

APHIS Programmatic EIS – Implications for Crop Biotechnology Regulation

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Relevance

- What we have learned
- What trends are changing
- What we still need to know for the coming decade of crop biotechnology

What We Have Learned

- Technological advances challenge the scope of the current APHIS BRS regulatory program
- The National Environmental Policy Act “procedural” analysis requirement evolves with the times
- The APHIS DEIS reflects convergence and outlines the future

The NEPA Requirement

- For every “major Federal action significantly affecting the human environment” agencies must provide a “detailed statement” on
 - Environmental impacts of the proposed action;
 - Adverse environmental effects that can’t be avoided; and
 - Alternatives.

NEPA is a Big Tent

- Goes beyond the specific and substantive statutory authorities of USDA
- Procedural (does not dictate outcome)
- Extensive body of case law requires agencies to take a “hard look” at consequences – assumptions and general inadequacies

Purpose of NEPA

- Fulfill responsibilities as trustee for future generations;
- Attain widest range of beneficial uses of the environment without risk to health or safety or other undesirable and unintended consequences;
- Preserve national heritage and maintain an environment supporting diversity and variety of individual choice;
- Enhance quality of renewable resources.

APHIS Programmatic EIS

- The proposed federal action: revision of APHIS BRS regulations that
 - Provided regulatory framework for present degree of commercialization (corn, soybeans, cotton)
 - Facilitated co-existence
 - Have been challenged by AP

APHIS Preferred Alternative

- Fully utilize Plant Protection Act regulatory authorities:
 - Plant pests (current)
 - Noxious weeds
 - Biological control organisms

New Categories

- Noxious Weed: any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment
- Biological Control Organism: any enemy, antagonist, or competitor used to control a plant pest or noxious weed

Programmatic EIS

- Establish a tiered, risk-based, permitting system for plants
- Replace deregulation with unconditional and conditional approvals
- Permit conditions for pharma/industrial compounds in food and feed crops
- Regulate nonviable GE material (some)
- Create special multi-year permits with ongoing oversight (pharma plants)
- Identify no-action, low-level GE presence

Issue Discussion

- DEIS gives dimension and context to current/future issues
- Trend toward
 - more highly varied organisms (traits to address environmental stress on plants, plant-derived biofuels, plant-produced proteins, substances with industrial applications)
 - presenting more diverse environmental issues that may be closely related to economic or social issues

Alternatives Analysis

- Create a basis for informed public discussion
- A primer on the affected environment
 - Plants (plant biology, seeds and commercial seed production, self-pollinating plants versus outcrossing plants, etc.)
 - Insects and animals
 - Agronomic practices
 - Micro-organisms
 - Socioeconomic issues

Alternatives Analysis (cont'd)

- And on the environmental consequences of BRS regulations and possible changes.
- Effects on the human environment:
 - Potential changes in weediness and invasiveness;
 - Potential effects of GE plants on soil;
 - Potential Impacts on human health.

Public Participation

- 23,745 comments
- Continued polarization (few expressing middle ground)
- Requests for expanded discussion of impacts to organic and conventional agriculture, including socioeconomic impacts.
- Requests for discussion of negative impacts of excessive regulation on innovation and benefits of ag biotech
- Opposition to use of food/feed crops for pharmaceutical or industrial compound production and/or to unconfined production of same

Timeline

- Proposal of revised regulations
- Simultaneous finalization of the DEIS and the rules
- Current projected date: _____

What We Still Need to Know

- NEPA analysis applies to both the programmatic and individual action
- Changes in regulatory system designed to increase transparency and robustness of regulatory system and to solve some problems (e.g., AP)
- Actual effects of new traits to be evaluated under NEPA at time of permit and/or approval/conditional approval