

Biotechnology Regulatory Overview

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August 23, 2011

Biotechnology Regulatory Services

- APHIS has regulated genetically engineered organisms since 1987
- In 2002, APHIS established Biotechnology Regulatory Services (BRS)
- BRS' Mission: To protect America's agriculture and the environment using a science-based regulatory framework that allows for the safe development of GE organisms

What Does APHIS Regulate?

- Regulations under Title 7 Code of Federal Regulations Part 340
 - If the organism has been altered or produced through genetic engineering
 - If there is a possibility that the organism could be a plant pest or have characteristics of a plant pest
 - Plant pests are organisms that can pose a direct or indirect risk to plants in agriculture or the environment

Regulation Under the Coordinated Framework



- **Department of Agriculture (USDA-APHIS)**
 - *Plant Protection Act (PPA)*: Preventing the introduction and dissemination of plant pests.
- **Environmental Protection Agency (EPA)**
 - *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)*: Regulating the safe use of pesticides
 - *Toxic Substances Control Act (TSCA)*: Regulating toxic substances
- **Food and Drug Administration (FDA)**
 - *Federal Food, Drug and Cosmetics Act (FFDCA)*: Safe use of GE organisms in food and feed

Introduction of Regulated Articles

- BRS has oversight over the following activities for regulated articles:
 - Importation
 - Interstate movement
 - Release into the Environment/Field trial

Introduction of Regulated Articles for Field Trials

- For field trials, applicants must provide information on:
 - Biology of the organism
 - Conditions of the release, including measures to prevent escape
 - Potential to produce toxic substances
 - Site security, monitoring, and inspection
 - Plans for completion of trial, including:
 - Devitalization and disposal of material
 - Post-harvest monitoring and land use

BRS Actions for Field Trials

- BRS reviews the data submitted
- State and/or Tribes review and comment
- Issues a permit or acknowledges a notification
- Site inspections
- Field data reports

Petitions for Nonregulated Status



- Developers can petition BRS to determine “nonregulated” status
 - Nonregulated status means the GE organism would no longer be subjected to APHIS regulation
- Petition information should support conclusion that the regulated organism presents no more of a risk to plant health than the non-GE organism
- APHIS-BRS does two evaluations:
 1. Plant pest risk assessment
 2. Environmental Assessment (EA) or Environmental Impact Statement (EIS)

Petitions: Data Submitted



- Crop biology and taxonomy
- Inserted gene
- New protein(s) produced and function in plant
- Field test reports
- Experimental data, publications and other data upon which to base a determination
- Any unfavorable data and information

Petitions: BRS Actions



- BRS scientists conduct comprehensive scientific reviews of the data provided by the applicant
- Is the new plant line more likely than its conventional counterpart to:
 - exhibit plant pathogenic properties?
 - become a weed?
 - increase the weediness of sexually compatible plants?
 - harm other organisms in the environment?
 - change cultivation practices?
 - damage processed agricultural commodities?

Response to Petitions



- If BRS is able to reach a determination that the new GE organism does not pose a greater plant pest risk than the conventional organism, the agency can make a determination of nonregulated status
- BRS also performs an environmental review to consider the broader environmental consequences of a determination of nonregulated status as required under the National Environmental Policy Act

Crops with Nonregulated Status

- BRS has issued determinations of nonregulated status in response to 82 petitions, representing 14 crop species.
- “Deregulated” products are considered as safe as their conventional counterparts for use in agriculture and the environment
- Actual commercialization of nonregulated GE products is determined by market demand
 - It is the responsibility of producers or exporters to comply with regulations and requirements of domestic and foreign markets

For More Information



For more information about BRS:

<http://www.aphis.usda.gov/biotechnology/index.shtml>

Information on biotech products
that have completed regulatory review by
U.S. regulatory agencies :

<http://usbiotechreg.nbio.gov>

Questions?

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