

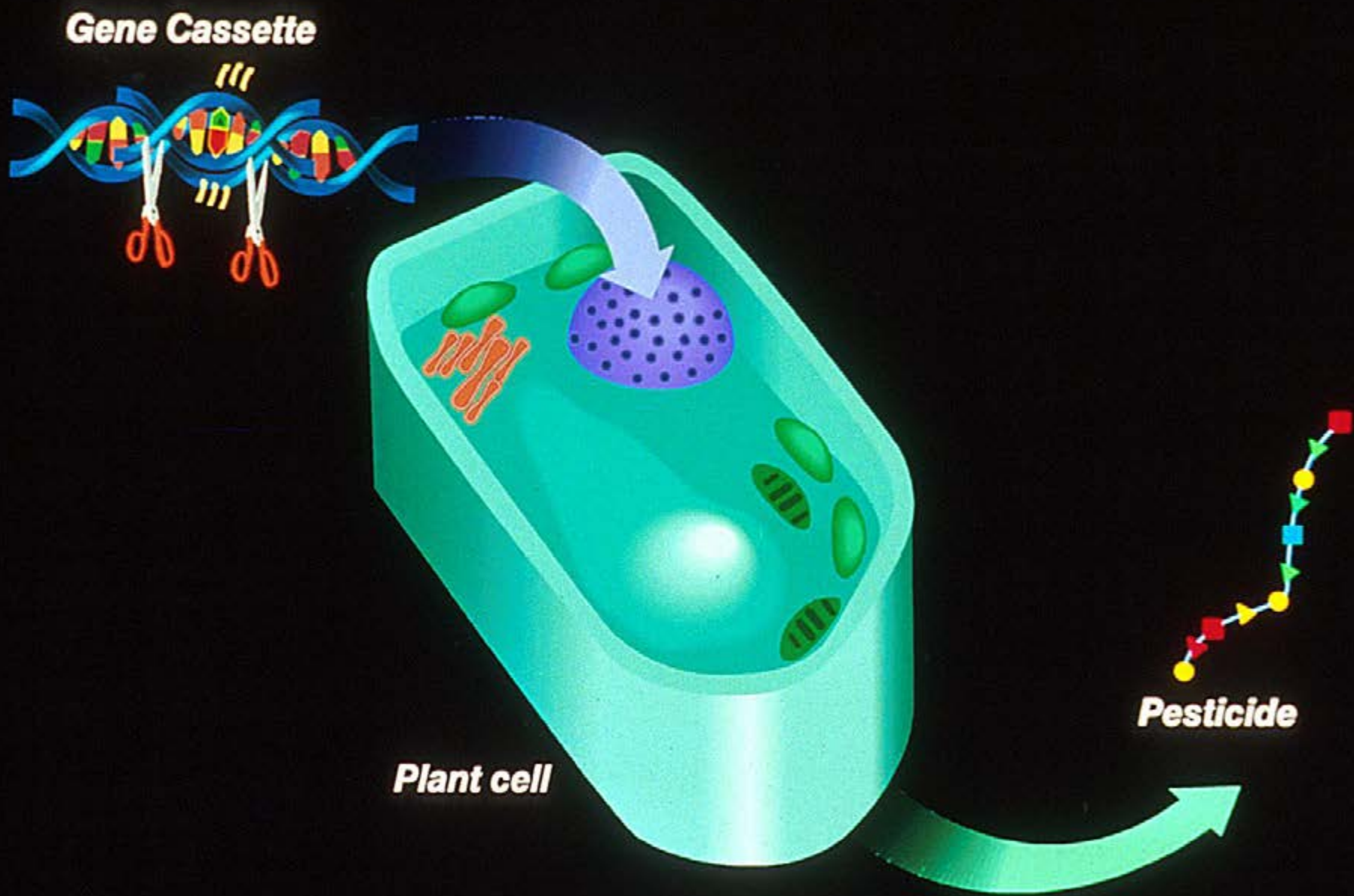


U.S. Regulation of Genetically Modified Organisms in Agriculture

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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



