

Regulation of Genetically Engineered Organisms at APHIS:

Plant Pest Risk Assessments

Biotechnology Risk Assessment Grants Program

2014 Project Director's Meeting



**Biotechnology Regulatory Services
Animal and Plant Health Inspection Service**

Regulation under the Coordinated Framework – 1986, OSTP

- **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



Regulation Under the Coordinated Framework



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

Regulation of GE products at USDA

Law: Plant Protection Act

Regulation: 7 CFR 340

We regulate if:

- The organism has been altered or produced through genetic engineering (recombinant DNA techniques),
and
- The organism is produced using plant pests, *or*
- There is otherwise a reason to believe that the organism is a plant pest.





Regulated Activities

- If a GE organism is regulated, a Permit or Notification is required for the following activities:
 - Importation
 - Interstate movement
 - Field test (confined release)



Confined Field Tests

- Field testing focuses primarily on confinement; a full data package on the GE trait is not needed.
- Risk assessment relies on familiarity with the plant, the trait, and the environment.
- Characteristics of the plant are often key:
 - Is it outcrossing or self-pollinating?
 - Is it weedy or invasive?
 - Are there wild relatives?
 - Can the plant or offspring persist after the test is over?
 - Would the trait be expected to change the plants weediness, invasiveness, or reproductive biology?



Petition Process for Nonregulated Status

- After safety has been established through field testing and other research activities, a developer may petition APHIS to grant “nonregulated status”
 - No longer a regulated article
 - Free to be moved and planted without permits or further APHIS oversight.



Petition Process for Nonregulated Status

■ Petition Evaluation

- Comprehensive scientific review – Team of scientists
- Crop biology and taxonomy
- Any genotypic differences
- Any phenotypic differences
- Field test reports for all releases conducted in the U.S.
- Relevant experimental data, publications and other data upon which to base a determination



Petition Procedure for Nonregulated Status

- APHIS BRS conducts two evaluations:
 - Plant Pest Risk Assessment to determine if the GE organism poses a risk as a plant pest (Plant Protection Act)
 - Environmental Assessment or Environmental Impact Statement to broader evaluate environmental impacts of APHIS-BRS decision (National Environmental Policy Act; NEPA)



Petition Process for Nonregulated Status

- Components of a Plant Pest Risk Assessment:
 - Create pest or disease problems for agriculture.
 - Become a weed.
 - Increase the weediness of sexually compatible plants.
 - Harm non-target organisms (beneficial, endangered).
 - Affect agricultural practices in a way which could create disease and pest problems.
 - Transmit the genes to organisms with which it does not normally interbreed.



GE Plants with Nonregulated Status

Over 100 Petitions Approved

In Production

- Corn – HT, IR, AP
- Soybean – HT, PQ, AP
- Cotton – HT, IR
- Canola - HT, AP, PQ
- Papaya – VR
- Squash – VR
- Tobacco – PQ
- Sugar beet – HT
- Alfalfa – HT
- Rose – AP

Not in Commercial Production

- Tomato – PQ
- Chicory – AP
- Potato - IR, VR
- Rice – HT
- Flax – HT
- Plum – VR

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



Categories of Products

- Reviewed many times over past 20 years
 - Corn, cotton, soy, canola
 - Herbicide resistance (mainly EPSPS and PAT) and insecticide resistance (Bt)
 - Highly familiar

- Currently reviewing
 - New types of plants - Eucalyptus, apple
 - New traits - Disease resistance, cold tolerance, yield increased, drought tolerance, new groups of herbicides, non-browning fruit, low acrylamide in cooked products.



The Future New Challenges

- New types of plants
 - Biofuel crops, ability to grow on marginal lands, not agricultural, some compatible with wild species, chosen for prolific biomass production
 - Trees (Exotic or native)
- New less familiar traits
 - entire metabolic pathways
 - stress tolerance
 - altered metabolism
- Microbes
 - Control plant pests and diseases
 - Algae for biofuels
- Insects
- Synthetic organisms?



The Future New Challenges

- New technologies – are there novel risks associated with new technologies?
 - RNAi (off-target binding, non-target species affected)
 - » Role of bioinformatics for assessments
 - Technologies using zinc finger nucleases, meganucleases, TALENS, CRISPR
 - Synthesis of chromosomes/genomes
- Appropriate comparator for exotic organisms
- Risk vs benefits



The Future New Challenges

- Unintended effects
 - Insertional mutagenesis
 - Intactness of insert
 - Pleiotropic effects
 - Are unintended effects comparable to those resulting from other types of breeding? Is there a regulatory role or are the standard plant breeding and variety development processes adequate to identify and eliminate undesired phenotypes.
 - Is the review of every event appropriate?





Thank You



United States Department of Agriculture

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