

The Regulation of GM crops in the United States

GMO Technology Conference:

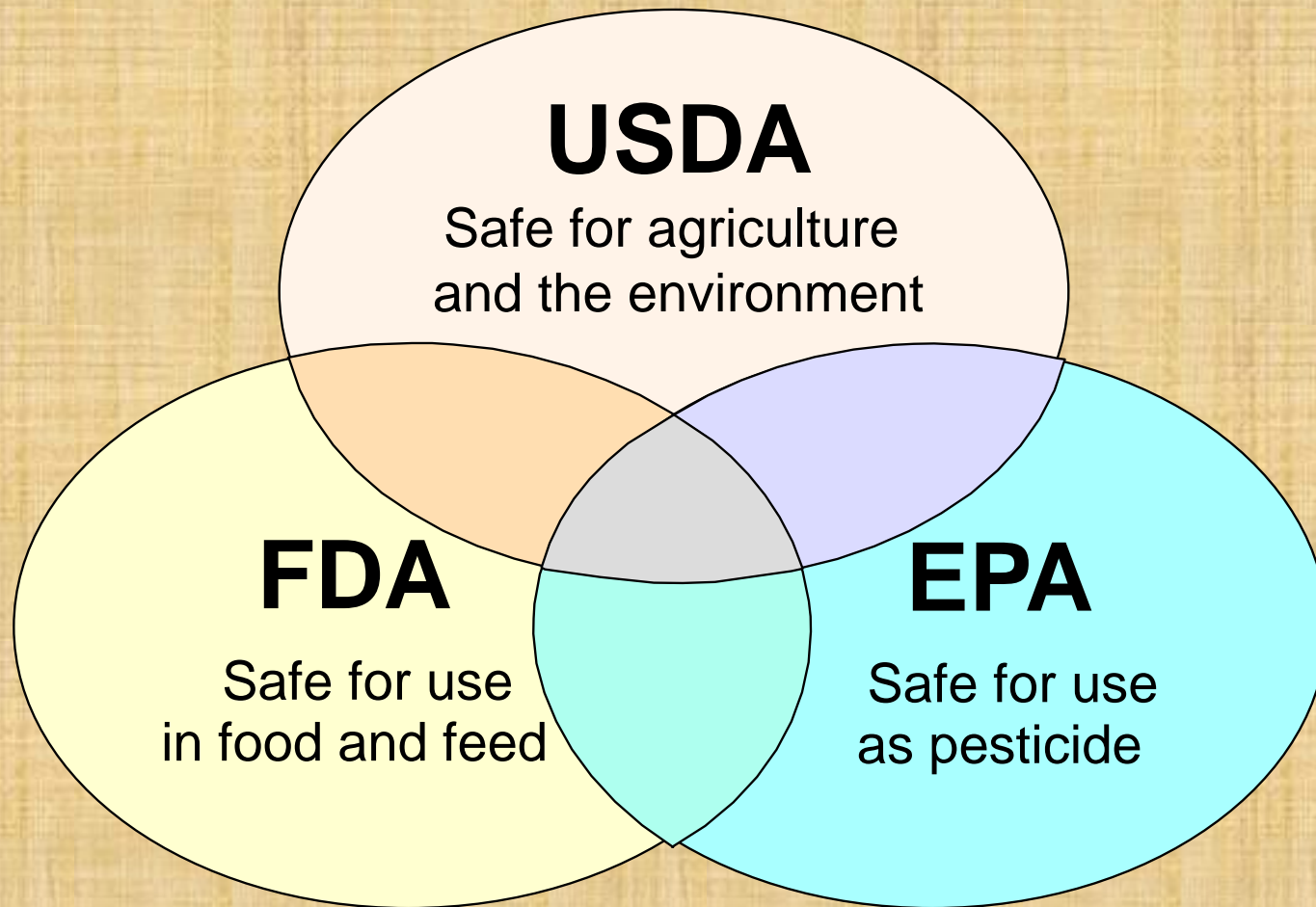
The Regulation and Use of GMO Technology in Ireland

10 - 11 October 2013 // The Printworks, Dublin Castle

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
- **Food and Drug Administration (FDA)**
 - FFDCA: Regulating safety of food, drugs, and cosmetics

FDA's 1992 Policy Statement

- New varieties must be as safe as conventional food.
- FDA established voluntary consultation procedures to help ensure that new products are safe and lawful.
- The safety assessment is multi-disciplinary:
 - Agronomic and quality characteristics; genetic, chemical, nutritional analyses
- The consultation process is working well.

