



Legal and Regulatory Challenges to Fueling and Feeding the World

**BIO State Government Relations Committee
Food and Agriculture Section**

May 4, 2010

Chicago, Illinois

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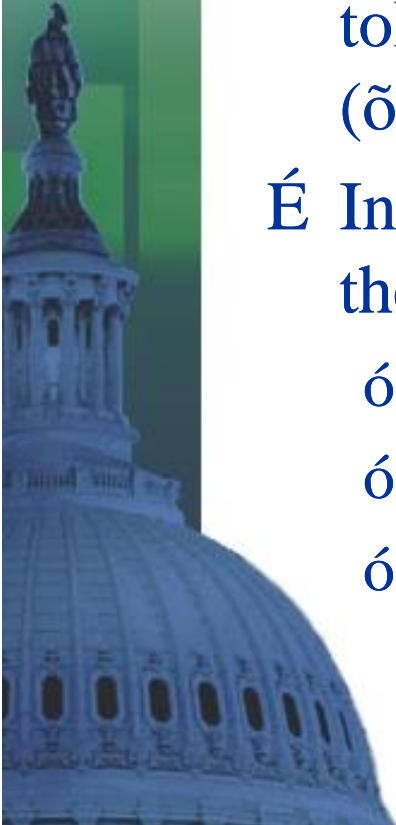
US Crop Biotechnology Overview

- É Since 1986 over 20,000 regulated field trials have been conducted of biotechnology-derived plants in the U.S. (including tests in virtually every state)
 - ó Over 4,000 with insect-resistant (õIRö) traits
 - ó Over 5,100 with herbicide-tolerant (õHTö) traits
 - ó Nearly 7,000 with product quality or agronomic traits
- É Some 78 biotechnology-derived plants have been cleared for commercialization (incl. 26 with IR traits and 36 with HT traits)



US Crop Biotechnology Overview

- É Major biotechnology-derived crops on the market today are either insect resistant (IR/Bt), herbicide tolerant (HT) or a combination of these two traits (õstackedö).
- É In 2009 biotechnology-derived varieties represented the vast majority of acres planted in the US for:
 - ó soybeans (HT): 91%
 - ó cotton (HT & Bt) : 88%
 - ó corn (Bt & HT): 85%



US Crop Biotechnology Overview

Notwithstanding intensive governmental, academic and commercial oversight, not a single instance of actual harm to health, safety or the environment has ever been demonstrated for any biotechnology crop that has successfully completed the U.S. regulatory review process.



Global Crop Biotechnology Overview

É Since 1996, a total of 57 countries have granted a total of 762 regulatory approvals for biotech crops

ó 155 events in 24 crops incl. corn, cotton, canola, potato and soy

ó Traits include HT, IR, virus resistance, delayed ripening and stacked



Global Crop Biotechnology Overview

- É Since the original commercial plantings in 1996, the first billionth acre of biotech crops was planted worldwide in 2005.
- É The second billionth acre of biotech crops was planted worldwide in 2008.
- É In 2009, 14 million small and large farmers planted biotech crops on 330 million acres in 25 countries representing over 50% of the world's population.



Global Crop Biotechnology Overview

In decreasing order of acreage, the 25 countries planting biotech crops in 2009 include:

- | | | |
|-----------------|------------------|----------------|
| 1. U.S. | 9. Uruguay | 18. Honduras |
| 2. Brazil | 10. Bolivia | 19. Czech Rep. |
| 3. Argentina | 11. Philippines | 20. Portugal |
| 4. India | 12. Australia | 21. Romania |
| 5. Canada | 13. Burkina Faso | 22. Poland |
| 6. China | 14. Spain | 23. Costa Rica |
| 7. Paraguay | 15. Mexico | 24. Egypt |
| 8. South Africa | 16. Chile | 25. Slovakia |
| | 17. Colombia | |



Global Crop Biotechnology Overview

- É Of the 25 countries planting biotech crops in 2009, 16 are developing countries and 9 are industrial.
- É Of the 14 million farmers planting biotech crops in 2009, 90% or 13 million are small, resource-poor farmers from developing countries.



Global Crop Biotechnology Overview

Biotech crops support sustainable development in numerous ways including:

- É Contributing to food security and more affordable food
- É Conserving biodiversity
- É Contributing to the alleviation of poverty and hunger
- É Reducing agriculture's environmental footprint
- É Mitigating climate change and reducing greenhouse gases
- É Contributing to cost-effective production of biofuels
- É Contributing to sustainable economic benefits



Global Crop Biotechnology Overview

É Total economic gains from the planting of biotech crops from 1996-2008 are estimated at \$51.9 billion

ó Increased yield/acre (reduced land use)

ó Reduced production costs (increased environmental benefit)

É Reduced pesticide use

É No or low-tillage of soil (reduced erosion)

