U.S. Regulation of Genetically Modified Organisms in Agriculture

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Key Points

1. Not all GMO's are created equal
2. Risks of GMO's include:
   - Traditional
   - Novel
   - Economic
   - Uncertain
3. U.S. Law is not well-equipped to address the risks of GMO's
4. Patent laws have impacted the ability of GMO's to do social good
Some Example of GMO’s

- B.t. Corn, cotton, soy and canola
- Herbicide resistant soy and corn
- Viral-coat protein protected crops
- Vitamin A-enhanced rice
Adoption of genetically engineered crops in the United States, 1996-2013

Data for each crop category include varieties with both HT and Bt (stacked) traits.
Benefits of GMO’s

- Reduced use of toxic pesticides
- More target-specific pest control
- Reduced exposure to non-target organisms
- Enhanced nutrition
- Enhanced storage and transport
- Increased crop yields
Risks of GMO’s

- Traditional Risks
  - Toxicity to humans and wildlife
- Allergenicity
- Novel Risks
  - Creation of “superweeds”
  - Uncontrolled spread in the environment
- Economic risks
  - Organic Farmers
  - Patent Infringement
  - Pesticide Resistance
- Uncertainty
U.S. Regulatory Approach to GMO’s

- Coordinated Framework (1986)
  - Reliance on existing statutory authority
  - Regulate “Product” not “Process” ("techniques of biotechnology are not inherently risky")
U.S. Regulatory Agencies with Statutory Authority

- National Institutes of Health (lab testing)
- Environmental Protection Agency
  - FIFRA (pesticides)
  - TSCA (microorganisms)
  - Federal Food, Drug and Cosmetic Act (pesticides in food)
- U.S. Department of Agriculture
  - Plant Protection Act
    (deregulated status for most crops)
- Food and Drug Administration
  - Federal Food, Drug and Cosmetic Act
    (Reliance on “substantial equivalency”)
Patent Issues

- A few large corporations control:
  - What farmers plant and how they farm
  - Prohibit sharing or replanting seed
  - What researchers can study
  - What products can be commercialized (profit-based rather than to promote social welfare)
Moving Forward

- Not all GMOs are alike
  - Pharmaceuticals?
  - Animal to plant?
  - GM Animals?
- We already have problems with outcrossing
- Should consumers have a right to know (labeling)?
- How certain is the science?
- Should we be precautionary?
- Will GMOs be needed to adapt to climate change?