Biotechnology
Regulatory Services Update

Neil Hoffman
Science Advisor,
Office of the Deputy Administrator

Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

National Plant Board
August 2, 2016
FY 15 Accomplishments

• Extensions Project
  • Leverage experience to increase efficiency
  • Expedited review of organisms similar to previously reviewed organisms
• GE Wheat authorizations to permit
• Coordinated Framework 2.0
Petitions

- FY15-8 approved
- FY16-6 approved
- 2 Remain-(EIS in both cases)
  - FT Eucalyptus
  - HT Creeping Bentgrass
FY15 USDA Biotech Inspections

Puerto Rico: 87
US Virgin Islands: 3
Hawaii: 100

Inspections

- >50: 30 to 50
- 30 to 50
- 11 to 29
- 5 to 10
- 1 to 4
- 0
Number of Authorizations for Organisms Produced with Gene Editing Technologies
USDA’s “Topline Messaging” (1 of 2)

- USDA’s biotech regulations have protected public health, welfare, safety, and our environment while protecting economic growth, innovation, competitiveness

- Science is changing rapidly

- Regulations are from 1987 (a few tweaks in 29 years)
7 CFR part 340
Revised Regulations

USDA’s “Topline Messaging” (2 of 2)

• Plant Protection Act of 2000
• Focus on risk
• Move from “Regulate first/analyze later” to…
• Regulatory Relief
Need for Change

• Regulatory Experience
• Plant Protection Act of 2000
• 2005 and 2015 OIG audits
• 2008 Farm Bill
• Focus on GE organisms that pose a risk to Plant Health
• Analyze First, Regulate as Appropriate
NOI (Notice of Intent) to Conduct an EIS (Environmental Impact Statement):

CURRENT PLAN: Three Alternatives

- No Action
- Current Thinking
- Regulate all GE organisms
New Regulations

This is our CURRENT THINKING

• From “Regulate First/analyze later” to “Analyze first/regulate when risk can be documented ”
• Broader Range must come in for review
  • Technically regulation, but…
• Require further oversight ONLY w/documentated risk
• Regulation will be Risk-based
Key Changes

• New Scope
  – Modify Plant Pest trigger → Review trigger
  • Drop vector as trigger
  – Add Noxious weed review trigger
  – Provide exemptions from regulation
• Add Regulatory status evaluations
Key Changes

- New definition of Genetic engineering (broader)
- Eliminate notifications, courtesy permits, and current version of petitions
Revising the Coordinated Framework (CF)

• White House Memo – July 2, 2015
  – to heads of FDA, EPA and USDA.
  – Biotechnology Working Group was established.

• Two components of the one-year mission:
  – Update the CF to clarify current roles and responsibilities (Neil Hoffman).
  – Develop a long term to ensure that the Federal regulatory system is equipped to assess the risks associated with future products (Sid Abel).
Revising the Coordinated Framework (CF)

• Requirement for Independent Assessment
  – A horizon scanning study will be conducted by the National Research Council.

• Public Meetings
  – Oct 30, 2015 – hosted by FDA in White Oak, MD
  – Mar 9, 2016 – hosted by EPA in Dallas, TX
  – Mar 30, 2016 – hosted by USDA in Davis, CA.
For More Information

USDA-APHIS-BRS:
http://www.aphis.usda.gov/biotechnology/brs_main.shtml

QUESTIONS?