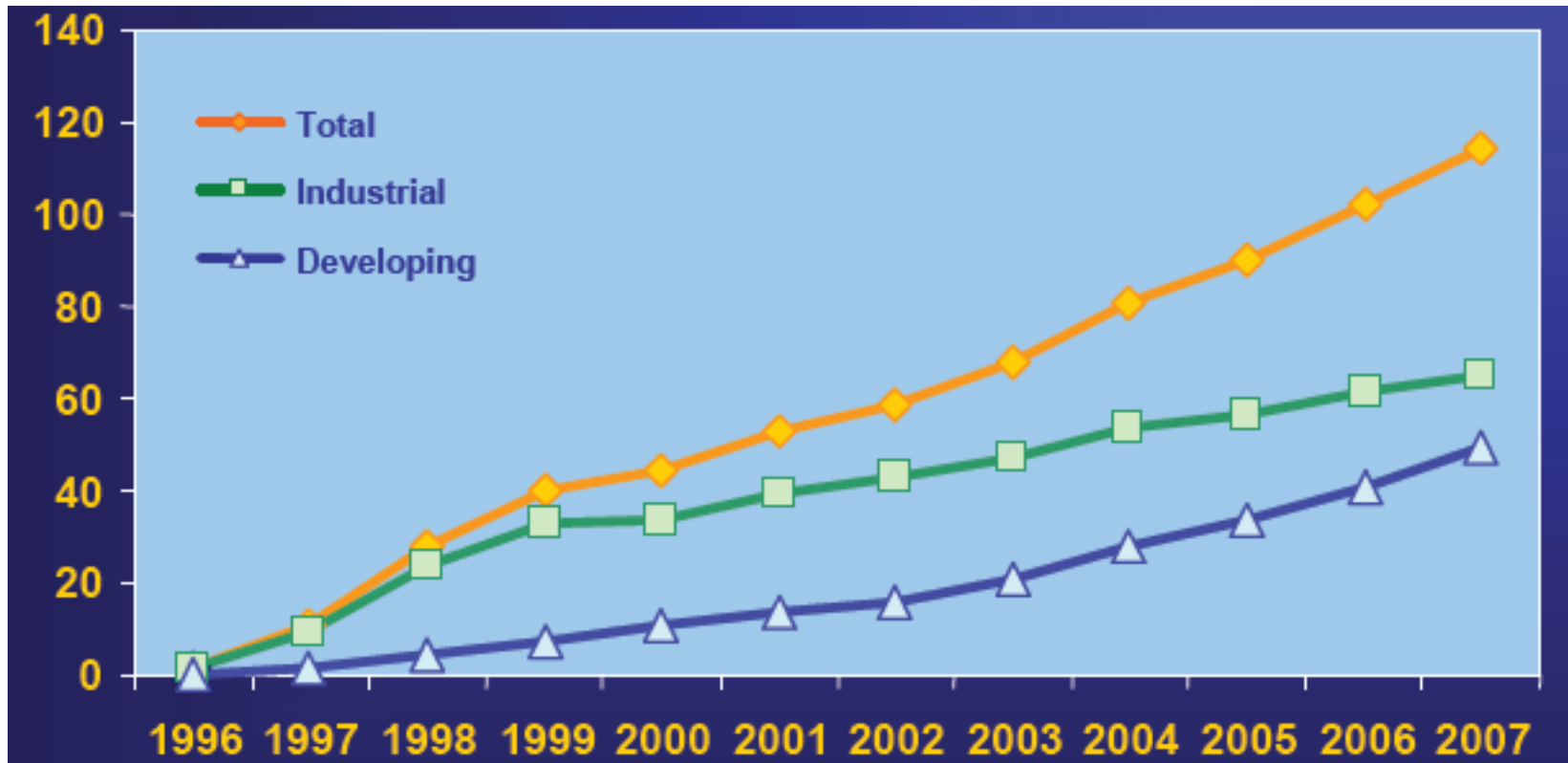
Cost categories	Range of costs incurred (\$)
Preparation for hand-off of events into regulatory	20,000–50,000
Molecular characterization	300,000–1,200,000
Compositional assessment	750,000–1,500,000
Animal performance and safety studies	300,000–845,000
Protein production and characterization	162,000–1,725,000
Protein safety assessment	195,000–853,000
Nontarget organism studies	100,000–600,000
Agronomic and phenotypic assessments	130,000–460,000
Production of tissues	680,000–2,200,000
ELISA development, validation and expression analysis	415,000–610,000
EPA expenses for PIPs (e.g., EUPs, tolerances)	150,000–715,000
Environmental fate studies	32,000–800,000
EU import (detection methods, fees)	230,000–405,000
Canada costs	40,000–195,000
Stewardship	250,000–1,000,000
Toxicology (90-day rat)—when done	250,000–300,000
Facility & management overhead costs	600,000–4,500,000
<i>Total</i>	<i>7,060,000–15,440,000</i>