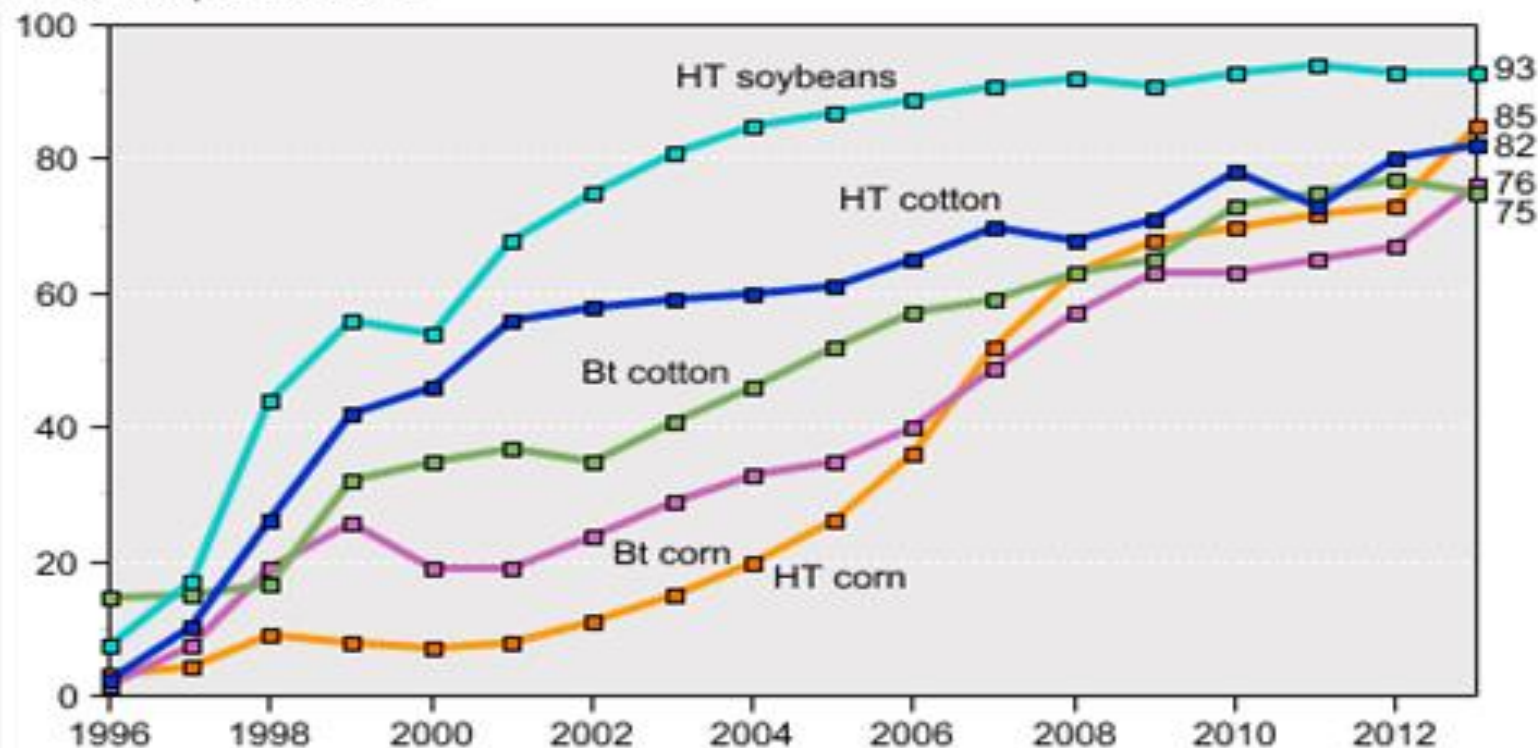


Some Example of GMO's

- 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

Percent of planted acres



Data for each crop category include varieties with both HT and Bt (stacked) traits.

Sources: USDA, Economic Research Service using data from Fernandez-Cornejo and McBride (2002) for the years 1996-99 and USDA, National Agricultural Statistics Service, June Agricultural Survey for the years 2000-13.

