The U.S. Approach for Fostering New Biological Technologies and Assuring Their Safety

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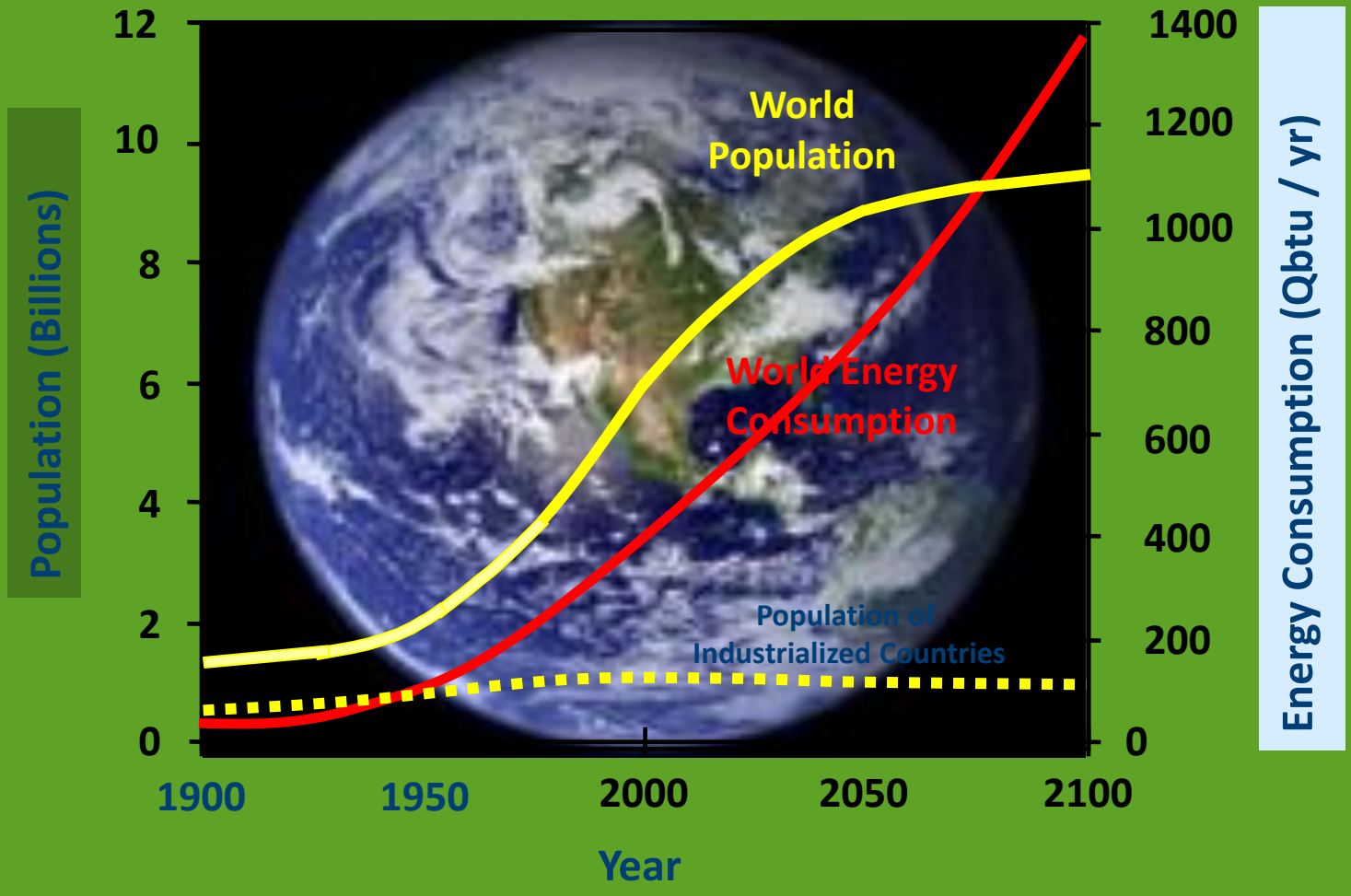
Agriculture is a Priority for the US Economy

