



Update on Guidance for Field Testing and Petitions

BRS Stakeholder Meeting

November 20, 2013

John Turner, Ph.D.



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

Design Protocol Review

- Currently reviewing Design Protocols to be used in field tests under notification
- Objectives:
 - Ensure protocols are adequate to maintain confinement and identity of regulated materials in field tests
 - Provide timely review
 - Coordinate reviews with BRS compliance staff to avoid duplication of efforts and ensure coordination of regulatory communication and actions
 - Assure consistency across applicants – all meet or exceed the minimum standards



Separation Distance Table

- New table of separation distances published on August 30, 2013
- URL is:

http://www.aphis.usda.gov/biotechnology/downloads/sep_dist_table_0813.pdf

- Handouts of current table are available
- Minimum distances for 9 major crops (comprise a large majority of our permits and notifications)



Separation Distance Table



- Table is general – In special cases, greater or lesser distances are appropriate
- Regulated trials must be separated by minimum 10 ft. from any commercial crop regardless of sexual compatibility, to prevent mechanical mixing
- Greater distances must be used for equipment requiring >10 ft. for access and operation. This zone is often fallow, but sometimes planted with a cover crop to be plowed under.
- Table is “living document” – Crops to be added over time and adjustments made, as needed, based on new information and best available science



Cotton Confinement

- Our minimum standard for all cotton was
 - 660 ft. from any sexually compatible cotton *or*
 - 40 ft. of border rows comprised of a similar synchronously flowering cotton
- When table published in August, we added condition that cotton be separated from seed production cotton or any sexually compatible wild, ruderal, or feral cotton by either
 - 1320 ft. separation *or*
 - 165 ft. separation which includes 60 ft. nontransgenic border rows



Cotton Confinement

- New small adjustment
- From seed production cotton or any sexually compatible wild, ruderal, or feral cotton:
 - 1320 ft. separation *or*
 - 165 ft. separation which includes:
 - 60 ft. nontransgenic border rows *or*
 - 40 ft. of nonregulated border rows if effective measures taken to restrict cross-pollination by insects. Effective measures must be validated as effective, their implementation documented for inspection purposes, and pesticides used must be applied in accordance to approved labels



Number of Test Sites for Petitions

- Last year we amended our guidance for corn to recommend 8 test sites (formerly 16)
- Recently decided to expand this guidance to cover our most commonly petitioned crops: corn, soybean, cotton, canola



Number of Test Sites for Petitions cont.



- As with corn, there are general considerations that accompany any recommended number of sites. From the corn guidance:

“...data should be collected on enough sites to adequately represent the major growing regions targeted by the product. The sites should also be selected in a way to ensure exposure to a reasonably wide range of environmental conditions. For corn with common agronomic traits or previously deregulated traits, APHIS recommends a minimum of eight sites be selected to represent the major growing regions in the U.S. Data from the eight sites may be collected in one or more years. When field-testing corn with less familiar traits or for traits where there is a reason to expect plant pest effects, more sites should be considered.”

Questions?

???

