Transgenic Crop Regulation: Present and Future Challenges

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Second Decade of Crop Biotechnology
January 16, 2008

Historic Milestones in Biotechnology

- 1953 - Watson and Crick describe the structure of DNA.
- 1971 - Cohen and Boyer develop the tools of genetic engineering and move genes between unrelated species.
- 1977 - The National Institutes of Health (US) issues guidelines for recombinant DNA research focusing on containment conditions to prevent unintended releases.
- 1983 - First transfer of plant genes between unrelated plant species
- 1986 - U.S. government publishes "Coordinated Framework for the Regulation of Biotechnology". This establishes regulatory authority for the U.S.

Historic Milestones in Biotechnology

- 1987
  - USDA Finalizes regulations for importation , interstate movement and field testing under permit.
  - First field test permit for a transgenic plant (bromoxynil tolerant tomato, Calgene).
- 1992 – Delayed ripening tomato “de-regulated” by interpretational ruling
- 1993 – Regulations revised to include a streamlined process for authorizing field tests (notification) and a process to “de-regulate” crops after they are shown to be safe
- 1994 - First glyphosate tolerant soybean line de-regulated.
- 2004 – USDA publishes an Notice of Intent to prepare an EIS to explore potential regulatory alternatives that may be needed to meet the needs of the dynamic field of biotechnology
- 2007 - EIS on new regulatory alternatives is published for public comments

The Coordinated Framework -1986

- US Department of Agriculture
  - Plant Protection Act (PPA)
- US Environmental Protection Agency
  - Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
  - Federal Food, Drug, and Cosmetic Act (FFDCA)
  - Toxic Substances Control Act (TOSCA)
- US Food and Drug Administration
  - Federal Food, Drug, and Cosmetic Act (FFDCA)

USDA-APHIS Regulation

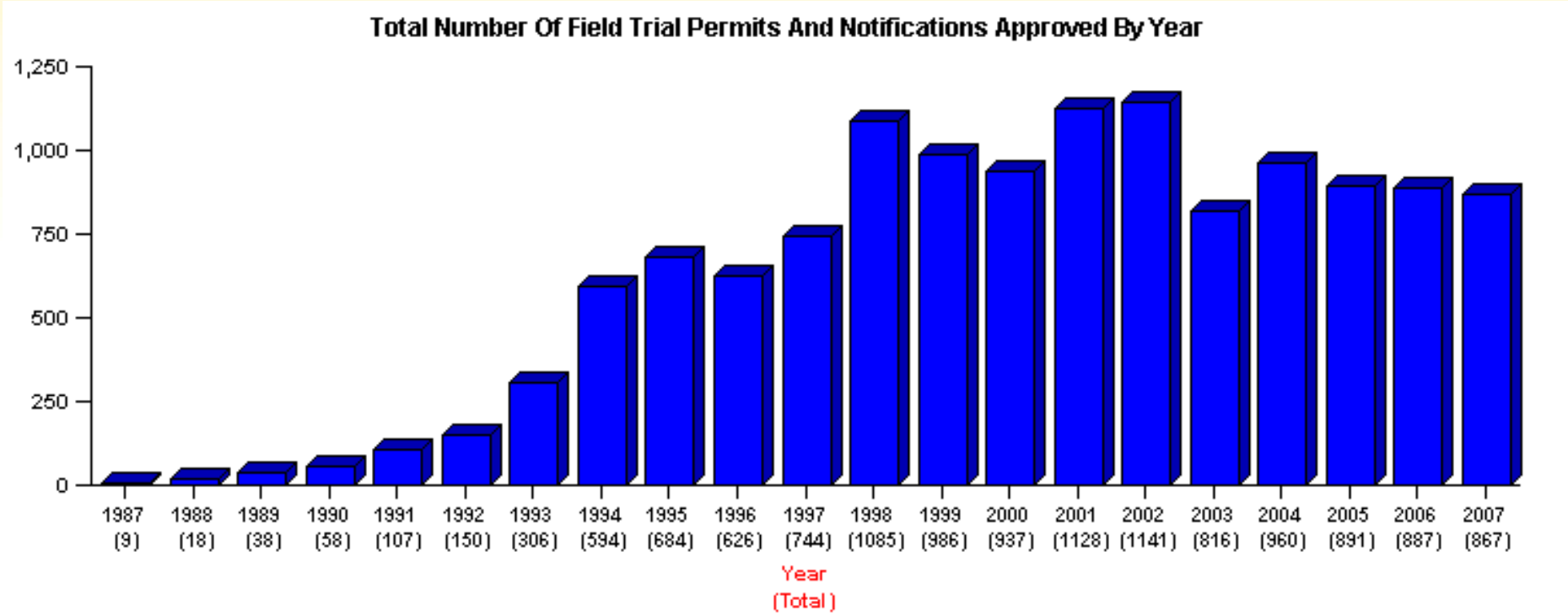
The goal of biotechnology at USDA-APHIS is to protect plant health