- Rural prosperity is essential for a healthy agriculture sector
- All forms of agricultural production are important to USDA and sustainability is a key goal
- Biotechnology, including GE agriculture, is a vital component of U.S. agriculture

Energy and Population



Energy Projections: "Global Energy Perspectives" ITASA / WEC
Population Projections: United Nations "Long-Range World Population Projections: Based on the 1998 Revision"

Research Objectives for USDA

Research activities address high priority thematic areas:

1. Climate change
2. Bioenergy
3. Food safety
4. Nutrition and childhood obesity
5. Global food security

Some Facts to Consider

Biotechnology has been key to record productivity in U.S. maize, cotton, soybeans

- There has been rapid adoption by farmers
- There has been an exemplary safety record from the perspective of environment and consumer safety
- Biotechnology has been a significant contributor to environmental stewardship in agriculture

More Facts to Consider. . .

- Achieving US goals for production of biofuels will likely be unachievable without advanced technology
- Adaptation to changing weather patterns will require advanced technologies, including biotechnology
- The same is true for reducing GHG emissions from agriculture (livestock and crop production)

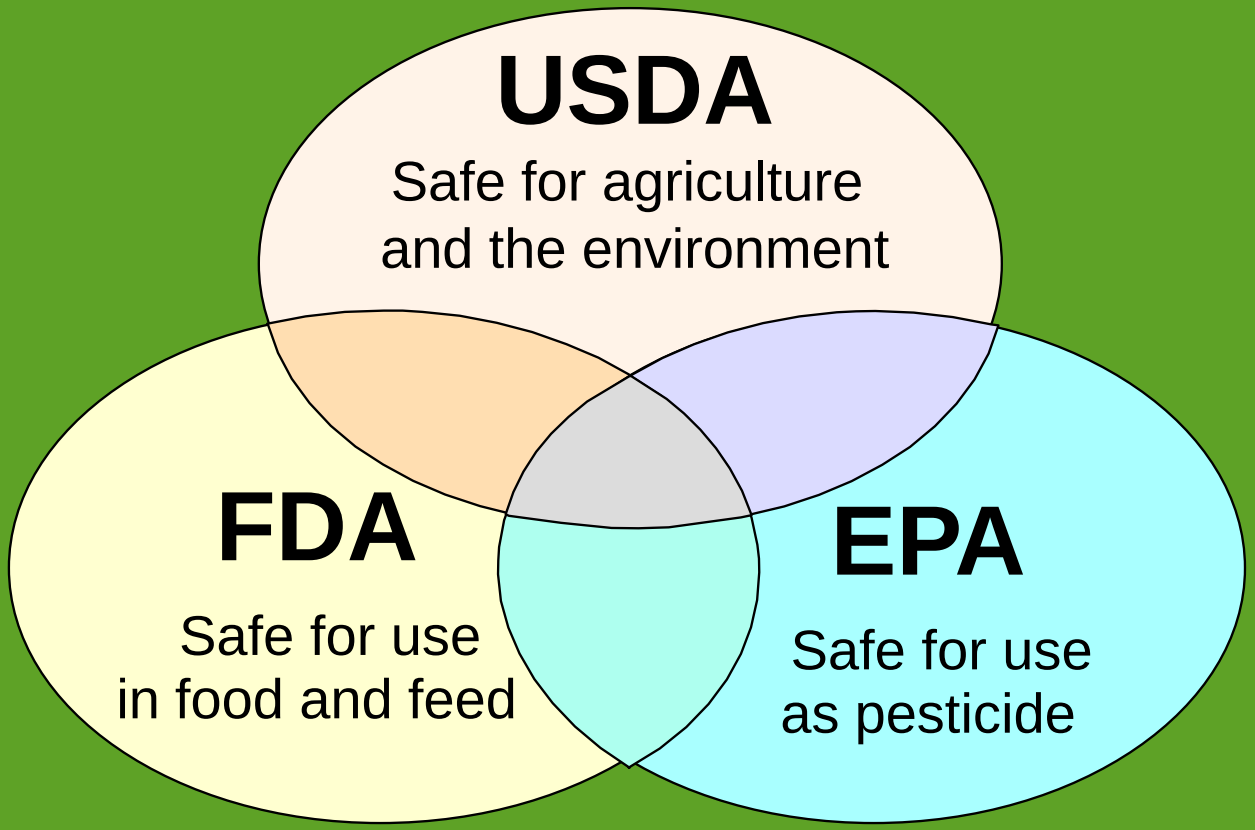
Regulation of Biotechnology in the U.S.

