FOREST HEALTH INITIATIVE ANNUAL MEETING

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REGULATIONS & POLICY

Duke Energy

U.S. Endowment for Forestry and Communities

Regulatory Presentation Part 1

Part 1: Context & Progress (Adam)

- Regulatory Backdrop:
  - What agencies regulate FHI's work?
- FHI Regulatory Position
  - Why FHI goes beyond the minimum requirements
  - How different technologies trigger different regulations
- Where we are today
  - Where and how the FHI is regulated
  - Pros, cons, and progress of different technologies

Regulatory Presentation Part 2

Part 2: Deregulation Options (Bill)

- Why we need a test case
- Where on the FH roadmap is chestnut
- Testing the process with a specific transgenic
  - Using oxalate oxidase as a model & some advantages
  - Same considerations needed for any chosen gene
- Why research needs non-regulated trees
- What deregulation might look like

3 Agencies Can Regulate Biotech Trees

Potential regulators in U.S.

- **APHIS** regulates transgenic plants based on process
- **EPA** regulates if there is a Plant Incorporated Protectant (PIP) under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- **FDA** regulates if the plant produces food for people or animals

Above and Beyond the Minimum

- Braided approach so each arm has a START and STOP button
- Outreach to the public
- Public perception survey
- Early & often regulatory meetings (even with FDA which is voluntary)
- Following high transparency Responsible Use Principles

3 Types of Trees, 3 Regulatory Paths

- 3 types of trees planted in field trials
  - Transgenic trees with genes of interest from non-sexually compatible species (Transgenics)
  - Transgenic trees with genes of interest from sexually compatible species (Cisgenics)
  - Somatic Embryo Clones (SE Clones)
- Each type serves a different purpose
  - **Transgenics** can use a wide variety of genes to find maximum blight resistance
  - **Cisgenics** use Chinese chestnut genes for resistance to eliminate new protein production and reduce public concern
  - **SE Clones** Provide clonal replicates to test conventionally bred genotypes for blight resistance and provide controls to transgenics

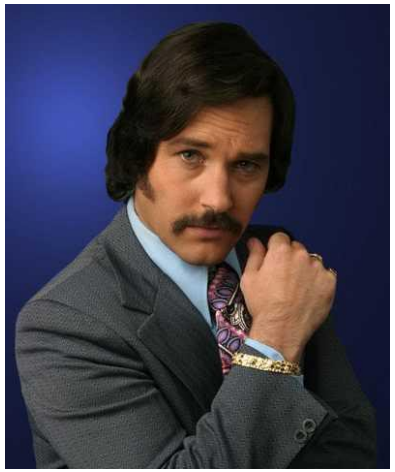
Where and How FHI is Regulated

Transgenic trees require a lot of attention

- Permits are required whenever a transgenic is:
  - Moved over state lines
  - Planted outside
- Reports are filed:
  - When plantings occur
  - If unexpected events occur (early flowering, heavy mortality, escape, etc)
  - Annually
- FHI has 2 primary field trials at Virginia Tech
  - Kentland
  - Powell River
- Other trials at UGA, ESF, and Joe James Farm

Pros, Cons, and Regulatory Progress

- Each tree type has strengths and weaknesses from a regulatory standpoint
- FHI is working to understand tradeoffs of each
- Note that FHI is not set up for restoration
- Containment is expensive on a small scale, unrealistic on a large scale



SE Clones Tradeoffs

Advantages

- Not regulated
- Provides controls to transgenics
- Allows for tests of conventionally bred trees
- Can be cryostored

Disadvantages

- Not a forest health strategy in itself
- Relies on selection and breeding programs to provide potentially elite germplasm
- Seed-based system can't directly clone trees

Cisgenic Tradeoffs

Advantages

- Potentially* less regulation than transgenics
- Produces no new proteins (FDA)
- Strong argument for exclusion under FIFRA

Disadvantages

- Genes must come from a sexually compatible species
- Unless a process is used that doesn't trigger APHIS, much of the same risk analysis is required as a transgenic

*Extent of regulation is unknown until the process is actually tested

Transgenic Tradeoffs

Advantages

- Maximum regulation
  - NEPA,
- Large selection of genes available
- Fastest approach to produce resistant trees in the lab

Disadvantages

- Maximum regulation
  - NEPA
- Public perception concerns
- Likely to require the most risk assessment

Regulatory Hammers

- USDA: PPRA – What is the effect of the plant on the environment?
  - No GM tree has been granted non-regulated status for restoration
- EPA: PIP/FIFRA – What is the safety of an expressed protein?
  - May require licensing with renewal process.
    - Breeders would have to fill out paperwork, consumers would not
- NEPA: All Agencies
  - Requires agencies to integrate environmental **values** into decision making processes
    - The significance of an action must be analyzed in several contexts such as society as a whole (human, national), affected parties and regions
    - Agencies expect lawsuits
    - EA vs EIS …

How do we Quantify Benefits?

Each agency weighs benefits with safety risks

- Some benefits to consider include:
  - Social
    - Restoring a critical part of North America's natural heritage
    - A new tool to improve forest health
  - Environmental
    - Potentially fastest carbon sequester of any east coast hardwood
    - Restore native species to improve native biodiversity
  - Economic
    - High quality, naturally rot resistant timber
    - Income for historic tree farming communities (lumber, nuts)

How Do We Prove Safety?

No checklist, but we will *at least* need:

- Silvicultural information
  - Growth rates, nut production, time to flower
- Plant pest risk assessments
  - Is it weedy? Is it more susceptible to pests?
- Effects on non-target organisms
  - How does it effect herbivorous insects, mycorrhizae, and pathogens?
  - How does it affect sexually compatible species that aren't chestnut?
- Information on how the tree produces & metabolizes proteins
  - Are produced proteins toxic or produce allergies in people or animals?
  - Are metabolites different from non-transgenic and if so, how?
- A sample reintroduction model
  - How will the tree affect larger scale ecology?

Tackling the Tough Questions

Transgenic trees pose big challenges:

- Should non-regulatory status (deregulation) be pursued in general?
  - If not, what is the fate of the current trees and research?
  - If so, which tree should begin down the road?
  - What is the end goal?
- What do we know?
  - It is a long process
  - Tort lawsuits from organic chestnut growers is possible
- What do we need?
  - More field trial data!
  - Better understanding of social perceptions
  - A test tree among test trees (Bill has some ideas!)