



United States Department of Agriculture

USDA-APHIS Regulatory Experience with Genetically Engineered Insects

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USDA-APHIS-BRS
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USDA-APHIS Regulation: The Plant Protection Act

Provides two authorities that could be used to regulate GE organisms



Current Regulations – Plant Pest Authority only

APHIS-BRS regulates the importation, interstate movement, and environmental release of GE organisms that are likely to result in the introduction or dissemination of plant pests.

What Does APHIS Regulate Under the PPA?

“Regulated articles” (7 CFR part 340)

- The organism has been altered or produced through genetic engineering, and
- The GE organism could be a plant pest or have characteristics of a plant pest
 - Donor, recipient, or vector organism is a plant pest
 - Plant pests (defined by statute): organisms that can directly or indirectly injure, cause damage to, or cause disease in or to any plant or plant product

APHIS-BRS Mission Delivery



Authorizations of Regulated Activities

Inspections and Compliance

Determinations of Nonregulated Status

Authorization Conditions

- Performance standards or Standard conditions are placed on both movement and release authorizations to minimize the possibility that the GE organism will:
 - Persist in the environment
 - Produce offspring that will persist in the environment
 - Significantly impact non-target organisms
- Supplemental conditions are added to some regulated field trials in order to maximize confinement
 - Customized to the organism, trait and release locations
 - *Probability of persistence should be near zero*

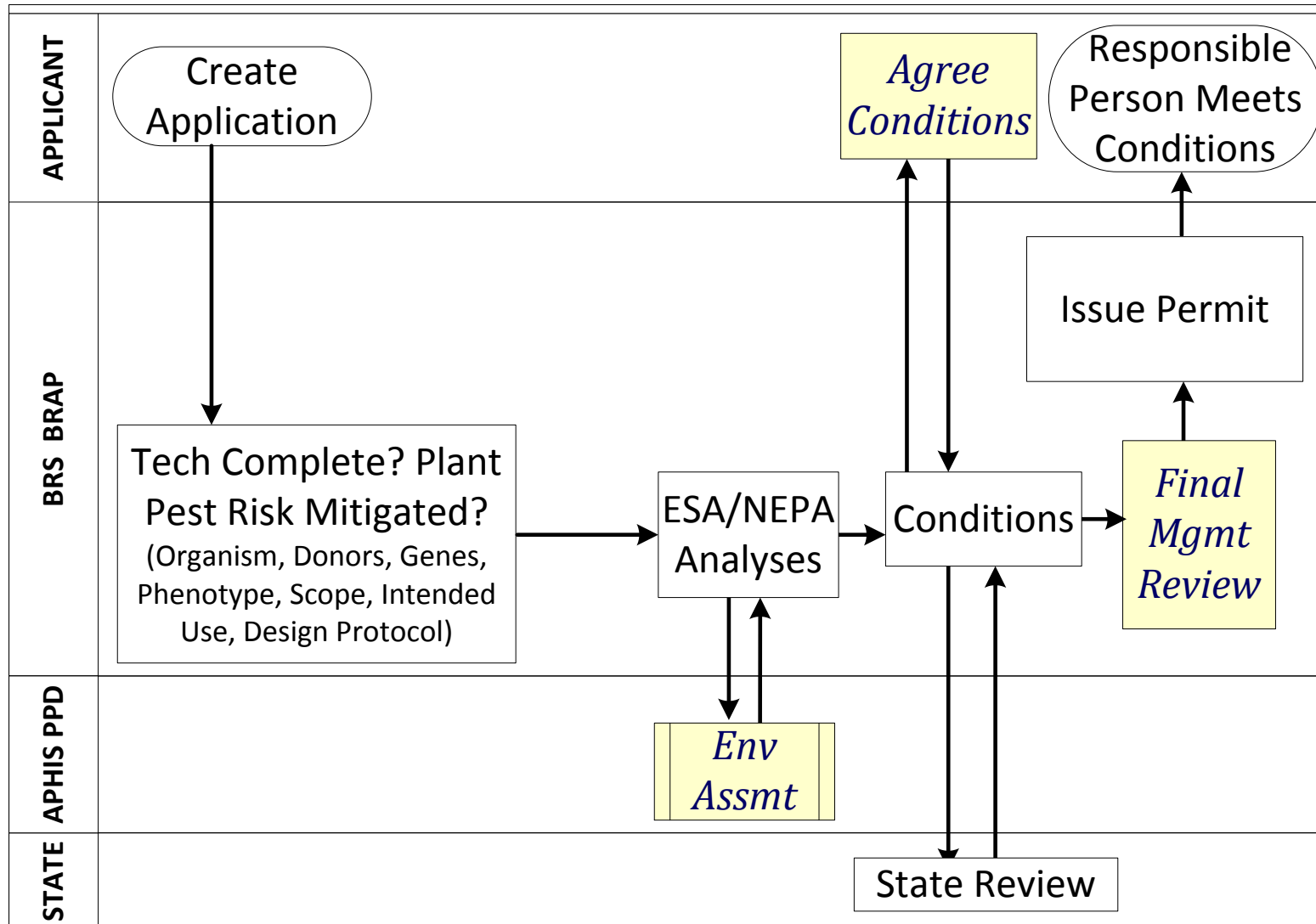
GE Insect Authorizations Since 1998

- 17 authorized movements (excl. *D. melanogaster*, *T. castaneum*, mosquitoes)



