

Regulation of Agricultural Biotechnology in the United States:

Role of USDA-APHIS Biotechnology Regulatory Services in the Coordinated Framework

Brief Overview

Michael J. Firko, Ph.D.

Associate Deputy Administrator

Biotechnology Regulatory Services (BRS)

Animal & Plant Health Inspection Service (APHIS)

U. S. Department of Agriculture (USDA)



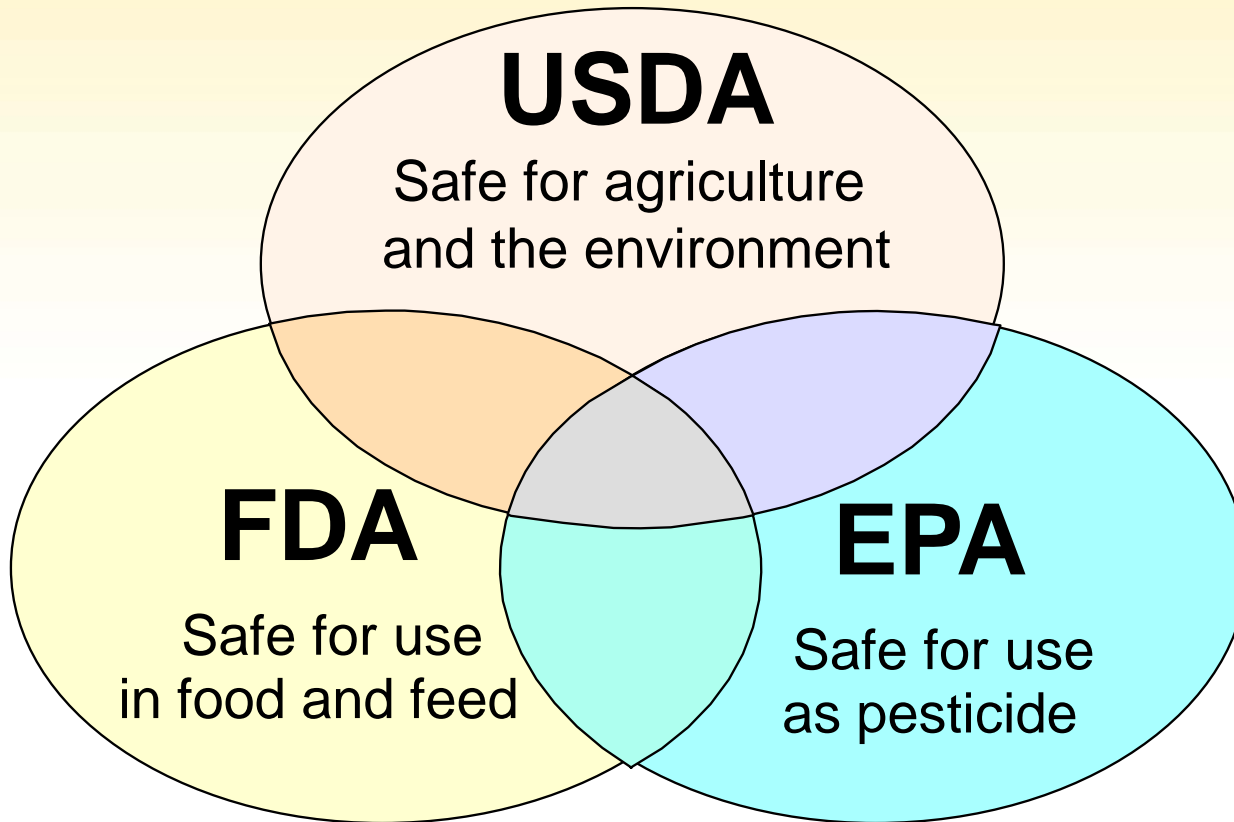
Coordinated Framework (1986)



Federal role in the safe use of biotechnology:

- The safety risks of GE organisms are not fundamentally different from safety risks posed by non-GE organisms with similar traits.
- The existing laws provide adequate authority.
- Regulation should be science-based and conducted on a case-by-case basis.