However,

Effective regulations serves a number of other important purposes including:

- Maintaining public confidence
- Facilitating trade
- Identifying broader environmental risks (under NEPA)

Field Tests Authorized by USDA, 1987-2005



Total Approved = 17,332

Products Granted Non- regulated Status by APHIS

- To date 74 petitions for non-regulated status have been granted. Herbicide tolerance and insect resistant traits dominate commercially produced lines.

  - Herbicide Tolerance – 37%
  - Insect Resistance – 28%
  - Product Quality – 16%
  - Virus Resistance – 11%
  - Agronomic Properties – 8%

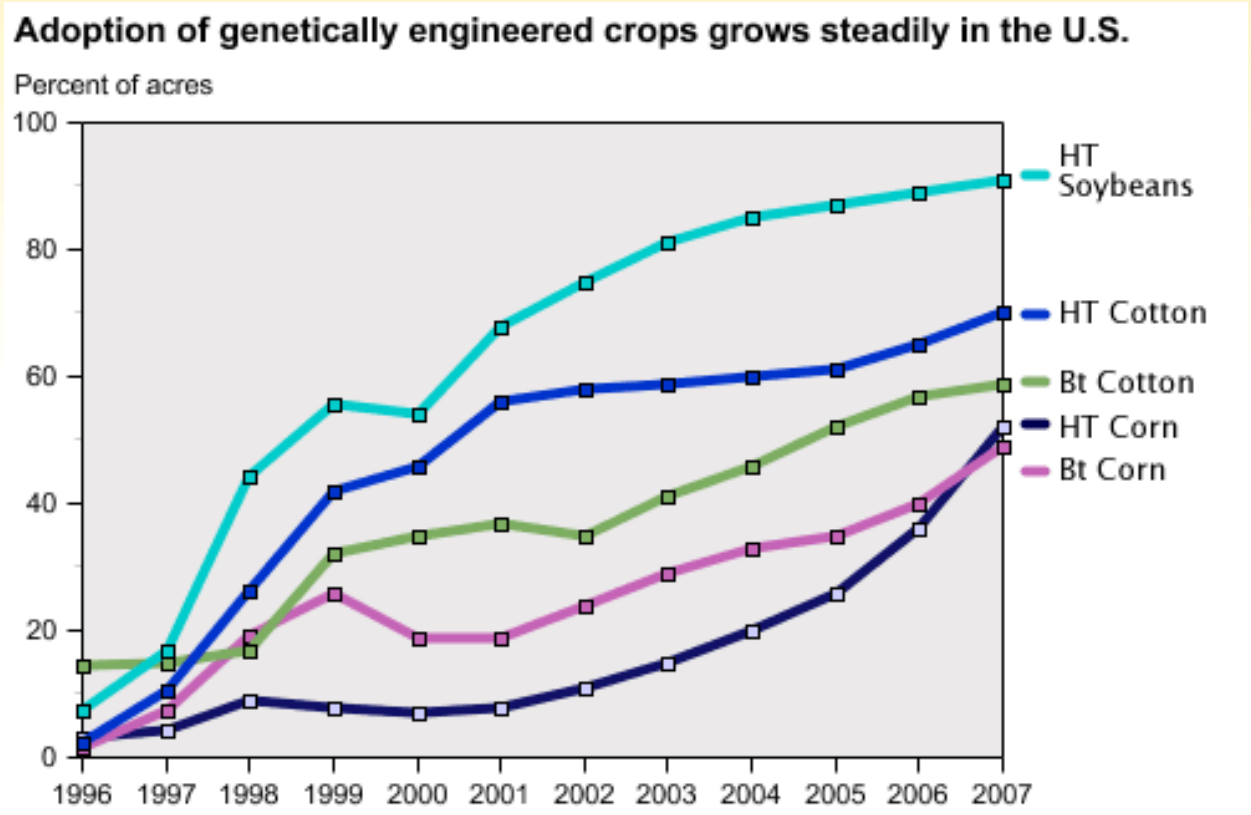
Products Granted Non-regulated Status by APHIS