- Facility inspection prior to authorization (APHIS-PPQ Containment Guidance for Nonindigenous Phytophagous Arthropods)
- 14 authorized open field releases of sterile insects (pink bollworm)
- 2 authorized caged field studies of conditional lethal insects (pink bollworm, diamondback moth)
- 1 pending caged and open field release of conditional female lethal insects (diamondback moth)

Diamondback Moth Release Authorization Process



Environmental Assessment (EA)

Conducted in accordance with the National Environmental Policy Act (NEPA)

Categorically Excluded Actions: Permitting for confined field releases of genetically engineered organisms

Except

When the confined field release involves new species or organisms or novel modifications that raise new issues

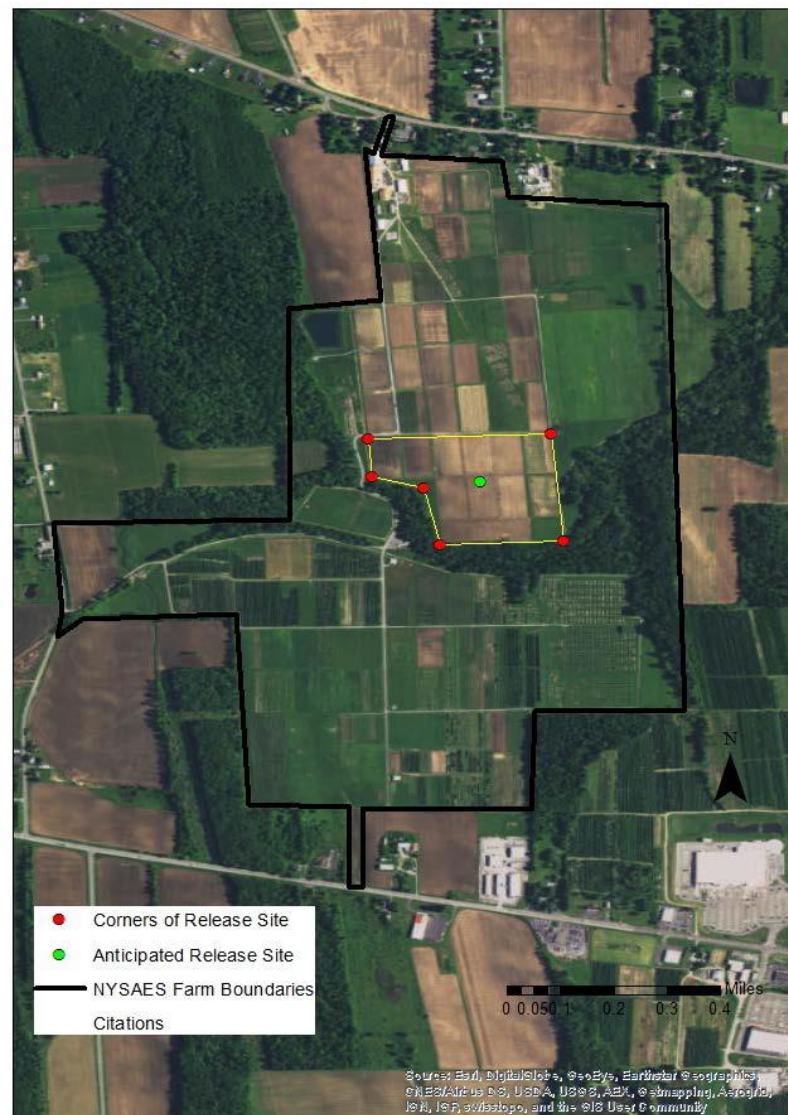
EA Issues Addressed

- Definition of the Affected Environment
- Identification of Alternatives: Deny permit, Grant permit
- Evaluation of potential environmental impacts
 - Physical: soil and water resources, air quality, climate change
 - Biological: wildlife, plant communities, biological diversity
 - Human health: farmworker health, health of the general public
- Cumulative impacts
- Threatened and Endangered species

Draft EA Finding: Impacts are similar under both alternatives and there will be no effect on threatened or endangered species or their critical habitat

Diamondback Moth Release

New York State Agricultural
Experiment Station
Geneva, NY



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Supplemental Permit Conditions

