Regulation of Products of Agricultural Biotechnology in the United States: Role of the U.S.D.A.

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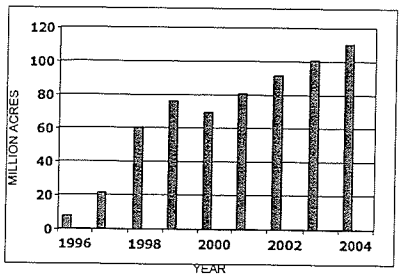
Adoption of Biotech Crops:

Acreage of transgenic corn, soybeans, cotton in the U.S.



Biotech Crops in Large-Scale Production

- Soybeans
  - herbicide tolerant (Roundup Ready)
- Corn
  - insect resistant (Bt)
  - herbicide tolerant
- Cotton
  - insect resistant (Bt)
  - herbicide tolerant
- Canola
  - herbicide tolerant

The Coordinated Framework -1986

- Crops produced using genetic engineering pose the same kinds of risks as crops produced by conventional breeding for similar traits.
- Regulation should be science-based and should be conducted on a case-by-case basis.
- The existing laws provide adadequate authority for regulation of the products of biotechnology.

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)

Regulation of Agricultural Biotechnology in the U.S.

Department of Agriculture (USDA)
- Evaluate potential risks to agriculture and the environment.

Food and Drug Administration (FDA)
- Food and feed Safety

Environmental Protection Agency (EPA)
- For GE plants which produce pesticides, EPA evaluates environmental risks, and sets the tolerance in food for the pesticide

Examples of Agency Involvement

New Trait/Crop	Agency	Review
Insect resistance in food crop	USDA EPA FDA	Agricultural safety Environmental, food/feed safety Food/feed safety
Herbicide tolerance in food crop	USDA EPA FDA	Agricultural safety New herbicide use Food/feed safety
Herbicide tolerance in ornamental crop	USDA EPA	Agricultural safety New herbicide use
Modified oil in food crop	USDA FDA	Agricultural safety Food/feed safety
Modified flower color	USDA	Agricultural safety

Goals of the USDA Regulatory System

- Regulatory system should be flexible, adapting to changing trends and new scientific knowledge.
- Regulations should be rigorous, science-based, and easily understood.
- Regulations should, to the extent possible, encompass the interests of the full range of stakeholders.
- Regulations must meet both domestic and international needs.
- Regulatory oversight should be proportionate to the risks

Within USDA-APHIS Genetically Engineered Organisms are Regulated by:

Biotechnology Regulatory Services

- Process and evaluate requests for introduction of genetically engineered organisms into the US
- Compliance
- Harmonization of biotechnology review processes with other countries
- Develop, update and implement regulations

What is regulated under APHIS regulations at 7 CFR 340?

Regulated articles

- If the organism has been altered or produced through genetic engineering

  and

- there is a possibility that the organism could be a plant pest

APHIS Regulations

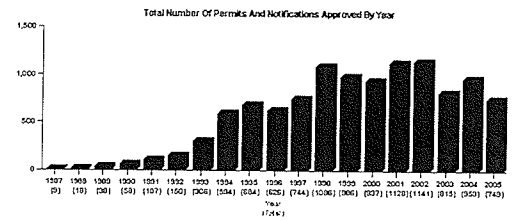
- Regulated status ("regulated articles")
  - Field testing / confined cultivation
  - Importation
  - Interstate movement

- Determination of nonregulated status
  - Developers of new biotech products can petition APHIS to "deregulate" the new product
  - Allows cultivation without APHIS oversight (commercialization)

Permits and Notifications

- All field testing, importation, or interstate movement of "regulated articles" must be done under APHIS oversight
  - Permits – 120 day review, more details
  - Notifications – 30 day review
    - Simplified review for certain traits and plants
    - Eligibility criteria
- State concurrence; site inspections, field data reports

Field Tests Authorized by USDA 1987-2005



APHIS Review of Confined Field Tests

- Reproductive biology of the organism
- Biology of engineered trait
- Environment and conditions of the release, including measures for physical and reproductive isolation
- Site monitoring and inspection
- Plans for termination, devitalization, disposal, and post-harvest monitoring and land use

