The Role of USDA APHIS in Regulating Biotechnology in the U.S.

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Specialty Crop
Regulatory Assistance Workshop
December 6-8, 2011

What Does APHIS BRS Regulate?

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 either -

- The recipient organism is a known plant pest or was constructed using genetic sequences from known plant pests, ***or***
- There is a reason to believe that the organism is a plant pest

Introduction of Regulated Articles

- Regulated organisms are called “regulated articles” in our regulations.
- A Permit or Notification is required for the following activities with regulated articles:
  - Importation
  - Interstate movement
  - Release into the environment (field tests)

BRS Permits and Notifications

- Review the information submitted
  - ➢Organism, genes, protocols, locations
- Share information with States
- Issue a permit or acknowledge a notification
- Verify compliance (e.g., inspects sites, audits records)
- Review field test reports

Compliance Assistance

- Services
  - APHIS Biotechnology Quality Management System Program (BQMS Program)
    - Facilitate regulatory compliance through quality management
    - Provide tools for the APHIS regulated community
- Activities
  - Regulatory permitting and compliance workshops

Potential Challenges with Field Testing

- Border row plants do not germinate— (Solution: Increase spatial isolation or bagging of flowers or removing all flowers)
- Asynchronous flowering between regulated field and border rows (synchronous flowering is expected to prevent pollinators leaving the regulated field)—(Staggered planting of border rows to begin with or increase spatial isolation)
- Presence of cultured pollinators (such as honeybees) within the isolation area—(Remove pollinators if possible, remove or bag flowers of all regulated article)
- Incorrect spatial isolation
- Unexpected events (flooding, lightning, animal foraging etc.)
- Delay in submitting planting and field test report
- A few approved constructs (e.g. sterility constructs) failed to perform as expected
- Approved field location(s) could not be used (e.g. lack of germination, shortage of regulated article, etc.)

Navigating USDA-APHIS' Petition Process for Nonregulated Status

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USDA United States Department of Agriculture
Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

Petition Process for Nonregulated Status

- Anyone can petition BRS to determine "nonregulated" status (the GE organism is no longer subject to USDA-APHIS biotechnology regulations)
  - Petition information should support conclusion that the regulated organism does not pose a plant pest risk
  - Public is given the opportunity to review and comment on the petition and APHIS assessments before a final decision

Petition Process for Nonregulated Status

- Petition Evaluation
  - Comprehensive scientific review
  - Crop biology and taxonomy
  - Genotypic differences
  - 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 Process for Nonregulated Status

- Petition should address regulatory requirements noted in 7 CFR 340.6
  - ➢ Differences in genotype (see Appendix I)
    - – Transformation system and genes inserted
  - ➢ Differences in phenotype (see Appendix II)
    - – Changes in gene expression
    - – Disease and pest susceptibilities
    - – Weediness
    - – Agronomic characteristics

Guidance Documents for Petitions

- **Appendix I and II of Canada/ U.S. Bilateral on Agricultural Biotechnology**
  - Appendix I– Molecular genetic characterization data
    - Transformation method, DNA inserted, protein/ RNA produced, trait stability, etc.
  - Appendix II– Environmental characterization data for transgenic plants intended for unconfined release
    - Plant growth habit, vigor, outcrossing, seed production, impacts on pollinators, fertility, reproduction, stress adaptations, etc.

Key Considerations and Management Goals for Plant Pest Risk Assessment

- No significant…
  - Increase in pest or disease susceptibilities
  - Increase in weediness characteristics
  - Increase in weediness of sexually compatible plants
  - Increase in damage to processed agricultural commodities
  - Increase in harm to non-target organisms
  - Adverse impacts from changes in cultivation practices

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 to evaluate whether the APHIS-BRS decision is likely to have significant environmental impacts (National Environmental Policy Act; NEPA)
    - NEPA Pilot Project

GE Plants with Nonregulated Status

- BRS has issued determinations of non-regulated status in response to over 85 petitions, representing 14 plant species.

- Actual commercialization of nonregulated GE plants is determined by market demand, not the APHIS decision.