Regulation Under the Coordinated Framework



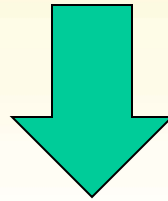
Regulation Under the Coordinated Framework



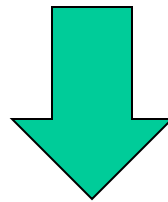
- **Department of Agriculture (USDA-APHIS-BRS)**
 - PPA: Protecting against damage from plant pests and noxious weeds
- **Environmental Protection Agency (EPA)**
 - FIFRA: Regulating the safe use of pesticides
 - FFDCA: Setting allowable levels of pesticides in food
 - TSCA: Regulating toxic substances
- **Food and Drug Administration (FDA)**
 - FFDCA: Regulating safety of food, drugs, and cosmetics

Plant Variety Development

LABORATORY / GREENHOUSE



FIELD TESTING



COMMERCIALIZATION

Regulation Under the Coordinated Framework



New Trait/Crop	Agency	Review
Insect resistance in food crop (Bt corn)	USDA EPA FDA	Agricultural and environmental safety Environmental, food/feed safety of pesticide Food/feed safety
Herbicide tolerance in food crop (glyphosate tolerant soybeans)	USDA EPA FDA	Agricultural and environmental safety New herbicide use Food/feed safety
Herbicide tolerance in ornamental crop (glufosinate tolerant tulips)	USDA EPA	Agricultural and environmental safety New herbicide use
Modified oil in food crop (high oleic acid soybeans)	USDA FDA	Agricultural and environmental safety Food/feed safety
Modified flower color (blue poinsettias)	USDA	Agricultural and environmental safety

What Does APHIS-BRS Regulate?

- “Regulated articles” (7 CFR part 340)
 - If the organism has been altered or produced through genetic engineering, **and**
 - If there is a possibility that the GE organism could be a plant pest
 - Plant pests are defined in the PPA as organisms that can pose a direct or indirect risk to plants or plant products.



Introduction of Regulated Articles



- APHIS-BRS regulates the following activities for regulated articles:
 - Importation
 - Interstate movement
 - Release into the environment (e.g. field test)
- Permit or notification procedures



BRS Permits and Notifications



BRS:

- Reviews the information submitted
- Shares information with States and/or Tribes for them to review and comment
- Issues a permit or acknowledges a notification
- Verifies compliance (e.g., inspects sites, audits records)
- Reviews Field test reports



Compliance Assistance



- **Biotechnology Quality Management System (BQMS)**
 - Voluntary compliance assistance by BRS Office of Compliance Assistance
 - Provides participants with the tools and guidance needed to develop a BQMS that is tailored to their organization's culture and needs
 - Participants include public and private sector organizations (19 organizations as of Nov 2012)



Compliance Assistance



- **Biotechnology Quality Management System (BQMS)**
 - Voluntary compliance assistance program includes:
 - Interactive training workshops
 - Documented guidelines and templates
 - A desk review and baseline assessment,
 - Internal audit training,
 - One-on-one targeted assistance as needed
 - Facilitated third-party audits

Petition Procedure for Nonregulated Status under 7 CFR part 340

- Anyone can petition BRS to determine “nonregulated” status (the GE organism would no longer be subject to this regulation)
 - Petition information should support conclusion that the GE organism is not a plant pest
 - Public reviews petition and APHIS evaluation before final APHIS determination

Petition Procedure for Nonregulated Status under 7 CFR part 340

- APHIS-BRS does two evaluations:
 1. Plant pest risk assessment to decide if the GE organism is a plant pest (Plant Protection Act)
 2. Environmental Assessment to evaluate the significance of any environmental impacts arising from the APHIS-BRS decision (National Environmental Policy Act; NEPA)



GE plants with Nonregulated Status under 7 CFR part 340



- BRS has made determinations of nonregulated status in response to over 90 petitions, representing 16 plant species.
- The determination of nonregulated status extends to the GE plant and its offspring.
- Actual commercialization of GE plants with nonregulated status is determined by market demand, not the APHIS decision.

GE plants with Nonregulated Status under 7 CFR part 340

- Corn – HT, IR, AP
- Soybean – HT, PQ, IR
- Cotton – HT, IR
- Canola – HT, AP, PQ
- Papaya – VR
- Squash – VR
- Tobacco – PQ
- Alfalfa – HT
- Sugar beet – HT
- ❖ Tomato – PQ
- ❖ Chicory – AP
- ❖ Potato – IR, VR
- ❖ Rice – HT
- ❖ Flax – AP
- ❖ Plum – VR
- ❖ Rose – PQ

- large scale production
- ❖ not in large scale production

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





For More Information



**“Unified” website for U.S. Regulatory Agencies
under the Coordinated Framework:**

<http://usbiotechreg.epa.gov/usbiotechreg/>

USDA-APHIS-BRS:

<http://www.aphis.usda.gov/biotechnology/index.shtml>

EPA:

<http://www.epa.gov/pesticides/biopesticides/pips/index.htm>

FDA-CFSAN:

<http://www.fda.gov/Food/Biotechnology/default.htm>