Plants Producing Pharmaceutical or Industrial Compounds

- Must be grown under "permit"
- Increased separation distances from adjacent fields
- Dedicated equipment and facilities
- Increased field site inspections
- More rigorous recordkeeping
- APHIS-approved training

Petition for Determination of Nonregulated Status

- Developers of new biotech products can petition APHIS for "nonregulated" status once data is sufficient to show there is no significant risk of the regulated article becoming a plant pest
- 180 days; comprehensive scientific review

Petition Requirements

- Crop biology and taxonomy
- Genotypic differences
- Phenotypic differences
- Field test reports for all releases conducted under permit or notification
- Relevant experimental data, publications and other data upon which to base a determination
- Any unfavorable data and information

➢User's Guide for Applicants on Web

Key Considerations for a Determination of Nonregulated Status

Is the genetically-engineered organism more likely than the non-engineered version to:

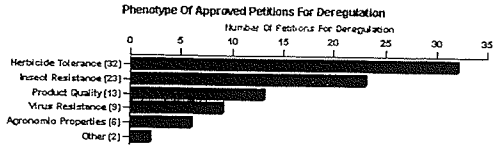
- exhibit plant pathogenic properties
- become a weed
- increase the weediness of any sexually compatible plants
- cause damage to processed agricultural commodities
- harm other organisms (beneficial, threatened and endangered species)
- change cultivation practices

Other issues are addressed on a case-by-case basis.

Granting of Nonregulated Status to Transgenic Plants

- APHIS has issued determinations of non-regulated status in response to 66 petitions. The plants represent 14 crop species.
  - Products granted nonregulated status can be used in food, feed, breeding programs in the same way as their conventional counterparts (assuming completion of applicable reviews at other agencies).
  - Commercialization of new, deregulated, biotech products is determined by market.
  - Some, but not all, varieties have entered commercial production; some removed for commercial reasons.

Phenotype Categories for Plants Granted Nonregulated Status



Products Granted Nonregulated by APHIS

- Corn - HT, IR, AP
- Soybean - HT, PQ
- Cotton - HT, IR
- ❖ Potato - IR, VR
- ➢ Tomato - PQ
- ➢ Squash – VR
- ➢ Papaya - VR
- ❖ Rice - HT
- Canola - HT, AP, PQ
- ❖ 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

• large scale production
➢ limited acreage
❖ not in commercial production

New Regulatory Challenges for APHIS

- Coordinated Framework allows for flexibility to reflect new biotech products and challenges
  - New products
    - New generation of crops with new types of traits (quality traits, environmental stress tolerance)
    - pharmaceutical plants
    - new crop types which may establish and persist without cultivation (grasses, trees)
    - transgenic animals
  - Development of biotech products in other countries
  - "adventitious presence", coexistence
  - Need for increased transparency and stakeholder input

USDA-APHIS is in the process of revising our regulations for genetically engineered organisms

- Revision is driven by new technological trends and extensive experience in regulation since the 1980s.
- Since original regulations came into effect in 1987, regulations have been revised twice:
  - 1993 Introduction of the de-regulation process and the notification process (streamlined permitting)
  - 1997 Notification process expanded
- The first step in the process will be the drafting of an Environmental Impact Statement (EIS) which will assess the impacts of all proposed changes on a broad array of environmental impacts.
- The next step will be proposed regulations, ultimately followed by final regulations.
- Stakeholder and public input is a key consideration throughout the process.

Current Status and Target Dates

- Public comment period on Notice of Intent (NOI) closed 4/13/04. We received over 3,700 comments.
- APHIS held two weeks of stakeholders' meetings with representatives of industry, crop associations, academia, and NGOs.
- We hope to have the Draft EIS published by late 2005 or early 2006 - *Public comment*
- A proposed rule will be drafted and published for comment, target, CY 2006 - *Public comment and public meetings*
- Final Rule published.

For More Information:

- www.aphis.usda.gov/programs/brs
- www.cfsan.fda.gov/~lrd/biotechm.html
- www.epa.gov/pesticides/biopesticides
- usbiotechreg.nbii.gov (USG unified site)