Regulating Agricultural Biotechnology: A Consumer Perspective

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Summary of Talk

- Background on CSPI
- A roadmap to consumer acceptance of GE products
- The need for a functional and protective science-based regulatory system
  - Length of time for regulatory review
  - Regulation of biopharming

Center for Science in the Public Interest (CSPI)

- Food and nutrition consumer organization.
- Nutrition Action Healthletter.
- No government or industry funding.

CSPI's Biotechnology Project

- Purpose
  - Identifying benefits and risks
  - Establishing strong regulatory systems in US and abroad
  - Educating and informing the public
- Positions
  - Current crops in US appear safe to eat and environmental risks are manageable
  - Some benefits from current crops
  - Future products need to be assessed individually
  - Regulatory systems in US and abroad need strengthening to address next generation of products

The Road to Consumer Acceptance

- Providing beneficial products
- Ensuring Biotech foods are safe to eat
- Eliminating, minimizing, and/or managing environmental risks
- Establishing transparent and participatory regulatory systems
- A more responsive and open biotechnology industry
- Avoidance of controversial products

Role of Government Regulation

- **Ensure safety to humans**
- **Ensure environmental safety**

- Alleviate public concerns
- Increase public confidence

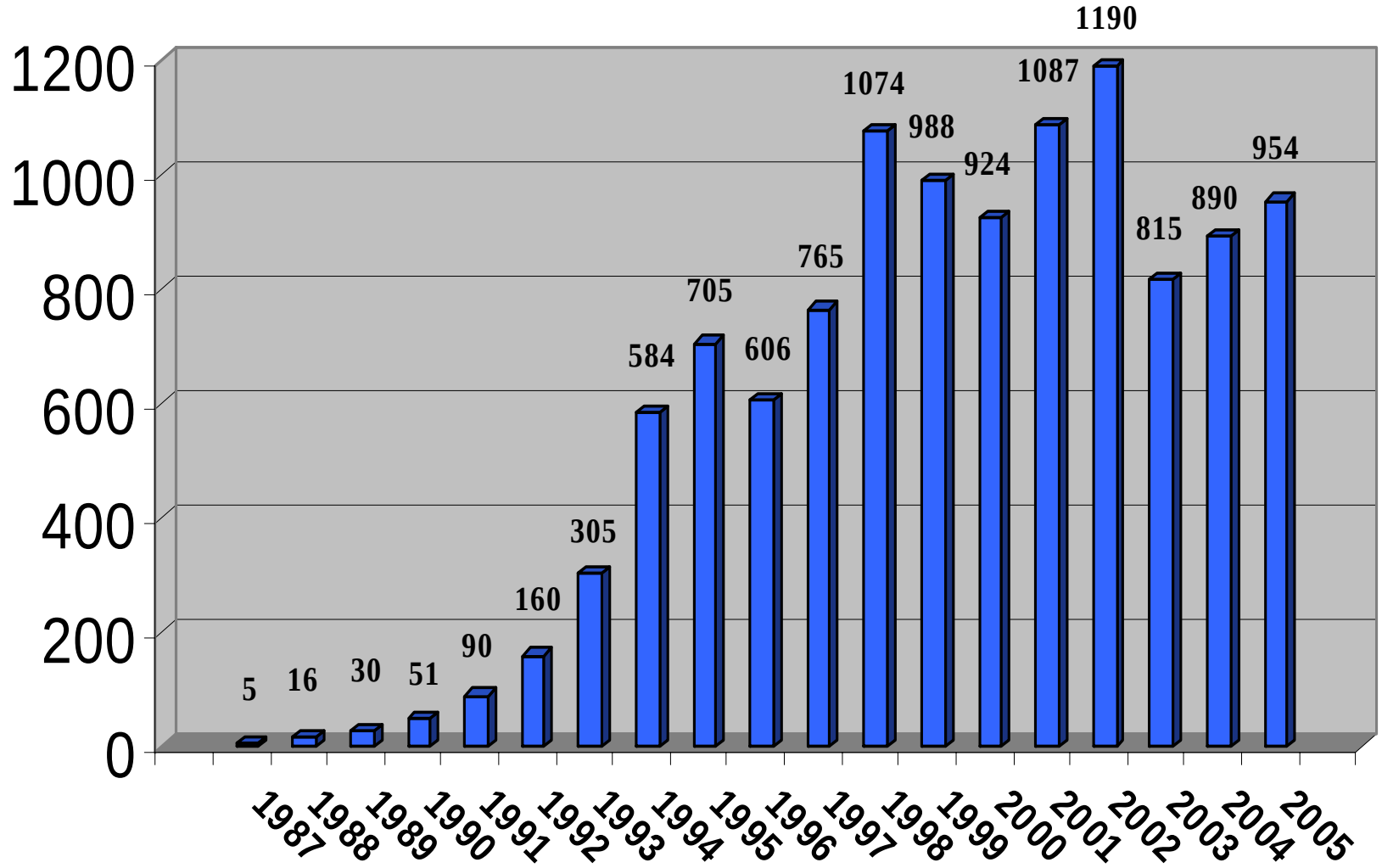
Characteristics of a Good Regulatory Regime