- The Coordinated Framework – 1986
  - The risks of crops produced using genetic engineering are not fundamentally different from risks of conventional products
  - Regulation should be based on the end use of the product and should be on a case-by-case basis.
  - The existing laws provide adequate authority for regulation of the products of biotechnology.

Three Agencies Regulate Agricultural Biotechnology in the U.S.

- Animal and Plant Health Inspection Service (APHIS); U.S. Department of Agriculture
- Environmental Protection Agency (EPA)
- Food and Drug Administration (FDA)

Regulation Under the Coordinated Framework



Most products are regulated by more than one agency

Key features

- Coordination and collaboration among regulatory agencies
- Regulatory updates to keep pace with scientific advances
- Product decisions based on scientific evidence
- Other non-regulatory activities as necessary to support the agricultural marketplace
  - e.g., verifying the accuracy of GE test methods and the performance of GE testing laboratories

USDA/APHIS oversight of field trials

- Applicants must design field tests for biological confinement
  - To minimize potential for the regulated article to persist in the environment or to produce offspring that will persist
  - Ensures no significant impact on non-target organisms

Petition for “deregulated status”

- Applicants can apply for “deregulated status”
  - Must provide sufficient data to demonstrate the organism will not present a significant plant pest risk
  - APHIS performs an Environmental Assessment based on information supplied by the applicant in the petition
  - The Public is given an opportunity to comment on EA
  - Sometimes additional environmental analyses are required by law.

Considerations for decision to grant “deregulated status”

- Information must be provided on a range of topics and must include ALL relevant experimental data, including field tests and any unfavorable information
- Data must include comparison to conventional crop

Deregulation of genetically engineered products by APHIS

- Deregulated status allows the product to be grown and marketed without further APHIS oversight
- Products undergo concurrent review by FDA and EPA, where appropriate

What is regulated by EPA?

- Regulation of pesticidal microorganisms and pesticidal substances produced by plants
  - Example: Bt corn; produces a protein toxic to specific insect pests
- Registration of pesticides and herbicides for specific use
  - Set tolerances (or exemption from tolerance) for pesticidal residues in food

Testing of Plant Pesticides

- Product characterization
- Effects on human health
- Ecological effects
- Environmental fate

Includes plans for resistance management

Covers both food/feed safety AND environmental safety

FDA Regulation of Foods and Feeds

- Designed to ensure that the safety of foods produced using genetic engineering are as safe for humans and animals as conventional foods
- Developers consult with FDA during product development regarding safety of product for use in food or feed
  - Toxicity
  - Allergenicity
  - Composition and nutritional value
  - Intended use
- Record of consultation

FDA regulatory policy

All food, whether derived from genetically engineered organisms or not, must meet the same standard of safety under the Food, Drug, and Cosmetic Act

The Impact of Genetically Engineered Crops on Farm Sustainability in the United States