GE plants with Non-regulated Status

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

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

- large scale production
❖ not in commercial production

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

Petition Process Improvement Project

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Petition Process for Nonregulated Status

Petition Received

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Petition reviewed– request more data if needed

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Prepare Draft Plant Pest Risk Assessment (PPRA)

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Prepare draft environmental document

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Draft PPRA and Environmental documents Published for public comment

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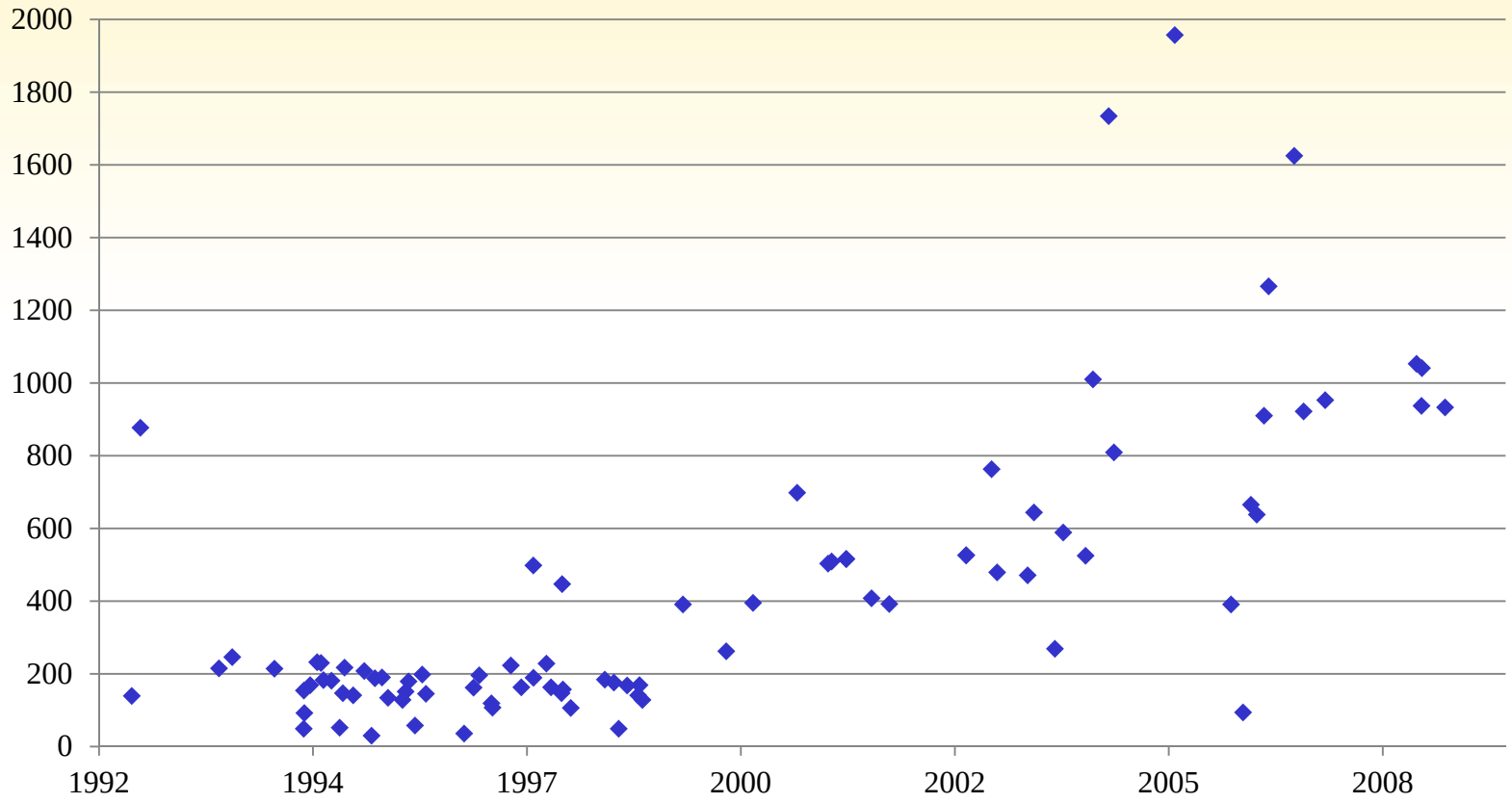
Comments analyzed-- Decision And Final documents published

Petition Process

How long does it take to get a decision on a petition?

