IR-4 Strategic Planning Conference

Plant Incorporated Protectants-Biotechnology

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What is a Plant-Incorporated Protectant?

- Plant-incorporated protectants or PIPs are pesticidal substances produced by plants and the genetic material necessary for the plant to produce the substance, if humans intend to use these substances for preventing, repelling or mitigating any pest
- PIPs are regulated specifically by EPA, but also by USDA and FDA

EPA Regulations

- EPA grants Registrations under the Federal Insecticide Fungicide and Rodenticide Act and Tolerances or tolerance exemptions under Federal Food Drug and Cosmetic Act
- For PIPs, regulations were proposed in 1994 and finalized in 2001 (40 CFR part 174)
  - Exemptions
    - PIPs and Inert Ingredients derived through conventional breeding from sexually compatible plants
    - DNA from the requirement of a tolerance
  - Proposed/Pending Exemptions
    - Certain Viral Coat Proteins and Selectable Markers- pending
    - PIPs that act primarily by affecting the plant – status unknown
  - No specific data requirements have been codified in 40 CFR 174 subpart H

EPA Involvement in Product Development and Commercialization

EPA Regulatory Actions[1]

- Experimental use permits – allows for field testing; required for field tests of new plant pesticides or uses in trials >10 acres/pest; Under PRIA 6-15 months for a decision; $82,688 - 165,375
- Seed bulk up registrations – grants registration for seed production activities prior to a registration for commercial use PRIA category
- Grants registration for use of herbicides on tolerant crops
- Registration – allows for the sale and distribution of a PIP; PRIA category allows 12 -21 months for a decision; $275,625 - $330,750
- Tolerances – sets a limit allowable in food/feed; timeline and fee included in Registration bullet point

[1]For timelines and fees see http://www.epa.gov/fedrgstr/EPA-PEST/2008/August/Day-05/p17936.htm

PIPs Reviewed by EPA

Commercialized

- Cry1, Cry2 and Cry3 proteins in corn, cotton, and potato
- VIP protein and Cry34/35 in corn
- Coat proteins in squash and papaya
- PLRV replicase gene in potato

Future PIP Technology and EPA Regulation

- Unless specifically exempt, EPA will regulate any technology, including RNAi, that meets the definition of a PIP
  - EPA registered the gene for PLRV replicase
  - EPA proposed to exempt, under certain condition, PIPs derived from one or more plant viral coat protein genes that produce only RNA and no virus-related protein (FR 72:19590); rule does not apply to insect, bacterial, or fungal resistance

EPA Regulatory Costs

- The regulatory costs to develop a USDA and FDA data package is approximately 15 million dollars
- Additional studies specifically to meet EPA data requirements cost approximately 1.5 million dollars
- For Bt crops, EPA requires, as a condition of the registration, grower education programs, baseline susceptibility insect studies, annual insect resistance monitoring, grower compliance monitoring for planting a refuge, and reports of sales linked to a grower license (up to $1 million/yr depending on the product).

Impacts to Domestic Markets

A key consideration in launching a biotechnology derived product is the impact to domestic markets

- Is the product a commodity where the biotechnology derived product would be comingled?
- What are the uses of the product?
- Where is the product exported? Need to obtain and maintain export approvals?
- Will the product be identify preserved?

Ways that IR-4 could help?

- Serve as a knowledge resource on US biotech regulations and data requirements
- Identify network of laboratories capable of generating quality data for regulatory submissions
- Serve as a liaison for commodity groups
- Work with EPA and other agencies to establish reasonable data requirements based on risk
- Identify crops of interest and traits of potential value to the public

Questions?