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

Chemical Pesticide

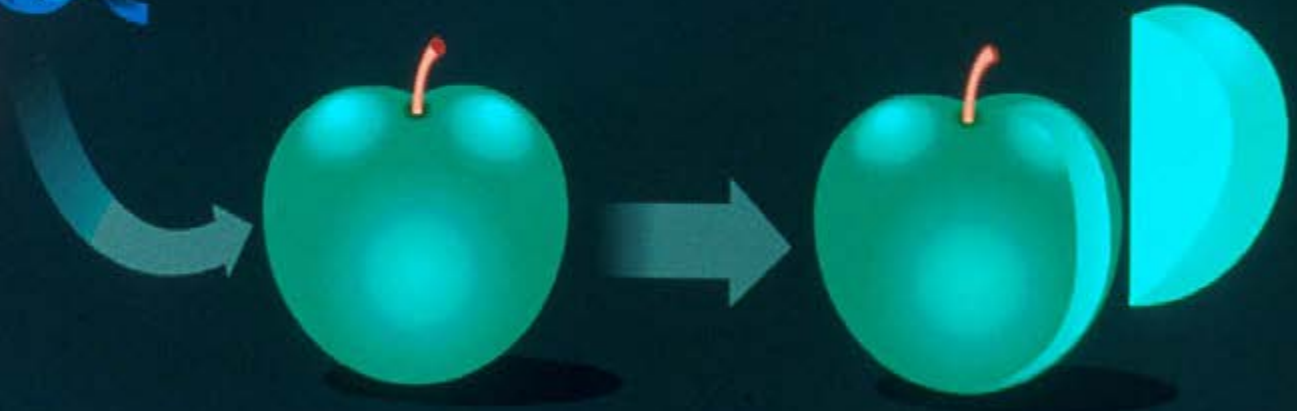
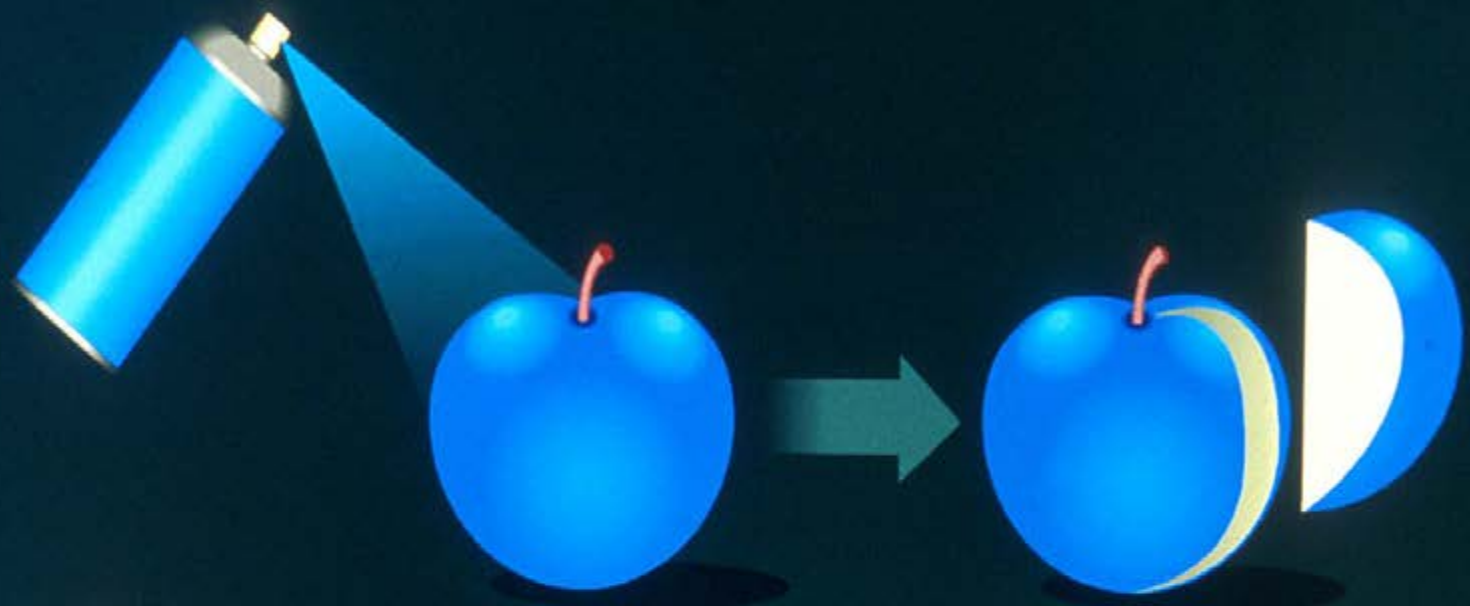


Transgenic Plant Pesticide



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?