Forest Health:
Catalyst for Regulatory Change

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Institute of Forest Biosciences
Science • Dialogue • Stewardship

A Revolution is Coming

1. GM for forest health ≠ GM for production
2. Regulatory Gaps
3. Coordinated Framework Reboot
4. Options & Initial Ideas
5. Expected Outcomes

Mountain pine beetle damage
Dezene Huber, Univ. Northern British Columbia

Trees Live a Long Time

- Current GM regs based on crops
  - Most crops are harvested annually, trees aren't
  - APHIS Permits are 3 years max
  - Gene flow highly manageable with crops
  - Renewals are cumbersome with mixed age stands
- Tree phenotypes change over decades
  - Data requires years to collect
  - High cost and burden for tree growers
  - No realistic approach in place for researchers

Fun Fact: The oldest known tree is a Bristlecone Pine in California at 5,064 years old

Public Domain GM Tree Research is Different

- Saving/returning trees for public good has unique risk profiles
  - Regulations are to be based on risks
  - Risks of INACTION is socially & ecologically significant during forest health crises
- Changing climates will create no analog changes
  - Pest & pathogen pressure at unprecedented levels in forests
  - ~5 KM/yr ecoregion shift >>> ½ KM/yr tree natural migration rate
  - What's the baseline? Should risks be based on paradigms?
- Conversion, Fragmentation, and Urbanization
  - 232,000,000 HA lost to houses, roads, etc. by 2050
  - 13,000,000 HA converted to agriculture and grazing per year

The scale, risk, & cost of inaction is **Massive & Uncounted**

Purple = >50% canopy density loss
from 2001 – 2013 globalforestwatch.org

Risk Profiles Should be Recognized Upfront

GM Tree Characteristics	Forest Health	Commercial Forestry
Intellectual Property ownership	Public	Private
Impetus for development	Threats / Sustainability	Productivity
Revenue potential	None - Low	Low - High
Risk of not using GM trees	High	Low
Window of beneficial use opportunity	Short	Long
Primary benefactor of success	Society	Shareholders
Primarily harmed by failure	Society	Shareholders
Deployment level	Forest Landscape	Plantations & Farms
Gene control potential	Low	High

Special Regulatory Treatment?

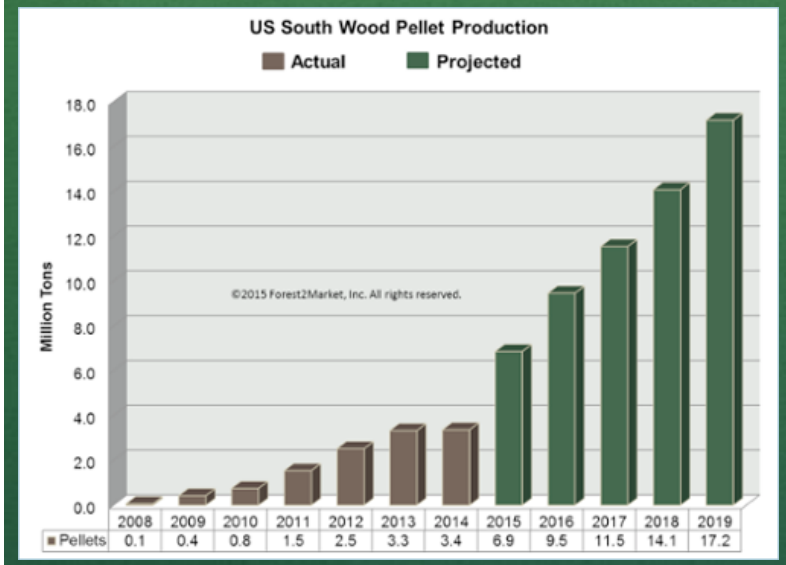
We AREN'T asking for special regulatory treatment

- commercial vs non-profit GM tree designation is not appropriate or necessary
- Need better recognition of different risks & benefits
  - Environmental
  - Societal
  - Deployment speed and scale
  - Who bears risks & benefits under success and failure scenarios

We need to revolutionize ALL GM tree regulation

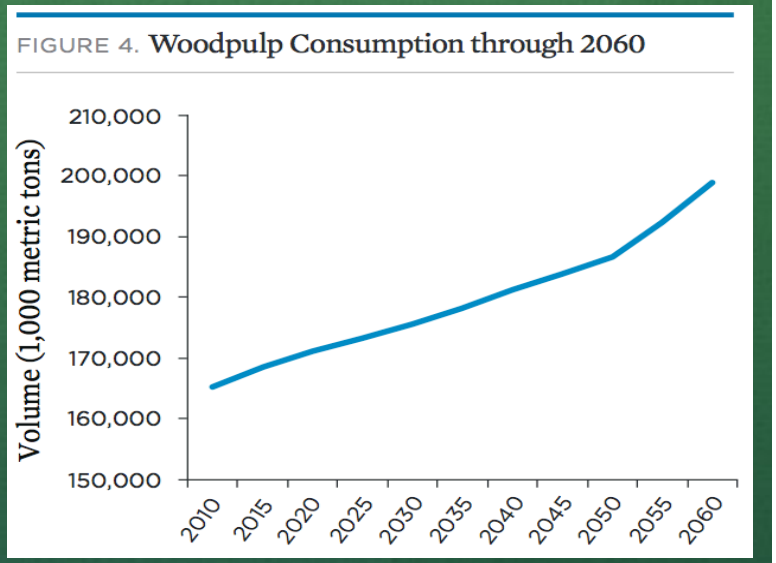
Fun Fact: The earth loses 48 football fields of forests every minute – mainly driven by ag land conversion. Forest product companies slow this process by planting trees and improving forests.