Corn - HT, IR, AP
Soybean - HT, PQ
Cotton - HT, IR
Potato - IR, VR
Tomato - PQ
Squash – VR
Rice - HT

Canola - HT, AP, PQ
Papaya - VR
Sugar beet - HT
Flax - HT
Chicorium –AP
Tobacco – PQ
Alfalfa - HT

HT – herbicide tolerance
IR – insect resistance
AP – agronomic properties
VR – virus resistance
PQ – product quality

Adoption of GE Crops



Note: Data for each crop category include varieties with both HT and Bt (stacked) traits.
Source: 1996-1999 data are from Fernandez-Cornejo and McBride (2002). Data for 2000-07 are avalable in the ERS data product, Adoption of Genetically Engineered Crops in the U.S., tables 1-3.

Future of GE Crops

Based on current research, the future is likely to bring a greater diversity of GE traits likely to include:

- Product quality traits aimed at the consumer
- Environmental stress tolerance
- Disease resistance
- Plants engineered to produce compounds for pharmaceutical and industrial uses.
- Biofuels
- Stacked traits

Pharmaceutical Plants

- First pharmaceutical permit issued in 1991
  - 80 permits issued to date

- Tobacco, rice, corn, safflower and barley

- Area Planted (Acres):
  - 2002 - 130
  - 2003 - 75
  - 2004 - 45
  - 2005 - 82
  - 2006 – 181
  - 2007 - 176

Pharmaceutical Oversight

- Stricter Confinement Measures
  - Increased isolation distances and fallow zones
  - Procedures for seed handling must be submitted and approved
  - All developers must have a required and approved training program for all personnel
  - Dedicated equipment and storage
  - Land use restriction

- Greater Government Role
  - Inspections increased to five times per year
  - Records audited

New Regulatory Challenges

- Plants which are engineered for purposes other than food (e.g. pharmaceutical plants) may no longer be appropriate for food.
- New generation of crops with new types of traits (nutritional enhancements and other product quality traits, environmental stress tolerance)
- New crop types which may establish and persist without cultivation (grasses, trees)
- Genetically engineered animals – new ethical issues

New Regulatory Challenges

- Development of biotech products in other countries that may arrive in the U.S. in commodity or seed imports
- Events of “Low level presence”, aka “adventitious presence” – disrupts trade and erodes public confidence
- Legal challenges to the regulatory system
- New technologies - synthetic genomes, mini-chromosomes, etc

Meeting the Challenges

- Regulatory flexibility and adapting to emerging trends with new regulatory policies
- Transparency and stakeholder input
- Recruitment, development, and retention of a skilled science staff for assessing risks of genetically engineered crops – utilize the best science
- Improving the quality and increasing the scope of environmental assessments
- Regulatory revisions to meet the demands of the future.

Regulatory Revisions Under Consideration

- Expanded scope of regulation
- Tiered permitting system
- Low-level presence addressed in regulations
- Pharmaceutical/Industrial traits
- Approvals: conditional & unconditional
- Importation of commodities
- Regulatory relief

For More Information

- www.aphis.usda.gov/biotechnology/brs_main.shtml/
- usbiotechreg.nbii.gov (USG unified site)