- Adequate legal authority
- Comprehensive
- Certain but also flexible
- Consistent, equitable and fair
- Easily Understandable
- Transparent and participatory
- Case-by-case scientific reviews
- Proportionate based on risk
- Workable and enforceable

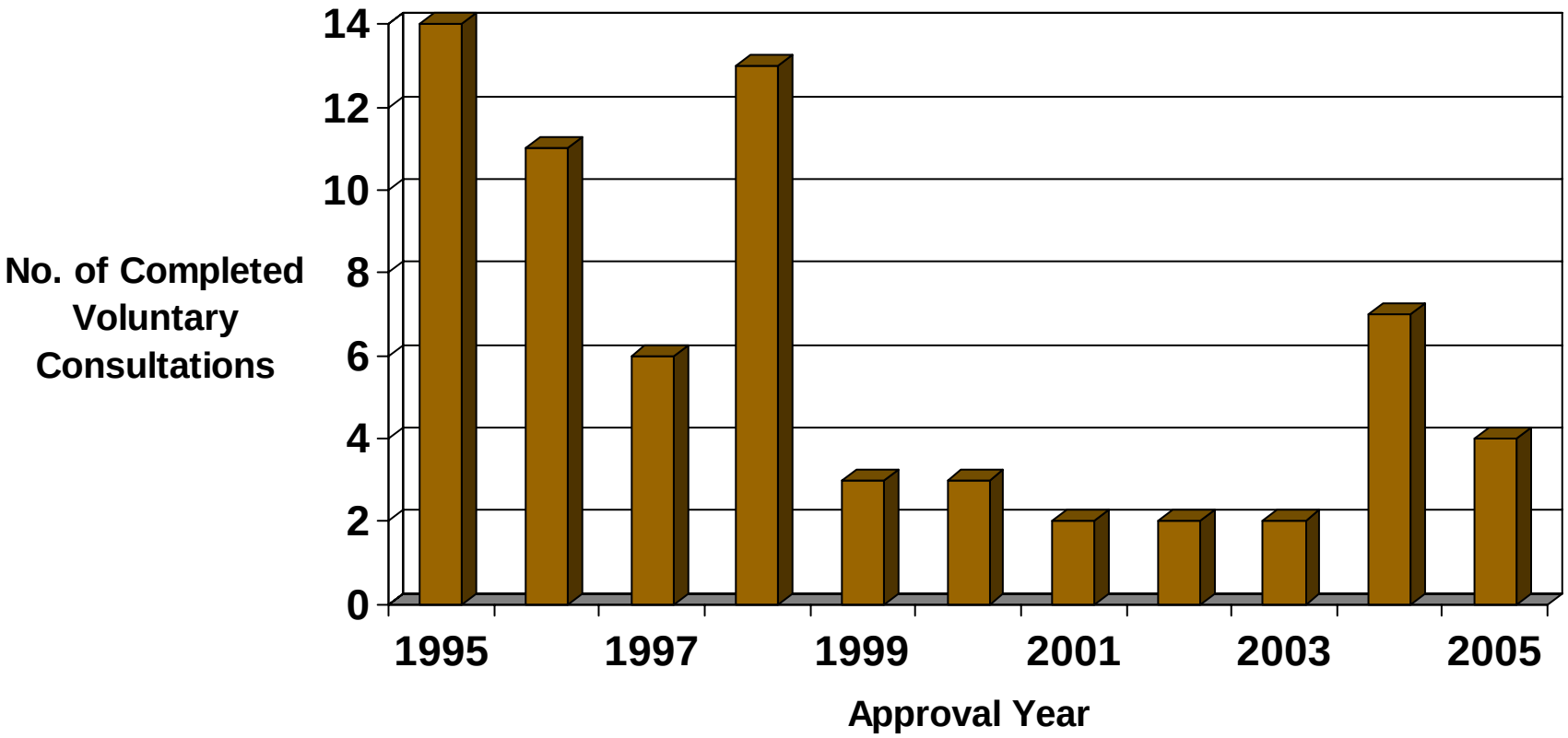
Example #1: Science-Based and Proportionate Regulation?