National Academy of Sciences Report

April 13, 2010

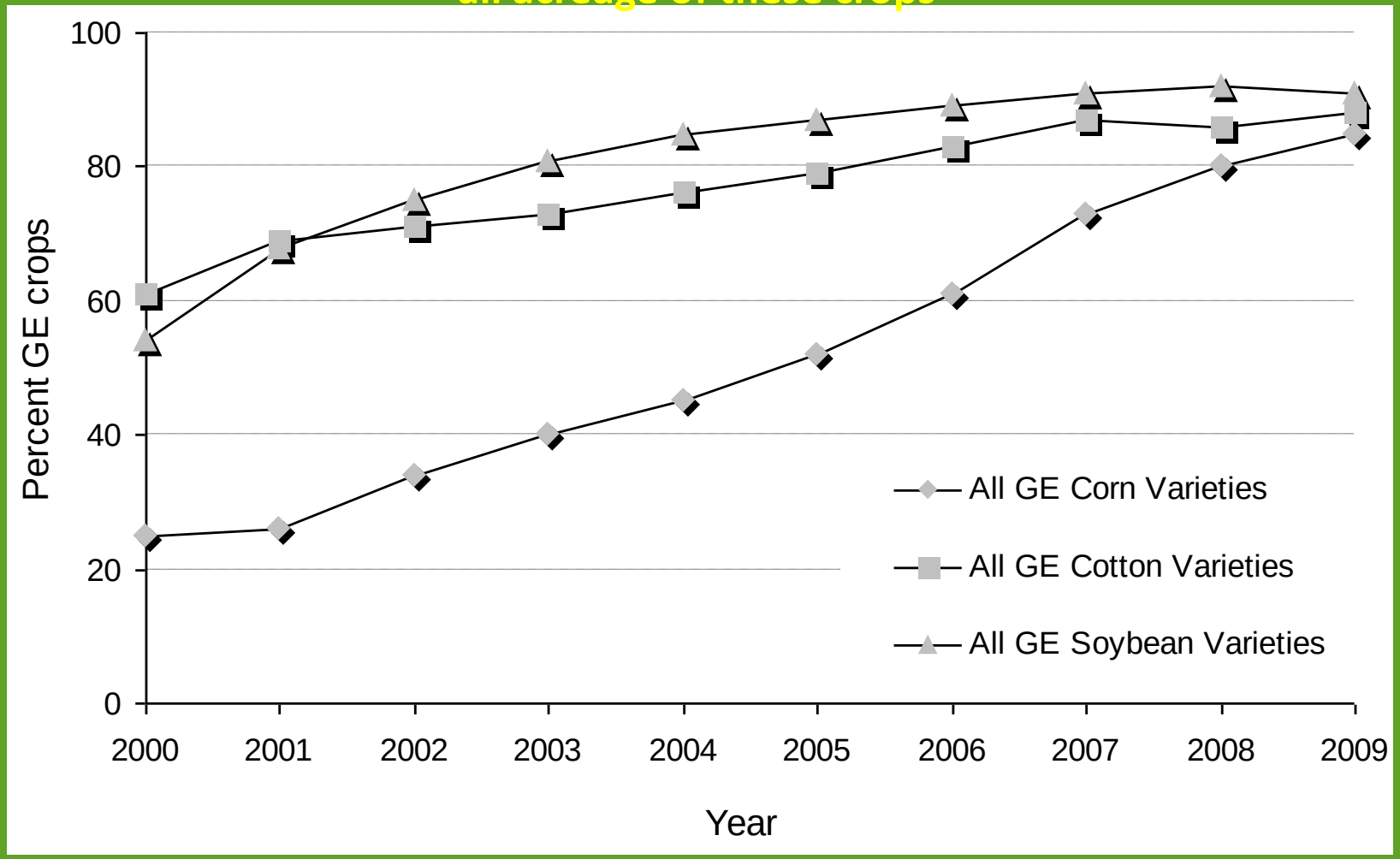
Economic Effects

Adopters have benefitted from:

- Cost-effective weed control
- Reduced losses from insect pests
- Reduced expenditures on pesticides and fuel
- Increased worker safety
- Greater flexibility in farm management
- Lower risk of yield variability

Genetically Engineering Crops

Nationwide acreage of GE soybean, corn, and cotton as a percentage of all acreage of these crops



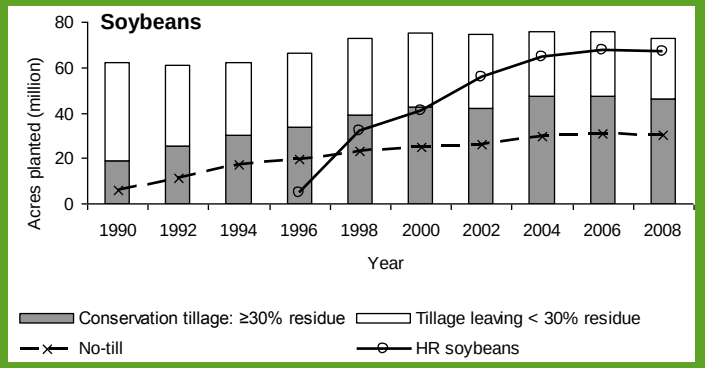
Source: USDA-NASS (2001, 2003, 2005, 2007, 2009b).

