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

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# Perennial Biofuel Crop GE Trait Development

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<td>Modified crop physiology or product quality through modifications in the expression or DNA sequences of native genes and pathways</td>
<td>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</td>
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<td>Substantially novel products or functions</td>
<td>Pest-resistance toxins, Abiotic stress-resistance proteins, Enzyme, material feedstock, pharmaceutical coproducts (bioreactor), Herbicide resistance, Bioremediation</td>
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<td>Biological and social facilitation</td>
<td>Domesticating traits of many kinds (e.g., semidwarfs, reduced response to shading, increased water or fertility requirements), Male- or female-sterility-lethality systems, Trait expression requiring chemical trigger or postharvest treatment</td>
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Source: Strauss et al., 2010
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)

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**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)

New GM Plant
“Potential Plant Pest”

Field Trials

Annual APHIS Permit

Notification Process

Deregulation Petition
“Non-Regulated Status”

NEPA Review by APHIS (EA or EIS)

Deregulation
“Not a Plant Pest”

Bio-pharming

99% of Trials

No NEPA review, but must review for “exemption to exemption”
Plant Protection Act: Noxious Weed Regulatory Process (7 C.F.R. § 360)

- Petition by "any person" to add or remove plant species
  - Response must be (1) timely and (2) "based on sound science"
  - "Weed Risk Assessment" conducted by APHIS
    - Species-Based Analysis
    - Trait-Based Analysis
    - Direct & Indirect Harm;
    - Establishment / Spread Potential
    - Control Strategies
    - Petition Decision

Substantial agency discretion on how to proceed: species vs. trait
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 USDA 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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