- 1992-1999: average 178 days
- Current: 2-5 years or longer
- Backlog of 22 pending petitions

Time to Final Decision
(days from submission)



Petition Process Improvement Project

- Initiative originated with Secretary Vilsack as a high priority goal
- Launched December 2010
- Team of 6 petition process experts led by BRS Chief of Staff Dr. Clint Nesbitt
- Used the business improvement process known as Lean Six Sigma

Petition Process Improvement Project

Goal:

Identify and implement solutions to significantly and measurably improve the ***speed*** and ***predictability*** of the petition process, without affect the ***quality*** of decision making

Petition Process Improvement Project

Findings:

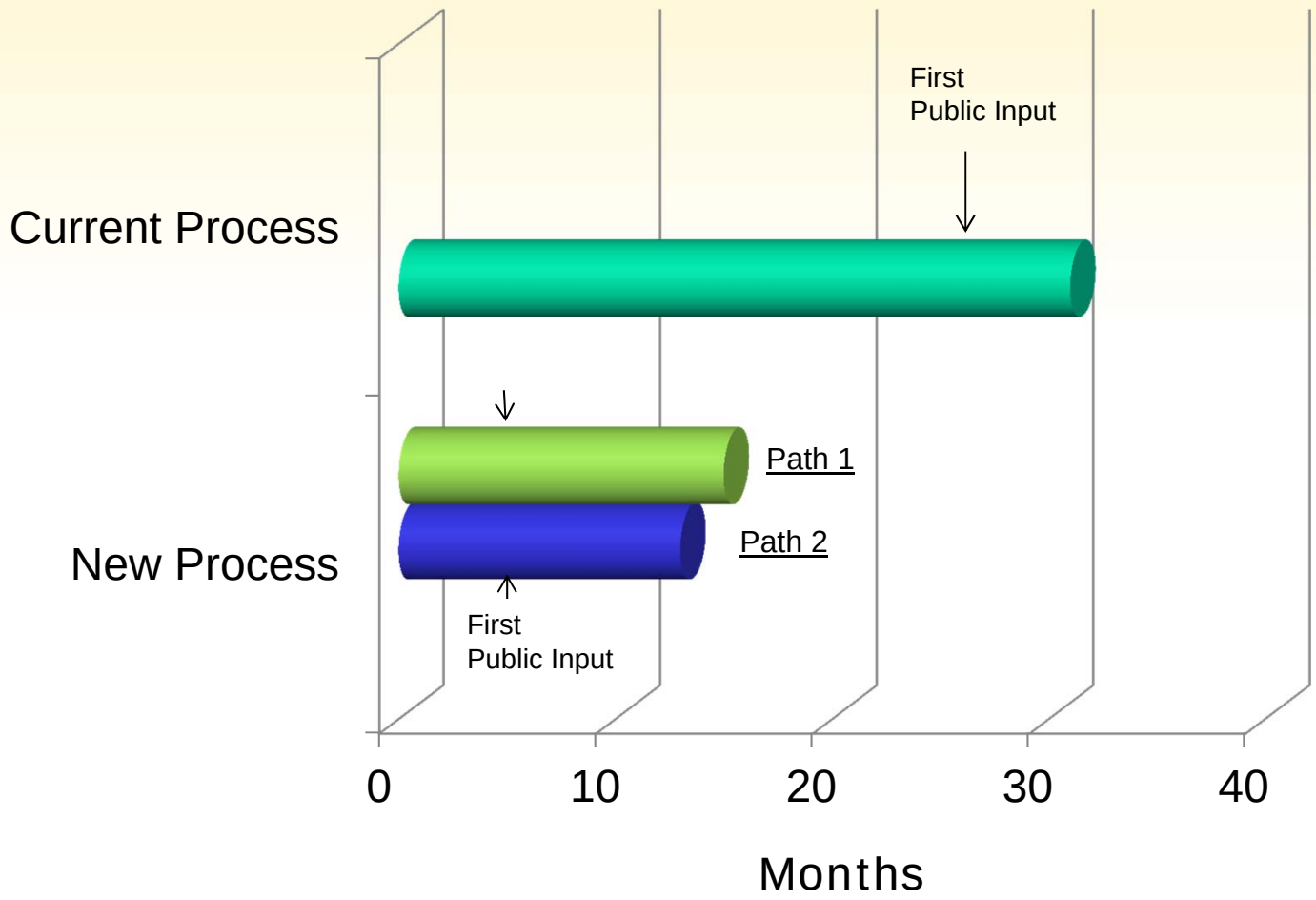
- *Unclear and variable steps in process*
- *No clear timelines for intermediate milestones*
- *Tracking ability limited*
- *Competing priorities divert staff resources from petition efforts*