Unhealthy Forests are Unproductive



← Forest2Market

Union of Concerned Scientists report: Planting for the Future →
↓



These predicted increases in demand for paper products and construction-related materials indicate that plantations, especially fast wood plantations, are likely to play a larger role in the future wood market.

A Tale of 2 Commercial GM Forest Trees

Commercial GM Eucalyptus trees

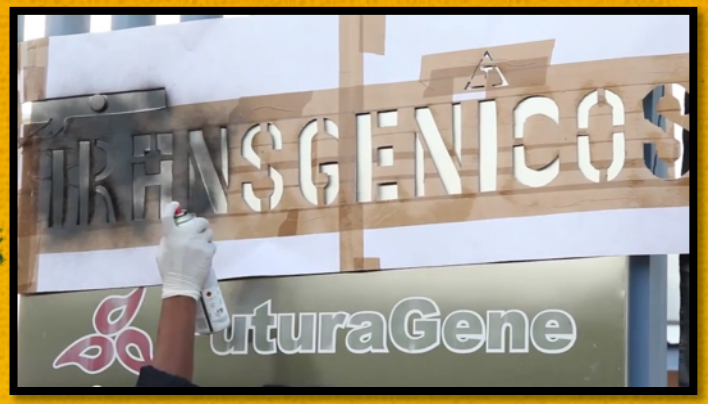
- FuturaGene submitted deregulation petition to CTNBio on January 19, 2014
  - Deregulated April 9, 2015
    - Took ~15 months to work through regulatory process

- ArborGen submitted a petition for non-regulated status on 1/19/2011. It was deemed complete by BRS on 12/15/2011.
  - 4+ years, public comment period still pending

FuturaGene Greenhouse Vandalism

March 5, 2015: 1,000 women of the Brazil Landless Workers' Movement (MST) vandalized FuturaGene's GM eucalyptus research greenhouse at Itapetininga, in São Paulo.

bit.ly/scinotviolence



Fun Fact: Since 9/11 ecoterrorism on U.S. soil declined significantly. This attack was largely instigated, organized, and partly funded by the Stop GE Trees campaign in Buffalo NY.

GM Technologies Over Time

Old (20+ years)
- Biolistics
- Agrobacterium mediated transformation (disarmed)

New (10 – 20 years)
- Cisgenesis
- Reverse breeding

Very New (1 - 10 years)
- Genome editing
  - Site-directed nucleases (ZFN, TALEN, CRISPR, meganucleases)
  - Oligo-Directed Mutagenesis
- RNA-dependent DNA methylation (RdDm)

Fun Fact: You can use a less precise technology, biolistics, to produce a GM tree that is not regulated (US)

Technique Based Risk?

- Higher development hurdles and costs when using *some* advanced GM technologies
- Abdicating use of GM trees for public benefit, even if it could save a species, ex. Ash
- Risk of NOT using biotech is given less weight than risk of using it

It appears we have a *risk assessment* problem above all else

GM Chestnut tree grown by Scott Merkle

Acceleration of Non-regulated GM Technologies

ENERGY & ENVIRONMENT

84 COMMENTS

By 'Editing' Plant Genes, Companies Avoid Regulation

By ANDREW POLLACK JAN. 1, 2015

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Its first attempt to develop genetically engineered grass ended disastrously for the Scotts Miracle-Gro Company. The grass escaped into the wild from test plots in Oregon in 2003, dooming the chances that the government would approve the product for commercial use.

Yet Scotts is once again developing genetically modified grass that would need less mowing, be a deeper green and be resistant to damage from the popular weedkiller Roundup. But this time the grass will not need federal approval before it can be field-tested and marketed.

Scotts and several other companies are developing genetically modified crops using techniques that either are outside the jurisdiction of the Agriculture Department or use new methods — like "genome editing" — that were not envisioned when the regulations were created.