- Visually inspect clothing before leaving release area and cages
- 10 meters bare ground buffer at perimeter + additional 50 meters free of clusters of host plants
- No release within one week prior to a major wind event, or insecticide treat within two days prior
- Weekly monitoring during field trial
 - passive traps at 8 equidistant locations on buffer edge
 - pheromone traps in at least four locations out to 1 km along each compass point
- Crop destruct and insecticide treatment at termination
- Post-termination monitoring until no GE moths detected for two consecutive months at temperatures conducive to development

Public Comments

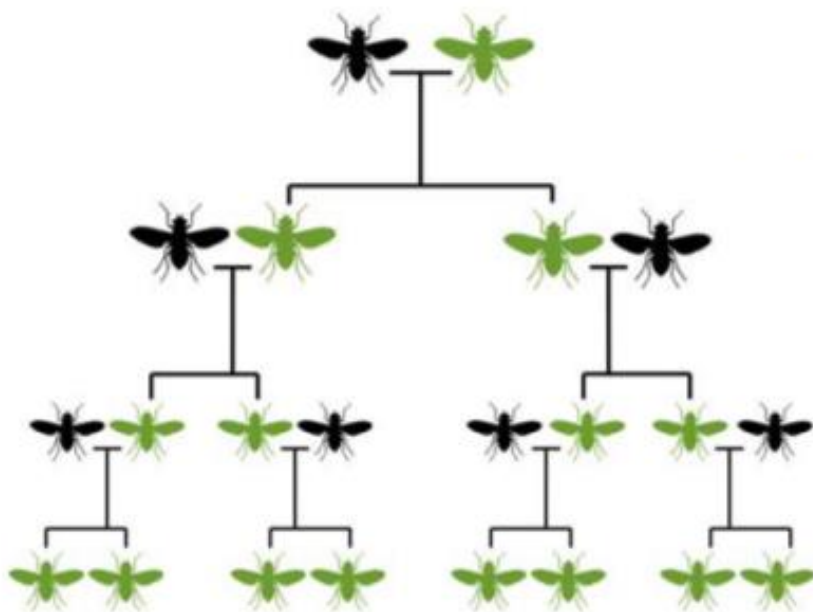
30 day public consultation on Draft EA

Approximately 670 comments: 68 support, 592 oppose

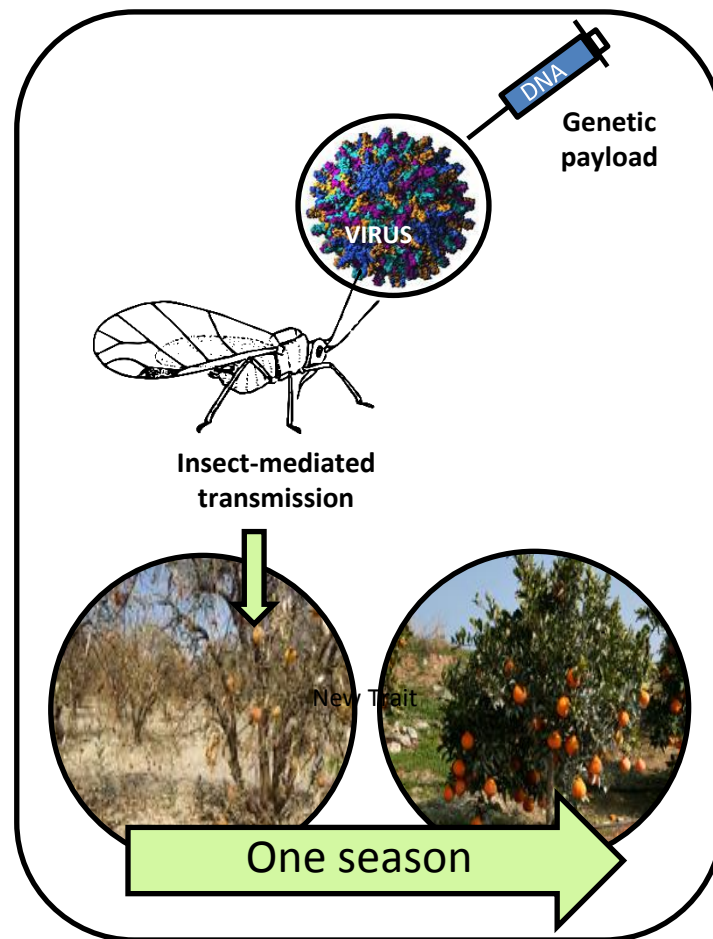
- Should prepare an Environmental Impact Statement
- Potential escape of GE DBM due to long distance dispersal and/or overwintering
- Unintentional survival of females due to resistance or tetracycline-mediated suppression
- Safety of tTAV protein – human health, non-target organisms
- Increase in tetracycline-resistant bacteria
- Horizontal gene transfer, particularly to microbes
- Increase in other pests, or in non-GE DBM outside the site
- Socioeconomic effects on conventional and organic farmers

Prospects

Additional RIDL insects



Gene Drives



DARPA: Insect Allies



For More Information

USDA-APHIS-BRS:

<http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology>