

*Federal Regulation of New
Technologies in the Bioenergy
Context: GMOs and Noxious Weeds*

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Meeting renewable energy mandates in the US (RFS, State RPS) will result in significant changes to the agricultural supply chain

- Food insecurity concerns
- Direct and indirect land use change
- Sustainability challenges
 - Increased intensification of biomass production
 - Biomass production on marginal or idle lands formerly in conservation reserves

Changing Land Use:

The Billion Ton Update and Dept. of Energy's Demand-Supply Analysis for Biomass

- At \$60 per dry ton...
 - 22 million acres of cropland and 41 million acres of pastureland shift to dedicated energy crop production
 - How will states and the federal government ensure the sustainability (or at least mitigate potential harm) of this production shift and intensification?

Agricultural Intensification: Ideal Traits for new Biomass Plants

Ideal Biomass Traits	Plant Traits
✓	Fast Growth
✓	Outcompete Local Vegetation
✓	Prolific Seed Production
✓	Tolerance to Variety of Soils
✓	Tolerance to Variety of Climatic Conditions
✓	Resistance to Pests/Diseases
✓	Lack of Predators in Recipient Ecosystem

Agricultural Intensification: Ideal Traits for new Biomass Plants

Ideal Biomass Traits	Plant Traits	Traits of Invasive Plants
✓	Fast Growth	✓
✓	Outcompete Local Vegetation	✓
✓	Prolific Seed Production	✓
✓	Tolerance to Variety of Soils	✓
✓	Tolerance to Variety of Climatic Conditions	✓
✓	Resistance to Pests/Diseases	✓
✓	Lack of Predators in Recipient Ecosystem	✓

Perennial Biofuel Crop GE Trait Development

Category of GE target	Traits
Modified crop physiology or product quality through modifications in the expression or DNA sequences of native genes and pathways	<ul style="list-style-type: none"> Form, stature Growth rate, yield Feedstock chemistry, structure, density Abiotic stress tolerance (e.g., cold, salt, heat, nutrition) Biotic stress tolerances (disease, insects) Herbicide tolerance Bioremediation
Substantially novel products or functions	<ul style="list-style-type: none"> Pest-resistance toxins Abiotic stress-resistance proteins Enzyme, material feedstock, pharmaceutical coproducts (bioreactor) Herbicide resistance Bioremediation
Biological and social facilitation	<ul style="list-style-type: none"> Domesticating traits of many kinds (e.g., semidwarfism, reduced response to shading, increased water or fertility requirements) Male- or female-sterility-lethality systems Trait expression requiring chemical trigger or postharvest treatment

Genetically Engineered Biomass?

- Convert *Miscanthus x. giganteus* (sterile, hybrid clone of *M. sinensis* and *M. sacchariflorus*) to a seeded variety for easier propagation and scaling for commercial production
- Cold-tolerant, male-sterile GE *Eucalyptus* field testing; currently pending USDA deregulation decision
- GE grasses and trees
 - Wild or feral relatives
 - Weekly domesticated
 - Spread/persist more readily than GE agric. crops

Federal Regulatory Regime

- Invasive Plants

- 1974 Noxious Weed Act (USDA)

- Biotechnology

- 1986 Coordinated Framework
 - FDA (Food, Drug, & Cosmetic Act)
 - EPA (FIFRA)
 - USDA (1957 Federal Plant Pest Act)

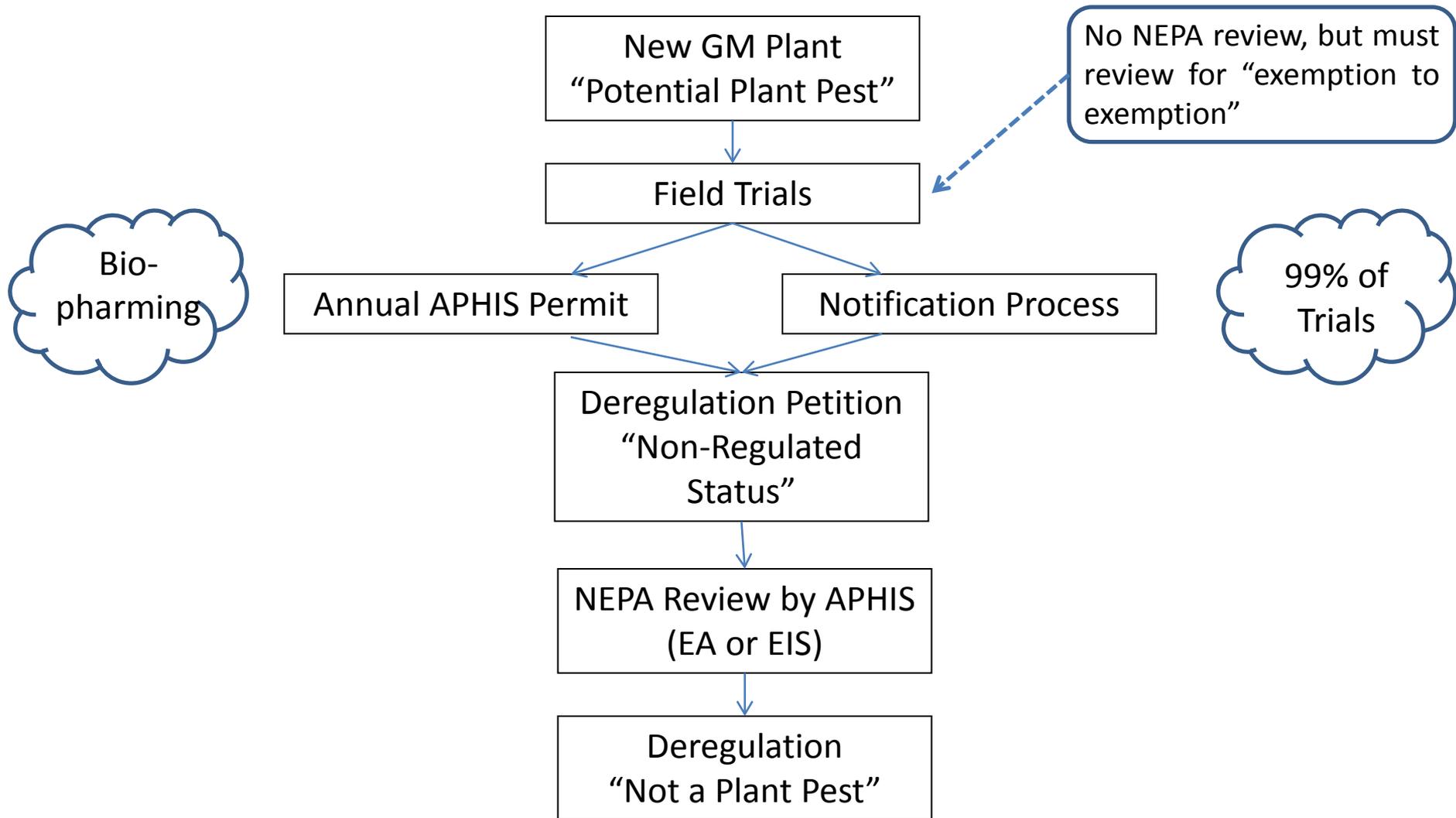
Plant Protection Act of 2000

- Consolidated the Noxious Weed Act and Federal Plant Pest Act

Plant Protection Act

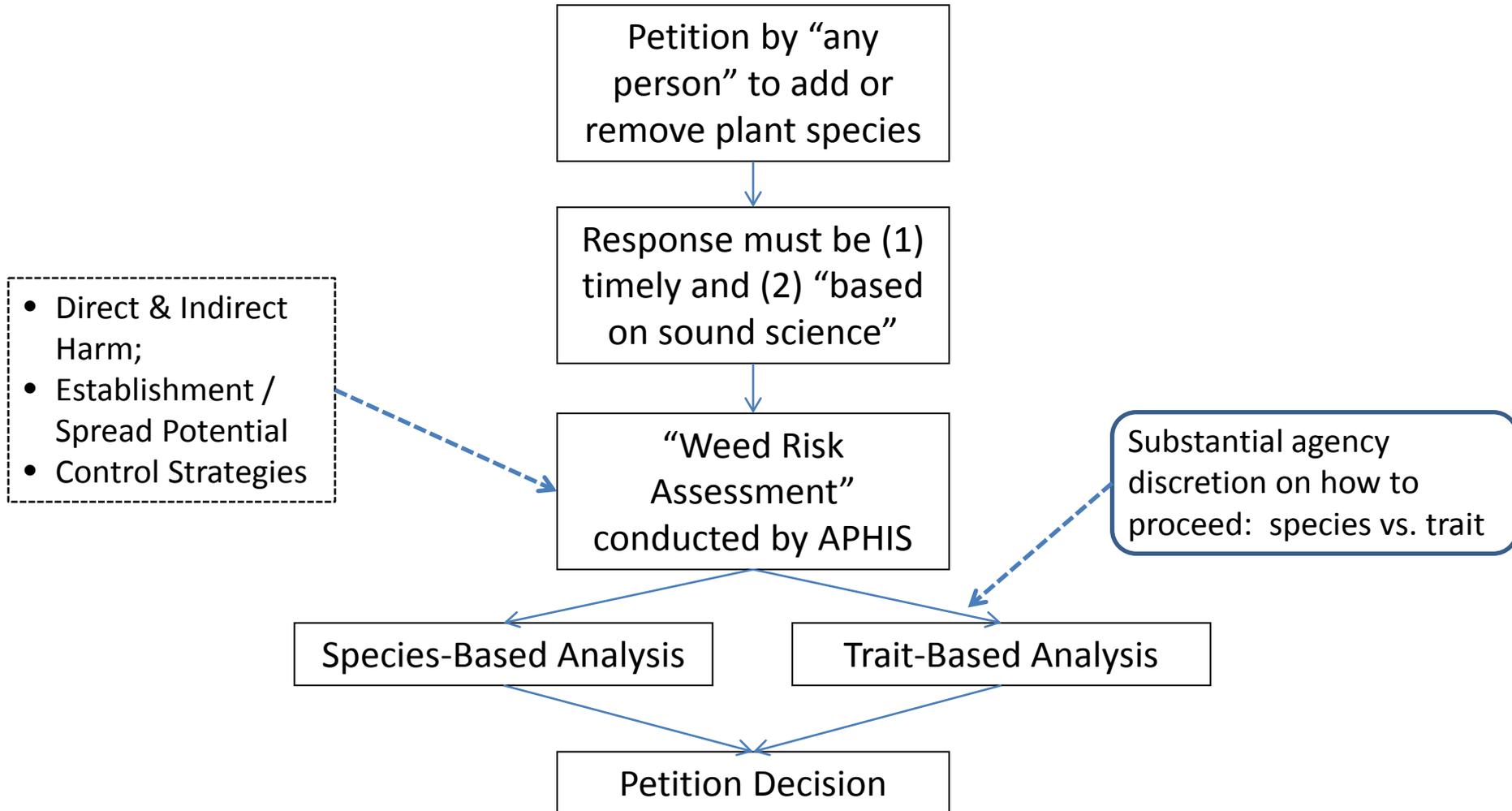
- **Noxious Weed**
 - any plant or plant product that can directly or indirectly injure . . . crops . . . , livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.
- **Plant Pest**
 - Organism which can directly or indirectly injure or cause disease or damage in or to any plant . . . or products of plants
- **Regulated Article (Potential Plant Pest)**
 - organism altered by genetic engineered if the donor, recipient, vector or vector agent is a plant pest or the APHIS Administrator has reason to believe is a plant pest

Plant Protection Act: GM Regulatory Process (7 C.F.R. § 340)



Plant Protection Act:

Noxious Weed Regulatory Process (7 C.F.R. § 360)



Operation of the Plant Protection Act: GM Alfalfa & The Scope of Regulatory Review

- Alfalfa engineered to tolerate glyphosate (“Roundup”)
- Developer conducted field tests and submitted petition for USDA/APHIS determination of non-regulated status
 - Determination that GM plant is not a “plant pest”
- Decision on petition triggers NEPA-based review of environmental impacts
- Subsequent litigation (*Geertson*) established that the agency must consider:
 - Coexistence
 - What are the potential impacts on non-GM growers
 - What methods are available to prevent commingling
 - Cumulative impact of technology/pesticide

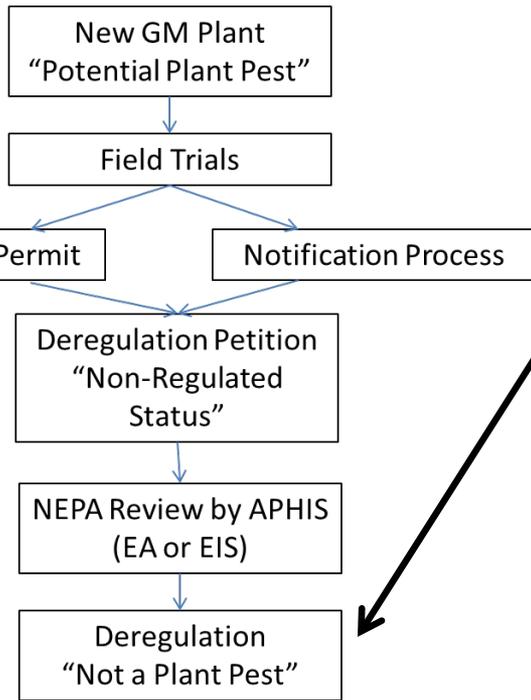
Operation of the Plant Protection Act: GM Bentgrass: Field Testing & Liability

- GM Bentgrass engineered for glyphosate tolerance
- During field testing in Oregon discovered species outside designated field testing area
 - Violation of permit conditions resulted in \$500,000 fine

Operation of the Plant Protection Act: GM Rice: Field Testing & Liability

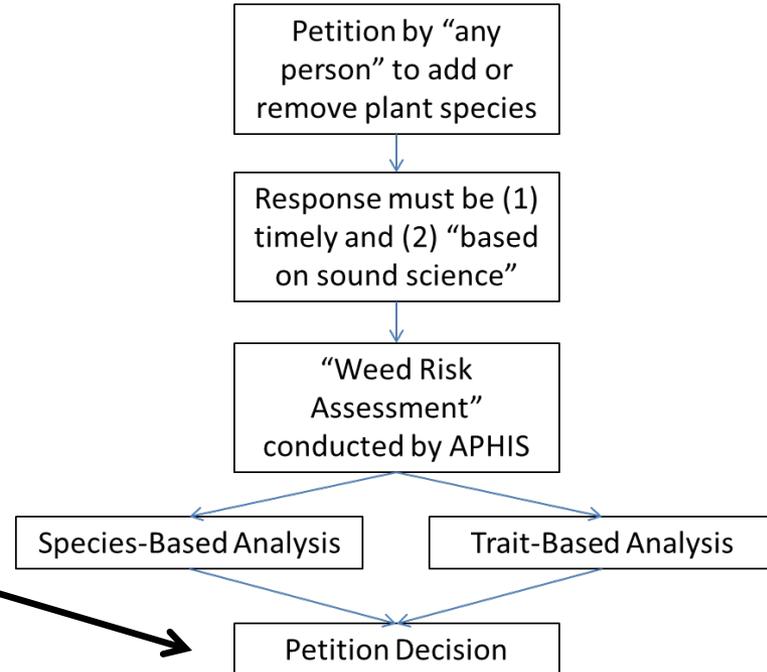
- Rice engineered for glufosinate (“Liberty”) tolerance
- While still in field-testing phase, rice variety discovered in commercial rice shipments to EU
- Violation of Plant Protection Act, but agency declined to take enforcement action; issued determination of non-regulated status (i.e., not a plant pest)
- Subsequent common law (negligence) litigation in federal and state courts (570 lawsuits; 11,300 plaintiffs)
 - Substantial liability judgments
 - \$ 434,000 average judgment per farmer
 - Nationwide (federal) settlement for \$750 million

GM Kentucky Bluegrass: Intersection of GM and Noxious Weed Regulation



- Preliminary determination that not a “regulated article”
 - Non-GM version not a plant pest
 - Transferred DNA not from a plant pest
- Not subject to APHIS review

- Parallel petition by NGO for noxious weed determination denied (species-based analysis)



Other Federal Initiatives

- National Invasive Species Council
 - Executive Order 13112 (1999)
 - Coordinate invasive species efforts across federal agencies
- Biomass Crop Assistance Program
 - Statute prohibits payments for establishment of potentially noxious or invasive plants
 - Precautionary restrictions in project awards
- Pending UDSA proposal to revise Plant Protection Act regulations to allow for the low-level presence of regulated GM plants without regulatory action

GM Biomass Outlook

- Continued Litigation
 - Challenges to GM plant deregulation decisions under plant pest rules
 - Petitions/Litigation seeking noxious weed listing for GM varieties
 - Trait versus Species Listing Process
- Efforts by plant developers to “design around” Plant Protection Act regulations to avoid APHIS jurisdiction
- Potential for state-specific restrictions
 - Close scrutiny by regulatory authorities
 - New regulatory requirements
 - Permits, performance bonds, zoning

Thank You
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