

## Biotechnology Events

First biotechnology patent granted. US researchers awarded a US patent that allows them to make human insulin from genetically modified bacteria

Scientists successfully create a recombinant organism for the first time by transferring viral DNA into a bacterium

1973

1974

1975

1976

1977

1978

1979

1980

1981

The National Institutes of Health Recombinant DNA Advisory Committee implements Guidelines for Research with Genetically Engineered Organisms



## Biotechnology Regulation Events

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The first biotech plant is produced – a tobacco plant resistant to an antibiotic

First authorized field trial of genetically engineered plants (virus resistant tobacco)

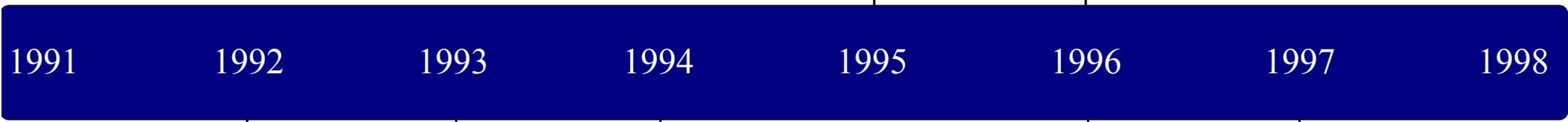


The Office of Science and Technology Policy (OSTP) publishes the “Coordinated Framework for Regulation of Biotechnology” that directs how existing laws and agencies including the USDA, EPA, and FDA should regulate biotechnology

APHIS creates the Biotechnology, Biologics, and Environmental Protection (BBEP) program to regulate biotechnology

USDA publishes first regulations permitting field tests of genetically engineered organisms (7 CFR 340)

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First commercial plantings of biotech crops, including insect-resistant and herbicide-tolerant corn and cotton

Herbicide tolerant soybeans are first introduced on the market

EPA registers insect-resistant corn and cotton

First genetically engineered whole food on the market – Calgene's FlavrSvr™ Tomato

APHIS dissolves the Biotechnology, Biologics, and Environmental Protection (BBEP) program and transfers regulatory activities to APHIS Plant Protection and Quarantine (PPQ)

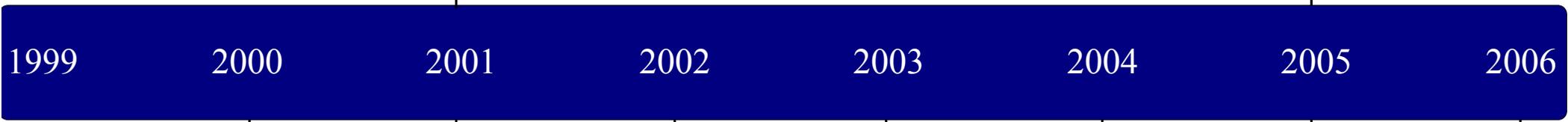
USDA revises its biotechnology regulations to include Notifications and Petitions

• FDA publishes its "Statement of Policy: Foods Derived from New Plant Varieties"  
• USDA APHIS deregulates a product for the first time, Calgene's FlavrSvr™ Tomato



First entire plant genome is sequenced, *Arabidopsis thaliana*

One billion acres of biotech crops planted since biotech crops were first introduced



The Plant Protection Act consolidates and extends USDA authority to regulate plant health

- The National Academy of Sciences provides recommendations in its report "Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation"
- APHIS establishes Biotechnology Regulatory Services (BRS) to consolidate all biotechnology-related regulatory activities

- BRS strengthens APHIS regulation of field testing of plants engineered to produce pharmaceuticals and industrials
- BRS established a dedicated Compliance and Inspection Branch

BRS provided leadership in the Specialty Crops Regulatory Initiative to examine the impacts of the regulatory process on small businesses, university research and small-market biotechnology applications

EPA renews registration of insect-resistant corn and cotton, stating that the crops do not pose any health or environmental risks

- USDA, FDA and EPA launch the Unified Website for Biotechnology
- BRS creates: (1) the Environmental Risk Analysis Division to consolidate activities related to the review and risk analysis of proposed genetically engineered organisms, and (2) the Regulatory Operations Division to facilitate document management and database development and to strengthen regulatory compliance
- BRS announces its intention to revise its biotechnology regulations

- APHIS launches an electronic permitting system to facilitate application submission and review
- APHIS BRS releases new guidance for crops engineered with pharmaceutical and industrial traits