- Report: "Withering on the Vine: Will Agricultural Biotech's Promise Bear Fruit?"
- Ten years of products in the US
- What are the trends?
  - Used publicly available data from USDA and FDA
  - Looked at products ready for commercialization

Number of Permits and Notifications Aprroved by Year: 1987-2005

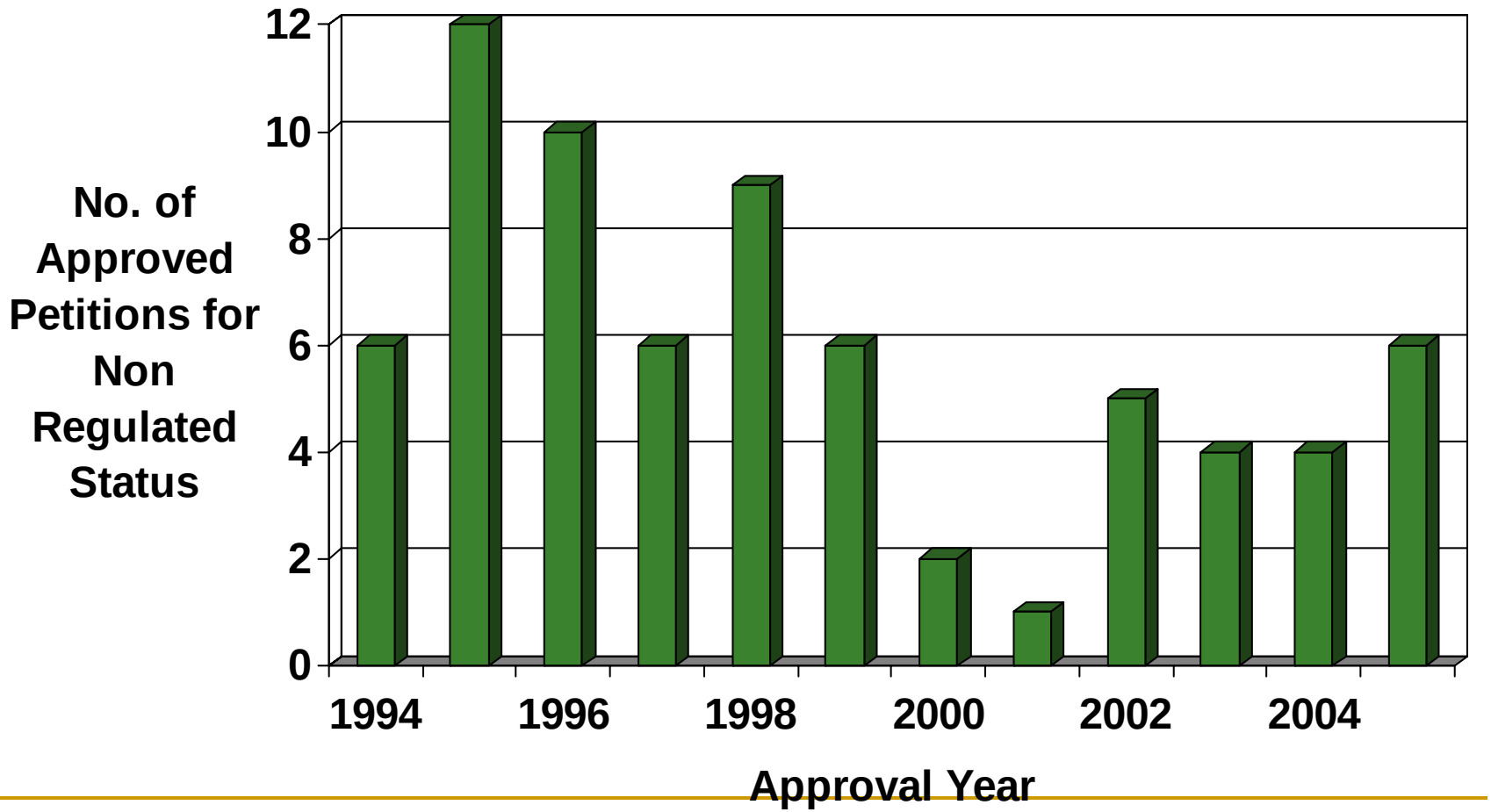


Completed Voluntary Consultations



Source: www.cfsan.fda.gov/~lrd/biocon.html

Approved Petitions for Non Regulated Status



Source: http://www.isb.vt.edu/CFDOCS/biopetitions3.cfm

The Trends -- Product Development

- Of the products reviewed by FDA and USDA, approximately 75% of products completed regulatory process between 1995 and the beginning of 2001
- Products completing regulatory process starting in 2000: (1) use existing genes and (2) same crops
- Conclusion: Not many products in 21st century and nothing new or novel. The pipeline seems to have shrunk considerably.

The Trends – Regulatory Review Times

- Time to completion at FDA (1995 – 2000) – 6.5 months
- Time to completion at FDA (2001 – 2005) – 15.2 months
- Time to completion at USDA (1995-2000) -- 6.1 months
- Time to completion at USDA (2001–2005) -- 15.4 months
- Conclusion: Regulatory review time doubled while product number decreased and products did not raise novel questions

Trend is Opposite of What is Expected

- Regulators are more experienced
- No evidence of harms from current products
- Less products should mean more government resources
- No new novel questions

Reasons for Trends?

- Science
- International Situation
- Economy and investment
- Disinvestment by regulators

Reason is not the "Science" or "Risk"

- Herbicide tolerant crops at FDA
- 1990s: Cotton -- 5 months; corn -- 6 months; sugar beets -- 5 months.
- 2001-5: creeping bentgrass – 12 months; wheat – 25 months; alfalfa – 14 months; sugar beets – 16 months; cotton – 9 months.

USDA Regulation

- Pest protected and herbicide tolerant corn
  - Two petitions in the 1990s: AgroEvo took 8 months and Mosanto took 6 months
  - Two applications after 2000: Mycogen, Dow, and Pioneet took 13 months and Dow took 16 months
- Herbicide tolerant cotton
  - Three petitions in 1990s: Calgene (7 months); Monsanto (5 months); Dupont (4 months)
  - Two petitions after 2000: Aventis (13 months) and Mosanto (9 months).

Example #2: Biopharming

- USDA regulation
  - Permit, not notification
  - No deregulation?
  - Some additional inspections?
- FDA regulation

- Key points: (1) very little difference from other transgenic crops; (2) no different regulatory requirements for food crops

NCR Report -- 2002

- “Some of the coming applications of biotechnology may involve the use of plants to produce pharmaceutical products, biologics, fuels, and other substances not intended for human food use. The introduction of such transgenes poses the potential for environmentally associated risks of a **wholly different order** than those associated with existing transgenic crops.

NRC Report (cont.)

- "If such a transgene moves into food crops, either through pollen transfer or physical contamination, **there could be serious human safety risk**. If such a transgene moves into a wild relative, there could be widespread environmental dissemination of the pharmaceutical substance or other nonfood substances that could have impacts on wildlife as well as microbial populations."

Science-based Regulation of biopharming

- Regulatory review and scrutiny should match the proposed risks
- More obligations for riskier applications
- Using food crops is riskier than using non-food crops

Key Components of Regulatory Scheme for Pharma Crops

1. Require a permit for each pharma planting. The permitting process should be transparent and allow for public participation.
   - Application provided to public (except CBI)
   - Opportunity to comment before issuance
   - Permit made available to public on website

Key Components of Regulatory Scheme for Pharma Crops (cont.)

2. Issue a permit only after a thorough environmental assessment.
   - Analyze risks of gene flow
   - Effects on non-targets
   - Broad ecological effects
   - Assume escape, not containment

Key Components of Regulatory Scheme for Pharma Crops (cont.)

3. Require strict biological and physical confinement measures.
   - Biological confinement (male sterility, chloroplast transformation, etc…)
   - Physical confinement (fences, greenhouses, netting, etc…)
   - Geographic restrictions (e.g. no corn in corn belt).

Key Components of Regulatory Scheme for Pharma Crops (cont.)

4. Permits should require conditions to ensure compliance
   - Training of farmers
   - Certification of farmers
   - Extensive documentation of compliance
   - Third party auditors with regular reports to APHIS and the public
     - Inspections
     - Testing
     - Interviews
     - Review of documents

Key Components of Regulatory Scheme for Pharma Crops (cont.)

5. Government inspection and oversight
   - Inspection at least four times a year
   - Inspection at least twice a year to neighboring fields
   - Collection of samples and analysis to confirm that confinement has worked

Key Components of Regulatory Scheme for Pharma Crops (cont.)

6. Mandatory FDA food-safety review and approval for all pharmaceutical applications that are grown in a food crop.

Grain Quality Workshop 2002

- “To urge the FDA that when future commercialization approvals of genetically modified grains and oilseeds for non-food and feed purposes are considered, these approvals also meet food safety requirements because inadvertently traces of these genetically modified grains and oilseeds will be detected in food and feed.”

Canadian Regulations on Plant Molecular Farming

- “The use of major food or feed crops for plant molecular farming is not recommended.”
- If using a food or feed crop species, “the developer must submit exposure and hazard data for human and livestock health effects assessments” by Health Canada.

Conclusion

- Consumers will support safe products that are beneficial
- Regulatory system needs to be improved to give consumers confidence that it is making the best safety decisions based on the best science available.

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