Petition Process Improvement Project

Enhancements being implemented:

- Streamlined, standardized process with defined timelines for interim steps.
- Resource management tools for tracking progress of petitions and making work assignments.
- Earlier public comment period – Public input can be incorporated sooner, other work can proceed in parallel with comment period.

Petition Process Improvement Project



New Process Paths

Path 1
Draft EA and PPRA published for 30 day comment, followed publication of final versions, RTC, and decision

Path 2
Final EA and PPRA published for 30 day review. Decision becomes final unless new information is received that could change it.

Getting Information About BRS Activities

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Sources of Information

- BRS Website
- U.S. Regulatory Agencies Unified Biotechnology Website
- BRS Stakeholder Registry
- Biotech Query
- Information Systems for Biotechnology

BRS Website

- Intended for stakeholders and public audiences
- Information about:
  - Permits, Notifications, Petitions
  - Compliance and Inspection Process
  - Current Activities and Hot Topics
  - APHIS Regulations and Federal Register Notices
  - BRS Organizational Information (About BRS)

BRS Website

- Main Page URL:
  http://www.aphis.usda.gov/biotechnology/brs_main.shtml
- Appendix I and II
  http://www.aphis.usda.gov/biotechnology/library_supportingdocs.shtml
- Petition Guidance
  http://www.aphis.usda.gov/biotechnology/petitions.shtml
- Notification Guidance
  http://www.aphis.usda.gov/biotechnology/notifications.shtml
- Permit Guidance
  http://www.aphis.usda.gov/biotechnology/permits.shtml
- NEPA Pilot Project
  http://www.aphis.usda.gov/biotechnology/nepa_pilot.shtml

Unified Biotechnology Website

- Maintained by U.S. Geological Survey on behalf of USDA, HHS, and EPA
- Describes coordination of activities related to biotechnology among USDA, EPA, FDA
- Resource for applicable laws and regulations
- Database of completed regulatory reviews
- URL:

  http://usbiotechreg.nbii.gov/index.asp

Stakeholder Registry

- Register to become a BRS stakeholder and receive e-mail updates on BRS news and activities.
- Register on the BRS website, right-hand navigation: https://web01.aphis.usda.gov/BRS/BRSWeb.nsf

Biotech Query

- Feature of BRS Website
- Provides avenue to get answers to your biotechnology questions
- Staffed by BRS communications staff with access to subject matter experts across the Program
- Number of Biotech Queries answered in 2010 to date: 391
- Email to: biotechquery@aphis.usda.gov

Information Systems for Biotechnology

- Developed and maintained by Virginia Tech using data from APHIS BRS
- Provides information resources to support use of agricultural biotechnology products
- Data on development, testing, regulatory review of GE plants, animals, microorganisms
- Search Tool - Data using variety of criteria (Location, Gene, Phenotype, Article, etc.)
- URL: http://www.isb.vt.edu