

# The Future of AgBiotech Regulations

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# Goals for APHIS Regulations

- Regulations must have science-based triggers that are rigorous, consistent, and easily understood
- Regulations should be effective, flexible, and dynamic
- Regulations should impose a degree of oversight proportionate to the potential risks
- Regulations must meet both domestic and international needs

# APHIS regulatory structure under 7 CFR § 340

- **Introduction of a GEO (Importation, Movement, Field Trials)**
  - **Notifications**
    - Plants only
    - Must meet eligibility criteria
    - Must develop performance standards to minimize risk
  - **Permits**
    - Any organism or trait
    - Details of biological containment are stipulated
  - **For both**
    - State concurrence sought
    - Sites inspected
    - Field data reports submitted
- **Nonregulated Status for Unconfined Release**
  - **Petitions**
    - Comprehensive scientific reviews

# Protection of Plant Health

<b>Current</b>	<b>Proposed</b>	<b>Impacts</b>
APHIS can regulate any GEO if there is reason to believe it could be a plant pest	Expand our authority to include GE plants that pose a noxious weed risk and/or biological control organisms	<ul style="list-style-type: none"><li>• Greater safety</li><li>• Analysis more firmly grounded in science</li></ul>

# Regulatory System

<b>Current</b>	<b>Proposed</b>	<b>Impacts</b>
Two-tiered system for field testing	<ul style="list-style-type: none"><li>• Multi-tiered system based on risk</li><li>• Crop/trait case by case analysis</li></ul>	<ul style="list-style-type: none"><li>• APHIS oversight would be proportionate to risk</li><li>• Analyses would be well grounded in science</li></ul>

# “Conditional” Deregulation

<b>Current</b>	<b>Proposed</b>	<b>Impacts</b>
Deregulation allows unconfined release	Unconditional or conditional authorization for unconfined release	<ul style="list-style-type: none"><li>•Increased safety</li><li>•Enhanced opportunities for data collection</li><li>•Increase in regulatory burdens</li></ul>

# Regulation of GE Plants Commonly Used in Research

Current	Proposed	Impacts
<p>GE <i>Arabidopsis</i> plants may be moved interstate without a permit</p>	<p>Add other well-studied, low-risk GE organisms to the list</p>	<ul style="list-style-type: none"><li>•Fosters research without increasing environmental risks</li><li>•Reduces the number of permits</li></ul>

# Regulation of Non-Living Plant Material

<b>Current</b>	<b>Proposed</b>	<b>Impacts</b>
APHIS regulates only living GE material	Regulate some or all non-viable material when risk warrants	Increased safety with some associated increases in regulatory burden

# Imported Commodities

<b>Current</b>	<b>Proposed</b>	<b>Impacts</b>
<p>APHIS reviews safety and issues opinion letters if item need not be regulated</p>	<ul style="list-style-type: none"><li>• Expedited risk analysis which incorporates appropriate reviews done by country of origin</li><li>• APHIS review similar to deregulation</li></ul>	<ul style="list-style-type: none"><li>• More efficient use of resources without compromising safety</li><li>• May conflict with domestic deregulation process</li></ul>

# Shipping Containers Used for Interstate Movement

<b>Current</b>	<b>Proposed</b>	<b>Impacts</b>
Prescriptive requirements for containers; APHIS issues variances when necessary	Performance-based standards	<ul style="list-style-type: none"><li>•Retains APHIS oversight</li><li>•Creates flexibility for applicants</li></ul>

# Regulation of Adventitious Presence

<b>Current</b>	<b>Proposed</b>	<b>Impacts</b>
No allowance for regulated articles in commerce	Low levels of specific genes would not trigger a regulatory response	Reduces emphasis on random, rare events and focuses analysis on actual risk

# Plant-produced Pharmaceuticals and “Industrials”

<b>Current</b>	<b>Proposed</b>	<b>Impacts</b>
<ul style="list-style-type: none"><li>•Field tests are allowed for P/I producing plants not intended for food/feed use</li><li>•Crops are never deregulated</li></ul>	<ul style="list-style-type: none"><li>•Long-term contract with applicant.</li><li>•Comprehensive initial review of permit and SOPs.</li><li>•Subsequent review of permit changes.</li></ul>	<p>No compromise of safety, but with increased efficiency and decreased paperwork</p>

# Current Status and Expectations

- Public comment period on Notice of Intent closed 4/13/04. We received over 3,700 comments.
- APHIS held two weeks of stakeholders' meetings with industry and NGO representatives.
- We hope to have the DEIS published this summer.
- The new rules will be drafted this year and sent out for public comment during CY 2006.