Regulation of Genetically Engineered Organisms at APHIS:

Plant Pest Risk Assessments

Biotechnology Risk Assessment Grants Program

2014 Project Director’s Meeting

USDA

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
<table>
<thead>
<tr>
<th>New Trait/Crop</th>
<th>Agency</th>
<th>Review</th>
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</thead>
<tbody>
<tr>
<td>Insect resistance in food crop (Bt corn)</td>
<td>USDA</td>
<td>Risks to plant health</td>
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<td></td>
<td>EPA</td>
<td>Environmental, food/feed safety of pesticide</td>
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<td>FDA</td>
<td>Food/feed safety</td>
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<td>Herbicide tolerance in food crop (glyphosate tolerant soybeans)</td>
<td>USDA</td>
<td>Risks to plant health</td>
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<td>Herbicide tolerance in ornamental crop (glufosinate tolerant tulips)</td>
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<td>Modified oil in food crop (high oleic acid soybeans)</td>
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<td>Food/feed safety</td>
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<td>Modified flower color (blue poinsettias)</td>
<td>USDA</td>
<td>Risks to plant health</td>
</tr>
</tbody>
</table>
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),
- 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 of 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 plant's 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