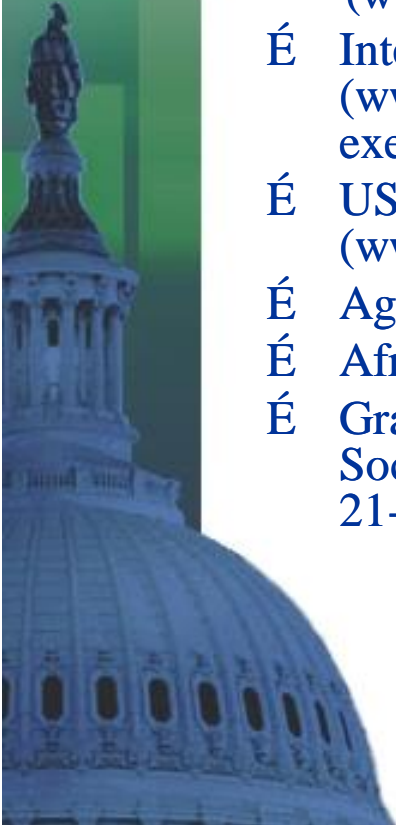
É Reduced fossil fuel use (tractors)



Crop Biotechnology Overview

References:

- É U.S. Regulatory Agencies Unified Biotechnology Website
(www.usbiotechreg.nbii.gov/)
- É International Service for the Acquisition of Agri-Biotech Applications
(www.isaaa.org/resources/publications/briefs/39/executivesummary/default.html)
- É USDA Economic Research Service
(www.ers.usda.gov/Data/BiotechCrops/adoption.htm)
- É Agbios (www.agbios.com)
- É Africa Harvest (www.africaharvest.org)
- É Graham Brookes & Peter Barfoot, 2008. Global Impact of Biotech Crops: Socio-Economic and Environmental Effects, 1996-2006. AgBioForum 11(1): 21-38 at: www.pgeconomics.co.uk/pdf/agbioforumpaper2008final.pdf



Historical Underpinnings

Oversight of rDNA Experiments

É NIH Approves First Field Test of Genetically Engineered Organism (1984)

ó University of California

ó *õlce Minusö* microbe

ó **Enjoined** by federal court

É Inadequate environmental assessment under National Environmental Policy Act (**NEPA**)

É Foundation on Economic Trends (FOET) v. Heckler (DDC 1984; DC Cir. 1985)



Coordinated Framework for Regulation of Biotechnology

É Federal Policy Announced by White House Office of Science and Technology Policy

ó Regulatory policies: USDA, EPA, FDA, OSHA

ó Research policies: NIH, NSF, EPA, USDA

ó 51 FR 23302 (June 26, 1986)



Coordinated Framework

Statutory Authority

É Department of Agriculture (USDA)

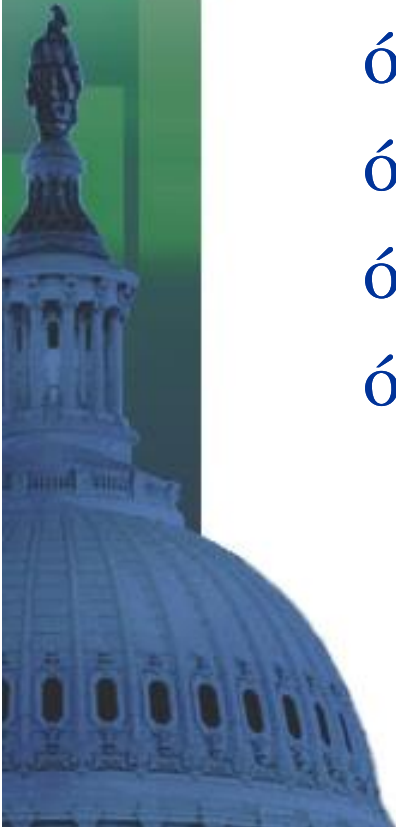
ó Plant Protection Act

ó Federal Seed Act

ó Animal Health Protection Act

ó Animal Welfare Act

ó Virus-Serum-Toxin Act



Coordinated Framework

Statutory Authority

É Environmental Protection Agency (EPA)

- ó Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (pesticides)
- ó Federal Food, Drug, and Cosmetic Act (FFDCA) (pesticide residues)
- ó Toxic Substances Control Act (TSCA) (chemicals not otherwise regulated by EPA or FDA)



Coordinated Framework

Statutory Authority

É Food and Drug Administration (FDA)

ó Federal Food, Drug, and Cosmetic Act
(FFDCA)



Coordinated Framework for Regulation of Biotechnology

É Federal Policy Upheld

- ó Complaint dismissed

 - É FOET v. Johnson (DDC 1986)

- ó First of several challenges to be filed since 1986 against the Coordinated Framework or actions taken by agencies under the Framework

 - É No successful challenges until 2006



Coordinated Framework

Unsuccessful Legal Challenges

- É EPA ó ice minus bacterium ó **preliminary injunction denied** ó FOET v. Thomas (DDC 1986)
- É USDA/APHIS ó recombinant pseudorabies vaccine ó **approval upheld** ó FOET v. Lyng (DDC 1988)
- É FDA ó recombinant bovine somatotropin (new animal drug) ó **approval upheld** ó Stauber v. Shalala (WD Wis. 1995)
- É FDA ó policy for regulation and labeling of food derived from new plant varieties ó **policy upheld** ó Alliance for Bio-Integrity v. Shalala (DDC 2000)



Coordinated Framework Overriding Statutory Mandates

- É All federal agency actions are subject to challenge for failure to comply with:
 - ó National Environmental Policy Act (NEPA)
 - ó Endangered Species Act (ESA)
- É Activities approved by federal agencies may also be regulated and challenged under various state and local environmental, land use, and health and safety statutes



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