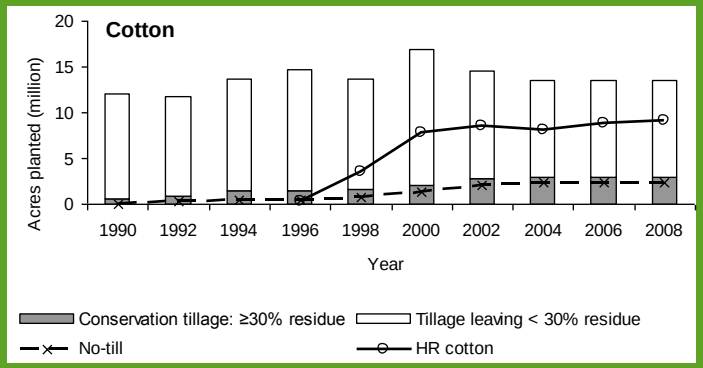
Environmental Effects

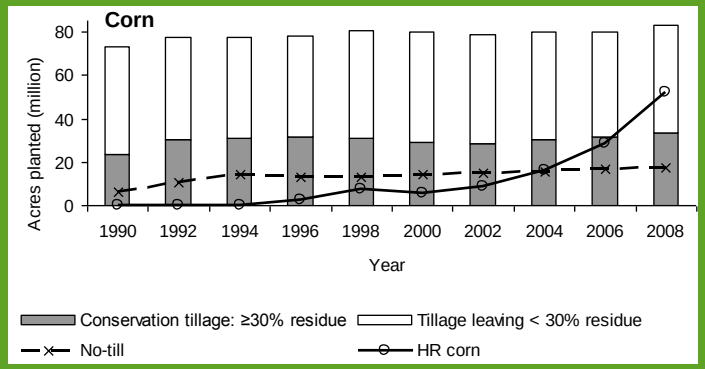
Herbicide-Resistant Crops

- Complementary adoption of HR crops and conservation tillage practices
  - – Improves soil retention
  - –Probable improvement in surface water quality
  - –Data not available to evaluate water quality effects

Trends in conservation tillage practices







Source: CTIC, 2009; USDA-ERS, 2009.

Economic Effects

Adopters have benefited from:

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- Reduced losses from insect pests using green technologies
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Economic Effects

Economic effects on non-GE producers are mixed and poorly understood

- Purchasing decisions of GE producers affect non-GE producers
- No quantitative estimate of economic impact on livestock producers
- Landscape-level effects on pests
- Costs of inadvertent gene flow
- Benefits of segregated markets
- [Control of insect pests via border effects]

Products recently deregulated by USDA

- Herbicide-tolerant alfalfa
- Herbicide-tolerant sugarbeet (partial deregulation)
- High amylase corn

- Petitions for many additional products are under review by APHIS, including some addressed to climate change and nutritional improvements.

Trends

- Some recent regulatory actions have come in the face of legal challenges.
- The Secretary of Agriculture has identified a need for increased dialogue among stakeholders with differing interests to enable further technology advances.
- The Advisory Committee on Biotechnology and 21st Century Agriculture is being revived to provide the Secretary with practical recommendations on bolstering coexistence in U.S. agriculture.
- President Obama has issued several Executive Orders that relate to improving regulations across the government—they stress reliance on science, collaboration, and coordination.

Facilitating Innovation

- U.S. law allows for a variety of forms of intellectual property protections for GE agricultural products, including patent and variety protections
- Mechanisms exist to facilitate the transformation of public sector technologies into products commercialized by the private sector
- Public-private partnerships will become increasingly important in the development of new technologies

Moving Forward

- Because many important developments come from groundbreaking public sector research, strengthening the pathway for product development through the public sector will be important.
- As intellectual property protections on the first agricultural biotechnology products begin to expire, the transition to a marketplace with “generic” GE products will raise additional IP, economic, and stewardship issues.