Compliance Costs: Herbicide-Resistant Corn

Cost categories	Range of costs incurred (\$)
Preparation for hand-off of events into regulatory	20,000–50,000
Molecular characterization	300,000–1,200,000
Compositional assessment	750,000–1,500,000
Animal performance and safety studies	300,000–845,000
Protein production and characterization	620,000–1,725,000
Protein safety assessment	195,000–855,000
Agronomic and phenotypic assessments	130,000–460,000
Production of tissues	680,000–2,200,000
ELISA development, validation and expression analysis	415,000–610,000
Herbicide residue study	105,000–550,000
EU import (detection methods, fees)	230,000–405,000
Canada costs	40,000–195,000
Stewardship	165,000–300,000
Toxicology (90-day rat)—when done	250,000–300,000
Facility and management overhead costs	560,000–4,500,000
Total	6,180,000–14,510,000

Global Area of Biotech Crops, 1996-2007

Industrial & Developing Countries (Millions of Hectares)



Effects of High Regulatory Costs

- ↓ Agbiotech innovation and product development (*Kalaitzandonakes et al, NBT 2007*)
 - ↓ Commercialization of already-developed R-DNA-modified horticultural crops (*Alston et al, J. Crop Improv. 2006*)
 - ↓ Potential for fruits and vegetables, tree fruits and nuts, and nursery and landscape crops (*Alston et al, J. Crop Improv. 2006*)
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Summary: Consequences of Flawed Regulation

- Inflated R&D Costs
 - Interminable delays
 - Fewer products in the pipeline (↓ benefits to farmers and consumers)
 - Dithering over “coexistence,” tolerances, labeling, etc.
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Consequences of Flawed Regulation

- Pseudo-crises
 - Vandalism
 - Intimidation of academics
 - Litigation
 - Malnourishment, illnesses and deaths
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Consequences of Flawed Regulation

- Food insecurity/malnutrition claim 24,000 lives per day.
- Many lives could be saved if Western societies would change their hostile attitude towards R-DNA modification.

--Prof. Dr. Ingo Potrykus

Risk-Based Regulation: The “Stanford Model”



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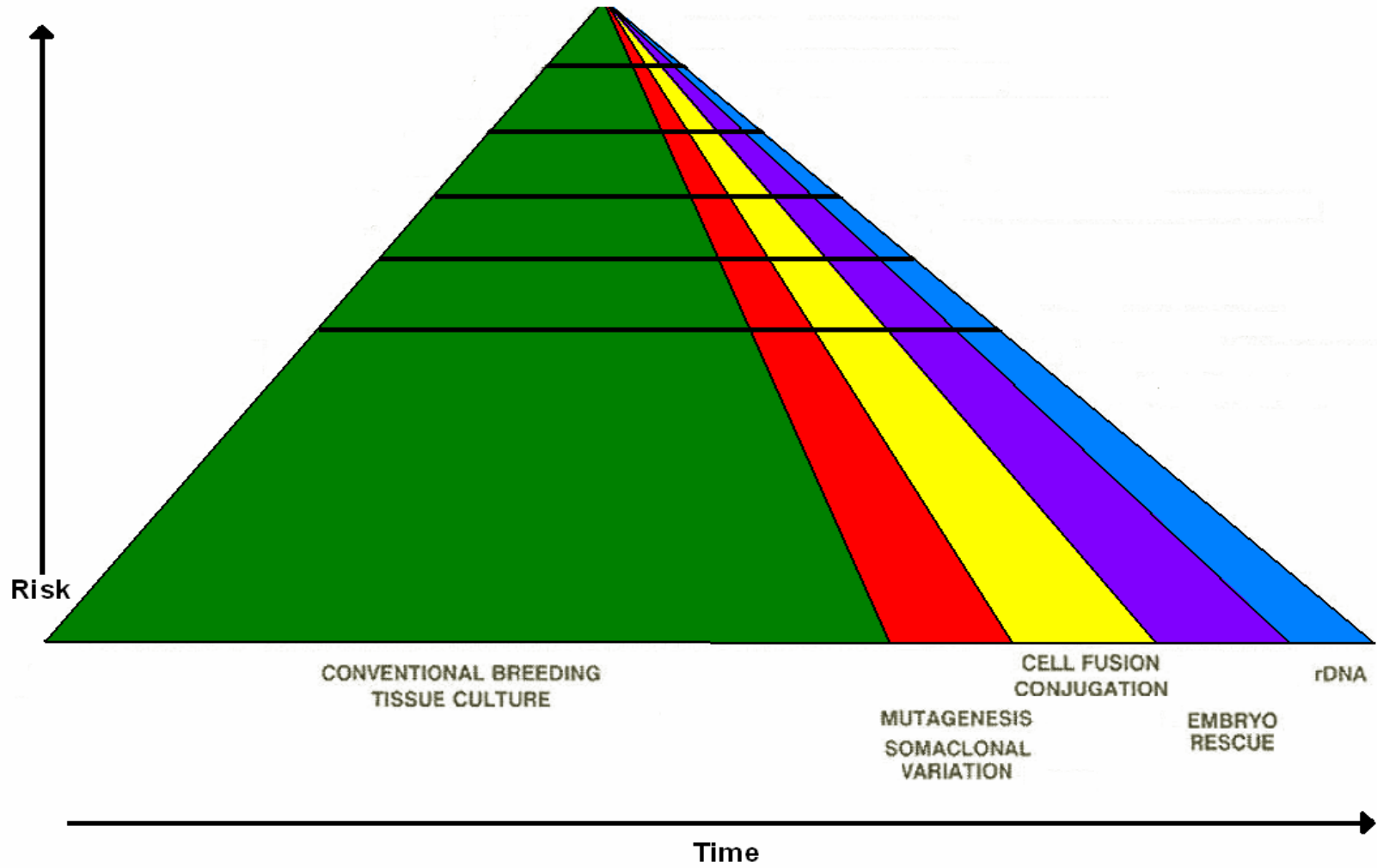
FEATURE