EPA regulation under FIFRA

- Plant-incorporated protectant (PIP)
 - Pesticidal substance produced by plants and the genetic material necessary to produce it
 - Example, Bt Cry insecticidal proteins in corn
 - It also includes any inert ingredient contained in the plant.
 - Example, marker gene
 - Exempted from registration:
 - PIPs that occur naturally in the plant and are moved through conventional breeding

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
 - Donor, recipient, or vector organism is a plant pest
 - Plant pest is defined by statute
- Is my GE organism a regulated article?
 - www.aphis.usda.gov/biotechnology/am_i_reg.shtml

Introduction of Regulated Articles

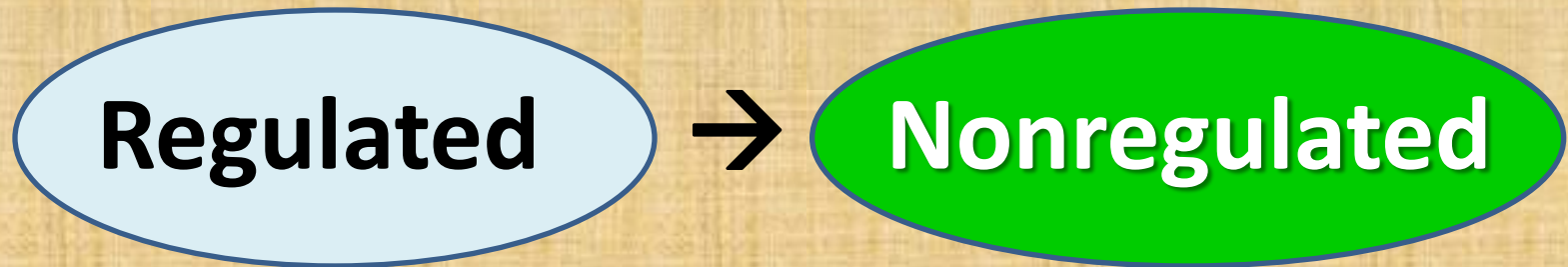
- APHIS-BRS regulates the following activities for regulated articles:
 - Importation
 - Interstate movement
 - Release into the environment (e.g. field test)
- Permit or notification procedures are used to authorize

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 Sept. 2013)

Petition Procedure for Nonregulated Status under 7 CFR part 340



Petition Procedure for Nonregulated Status under 7 CFR part 340

- Anyone can petition APHIS-BRS to determine “nonregulated” status (the GE organism would no longer 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
 - Public comments are online

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

- APHIS-BRS has made determinations of nonregulated status in response to over 100 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

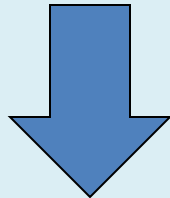
- Corn – HT, IR, AP
- Soybean – HT, IR, PQ
- Cotton – HT, IR
- Canola – HT, AP, PQ
- Squash – VR
- Papaya – VR
- Tobacco – PQ
- Alfalfa – HT
- Sugar beet - HT
- Tomato – PQ
- Radicchio – AP
- Potato – IR, VR
- Rice – HT
- Flax - AP
- Plum – VR
- Rose - PQ

HT = herbicide tolerance
VR = virus resistance
PQ = product quality

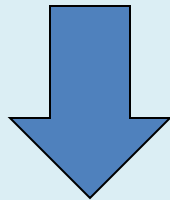
IR = insect resistance
AP = agronomic properties

Plant Variety Development

LABORATORY / GREENHOUSE



FIELD TESTING



COMMERCIALIZATION

APHIS-BRS

APHIS-BRS
EPA

APHIS-BRS
FDA
EPA

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

Communication with the public

Communication	USDA	FDA	EPA
Extensive website information	✓	✓	✓
Guidance to regulated public online	✓	✓	✓
Regulatory “decision documents” online	✓	✓	✓
Public information during reviews	✓		✓
Applications announced publicly	✓		✓
Public Scientific Advisory Panels			✓
Stakeholder news updates	✓		
Annual stakeholder public meeting	✓		

The Future

- Considering Federal regulatory approaches
 - Existing and newer technologies
 - White House “Holdren memo” on policy, March 2011
 - Objective: Protect safety, health, and the environment while avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers

Guiding Principles for Regulating New Technologies

- Benefits of regulation should justify costs
- Promote innovation while advancing protection goals (health, environment, safety)
- If no significant issues identified, consider not regulating
- Develop performance based regulatory approaches that are predictable and flexible in the face of fresh evidence

Guiding Principles for Regulating New Technologies

- Scientific integrity
- Public participation
- Communication
- Flexibility
- Risk assessment and risk management
- Coordination
- International cooperation

FDA

Internet Resources:

www.fda.gov

All things FDA

www.fda.gov/GEPlantFoods

Biotechnology consultation program

www.fda.gov/bioconinventory

Inventory of completed consultations

EPA

Internet resources:

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

Plant-Incorporated Protectants

http://www.epa.gov/pesticides/biopesticides/pips/pip_list.htm

Current & Previously Registered PIP Registrations

USDA-APHIS-BRS

Internet resources:

http://www.aphis.usda.gov/biotechnology/brs_main.shtml

BRS main page

<http://www.isb.vt.edu/search-release-data.aspx>

Searchable database of field tests

http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml

Petitions for nonregulated status