Canola plants at Cibus in San Diego, which has made the plants herbicide-resistant by changing their DNA instead of inserting foreign genes. Sandy Huffaker for The New York Times

nytimes.com/2015/01/02/business/energy-environment/a-gray-area-in-regulation-of-genetically-modified-crops.html

Basis of GM Regulations ~30 Years Old

Current US GM regulation is defined in the 1986 Coordinated Framework for the Regulation of Biotechnology

- 1992 Update clarified regulation be based on product characteristics, not the process used to create it *link*
- Last reboot attempt in 2008 failed.
  - Proposed rule withdrew on March 4, 2014 *link*
- Public consultations have started.
  - IFB submitted comments along with 196 others *link*

Coordinated Framework Reboot

July 2, 2015

MEMORANDUM FOR HEADS OF FOOD AND DRUG ADMINISTRATION, ENVIRONMENTAL PROTECTION AGENCY, AND DEPARTMENT OF AGRICULTURE

SUBJECT: Modernizing the Regulatory System for Biotechnology Products[1]

Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.[2] This memorandum initiates a process to modernize the Federal regulatory system for the products of biotechnology and to establish mechanisms for periodic updates of that system. The objectives are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment.

Each of the Federal regulatory agencies with jurisdiction over the products of biotechnology has developed regulations and guidance documents to implement its authority under existing laws, resulting in a complex system for assessing and managing health and environmental risks of the products of biotechnology. While the current regulatory system for the products of biotechnology effectively protects health and the environment, in some cases unnecessary costs and burdens associated with uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes have arisen. These costs and burdens have limited the ability of small and mid-sized companies to navigate the regulatory process and of the public to understand easily how the safety of these products is assured; and, accordingly, they have the potential to reduce economic growth, innovation, and competitiveness.

Advances in science and technology, moreover, have dramatically altered the biotechnology landscape since the 1992 update of the CF. Such advances can enable the development of products that were not previously possible. A further update of the CF is needed to facilitate the appropriate Federal oversight by the regulatory system and increase transparency, while continuing to provide a framework for advancing innovation.

Canada Regulates on Novelty of the Product

Chestnut & Ash ranges extend into Canada

- IF a GM forest tree is given non-regulated status in one country, will genes recognize the border and stay out?
- How would Canadian Food Inspection Agency (CFIA) view a cisgenic GM forest tree on novelty grounds?
- What can we learn from a system based on product novelty, and is process agnostic?

Fun Fact: The largest living organism is a colony of Quaking Aspens called Pando in Utah sharing a root system weighing approximately 13,000,000 pounds, or about 110 M1 battle tanks

FHI Has Learned a Lot

1. Current regulatory requirements placed on out-planting genetically modified (GM) forest trees represent a significant impediment to cost-effective and timely consideration of the potential of modern biotechnology as a tool to address forest health challenges.
2. It is reasonable to expect approvals for out-planting to take 15 years or more
3. There is no group like the FHI – we have a unique ability to affect positive change

FHI 2015 Regulatory Engagement & Communications Plan

FHI SC approved a plan to develop a strategy

we are here not started

- Objective: Explore if there are effective but less onerous regulatory options
- Approach: Focus on safety, efficacy, core values
  - Public ownership of IP
  - High transparency
  - Multi-stakeholder collaboration

Working With Steering & Science Committees

- Develop options with input from the FHI committees and external experts to detail the pros, cons, and opportunities associated with an Adaptive Management plan, or an alternative regulatory framework
- Establish a communication chain of command for ongoing regulatory activities
- Get approvals from the SC and the SAC before new information is given to government officials or the public
- The SC and SAC will weigh in on development of options
- The SC will decide whether and when to approve actions involving outreach and information sharing

Some Ideas

- We will be working with experts to develop a strategy. Some questions for discussion:
  - What if EPA took regulatory lead for forest health challenges where risk of inaction >>> greater than risk of action?
    - EPA is 'NEPA proof'
    - Product registration & renewal process in place
  - What if FIFRA were updated to exclude PIPs that naturally occur in the environment?
  - What if a tiered approach were implemented at APHIS to recognize differences between well researched vs novel traits (moving closer to Canada's PNT approach)?

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More Ideas

- What if APHIS's 'limited commercial release' was modified for forest health purposes?
  - Large-scale field trials extended to natural ecosystems with ongoing monitoring requirements
- What if forest management systems implemented GM tree mechanisms?
  - Incorporating a GM tree registration and monitoring system
  - Integrate management along research -> growth -> deployment chain instead of just at deployment
  - Public/private cooperation with reporting to agencies
- Note: Regulatory agencies should always have authority to rebut any presumptions, but have options for flexibility

Expected Outcomes

Provide FHI concrete deliverables showing:

1. We have furthered FHI's understanding of regulatory options (conventional release, limited commercial, …?)
2. We have helped evolve regulations and expanded prospects of using advanced biotechnologies for forest health by using using the Chestnut and Ash as a real-world examples
3. We have enlisted additional support from current and new stakeholders to expand public/private partnerships in the area of using advanced biotechnologies to improve forest health

To make FHI More

Nimble

Effective

Financially viable

Fun Fact: The Emerald Ash Borer is estimated to cost communities more than $10,000,000,000. This figure doesn't include damages to forests.