A model protocol to assess the risks of agricultural introductions

A risk-based approach to rationalizing field trial regulations.

*John Barton, John Crandon, Donald Kennedy, and Henry Miller**

Distribution of Risk in Field Trials



RISK-BASED REGULATION: THE “STANFORD MODEL”

- Stratification of organisms according to risk
 - Indifferent to technique of genetic alteration
 - Flexible
 - Scientifically defensible
 - Analogous to quarantine regulations
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Organism	Ability to colonize	Ecological relationships	Human effects	Potential for genetic change	Risk-management	Risk category
<i>Field Crops</i>						
Rice **+	2	2	1	1	2	2
Corn	1	1	1	1	1	1
Soybean+	1	1	1	1	1	1
Cotton +	1	2	1	1	1	1 if outside c.o. 2 if inside c.o.
Cassava **	1	2	1	1	2	1-2
<i>Vegetable crops</i>						
Chinese cabbage +	1	1	1	1	1-2	1
Eggplant +	1	1	1	1	1	1
Tomato	1	2 ^	1	1	1	2 ^
Chilli pepper	1	1	1	1	1	1
<i>Fruits</i>						
Mango ** +	1	1	1	1	1	1
Pineapple **	1	1	1	1	1	1
Papaya **	1	1	1	1	2	2
Banana ** +	1	1	1	1	1	1
<i>Tree crops</i>						
Oil palm **	1	1	1	1	1	1
Teak +	1	1	1	1	1	1
Coconut **	1	1	1	1	1	1
Rubber **	1	1	1	1	1	1
Cocoa **	1	1	1	1	1	1
<i>Ornamental</i>						
Orchids **	1	1	1	1	1	1
<i>Spices</i>						
Black pepper +	1	1	1	1	1	1

*1 is the lowest safety concern, 5 is the greatest safety concern.

**Introduction of this entity may be accompanied by an occult pest or pathogen of potentially high risk and thus may pose a quarantine problem.

+ Asian center of origin (c.o.).

^ Virally mediated gene transfer.

You Know the Risk Category: What Next?

Example 1:

- ❑ Category 1: Exempt
 - ❑ Category 2: Notification
 - ❑ Category 3: Prior approval
 - ❑ Category 4: Prior approval
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You Know the Risk Category: What Next?

Example 2:

- ❑ Category 1: Exempt
 - ❑ Category 2: Prior approval
 - ❑ Category 3: Prior approval
 - ❑ Category 4: Prior approval
-

The Stanford Model

- Flexible
 - Permits various degrees of risk-aversion
 - Permits discretion -- in a scientific context
 - Exempts field trials that should be exempt;
captures field trials that should be reviewed
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Conclusions

- *No* justification for GMO-specific regulation
 - Effects of GMO-specific regulation: catastrophic
 - Science shows the way
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Thank you!

Q&A
