Forest Health Initiative

Year 2 Annual Report:
July 1, 2010 – June 30, 2011

Executive Summary

The Forest Health Initiative (FHI) is a three-year project exploring whether there is an appropriate and valuable role for biotechnology in protecting and restoring North America's increasingly threatened forest ecosystems. FHI's focus on biotechnology is driven by the need for new tools to fight a growing number of pests, diseases and pollutants—and a host of new stresses induced by climate change—that each year destroy millions of acres of native forest. America's once-dominant Chestnut and Elm forests have been virtually wiped out by invasive disease while today, the fight is on to save the Eastern Hemlock of the Southern Appalachians, the ash forests of the Midwest, and the suddenly vulnerable conifer stands of the American west.

FHI believes the best way to fully explore the many scientific, environmental, social and regulatory challenges surrounding the use of biotechnology to protect natural forests is to develop a test tree that responds to an existing threat to forest health. FHI is currently supporting an effort to revive the American chestnut by developing and testing in confined field trials a transgenic variety that could provide a safe and effective way to rapidly achieve blight resistance.

The specific goals of this program include developing:

1. A holistic approach for biotechnology to address emerging forest health threats by assessing not just the science but the societal and regulatory issues concurrently.

2. Biotechnology tools (i.e., the science and technology) derived from genomics, marker-assisted selection, and transformation of American chestnut to be used to save other forest tree species that are threatened by catastrophic loss.

3. Concurrent dialogue with all stakeholders to better understand concerns, inform our science and regulatory efforts, and create a more informed citizenry about forest threats and opportunities to overcome these threats.

4. Acceptable protocols for testing transgenic forest trees, integrating biotechnology with traditional breeding and silvicultural practices, and using these appropriately for forest health purposes.

The project provides funds to accomplish objectives in three areas: 1) Scientific development of genetically engineered (GE) trees for forest health and, in particular, expansion of GE American chestnut as a model for testing forest health issues; 2) Regulatory and Intellectual Property needs/issues for GE forest trees, utilizing GE American chestnut as a test case; and 3) Addressing societal concerns about GE developed trees to answer forest health problems.

The project is organized around three fully coordinated groups in pursuing the initiatives objectives through a "braided" approach. These include a Science Group, a Social/Environmental Group and a Policy/Regulatory Committee. The effort is overseen by a Steering Committee.

FHI is funded by the US Forest Service, the US Endowment for Forestry and Communities, and Duke Energy and is guided by a steering committee that includes experts from the Environmental Defense Fund and The Nature Conservancy.

Steering Committee Members:

- Carlton Owen, *Chair*, President & CEO, US Endowment for Forestry & Communities; sponsor
- Dr. Jim Reaves, Deputy Chief for Research and Development, USDA Forest Service; sponsor
- Dr. Steven Hamburg, Chief Scientist, Environmental Defense Fund
- Mariann Quinn, Director, EHS Policy and Strategy, Duke Energy; sponsor
- Dr. Peter Roussopoulos, Retired – USDA Forest Service
- Dr. Faith Campbell, Senior Policy Representative, The Nature Conservancy

Summary of Accomplishments: July 1, 2010 – June 30, 2011

The Science, Social/Economic and Regulatory/Policy groups actively organized and pursued the objectives of the FHI over the past year. The second Annual Meeting was held in Washington, DC, June 2 – 3, 2011. Forty-five participants attended the meeting from the Steering Committee, Science Advisory Committee, Science Team, Social and Environmental Group, Regulatory and Policy Committee, as well as representatives from the regulatory agencies and invited stakeholders. The meeting highlighted research results, complimentary policy work, and showcased an outreach and communications presentation prepared by a communications firm.

Based on the reports of the science representatives, a clear path has been laid to have plantable trees ready in 2012. These trees will express genes identified under FHI as having potential for enhancing blight and ink disease resistance. The Science Group will document the collaborative processes employed so it may be used as a model in the future.

Given the feedback at the June session, the Social and Environmental Group is now prepared with an outreach and communications presentation to generate broad external discussion on the issues surrounding deployment of a transgenic American chestnut. This will be a critical component of the work of the FHI in the coming months. In addition the Thinking Tree project (described below) provides a framework for constructive discussion between FHI participants.

Following the advice from the Regulatory/Policy Committee members, a biological review paper for American chestnut, an intellectual property review, and NEPA overview for GE trees were commissioned. This information will help regulators determine necessary testing to be done and guide the research community in its permitting and field testing phase.

Included in this report are:

- Highlights of accomplishments from each of the three groups
- Summary reports from each group
- Appendix of supporting documents

I. Science Highlights

The Science Group is comprised of researchers from US Forest Service, Penn State University, University of Georgia, SUNY-ESF, and Clemson University. These institutions cover much of the natural range of the American chestnut and each has a long-standing and successful research program in this area. Summary research reports for each organization (UGA, SUNY, PSU, USFS) are attached.

Genomics – Genome sequencing

- Produced paired-end sequence data.
- Covered the physical map with BAC-end sequences.
- Commenced gene identification and characterization:
    - Transcripts aligned to the genome assembly
    - Assembly searched for genes
    - Preliminary annotations of genes conducted
- Strategy for resistance gene discovery updated.

Germplasm–Breeding and Testing

- Identified and prioritized high-quality candidate genes for transgene (going to cisgene) testing.
- Identified and mapped high-quality DNA markers for marker assisted selection.
- Identified and delivered high-quality germplasm for clonal testing and experimental materials to the clonal testing group.
- Developed and expanded new initiatives on early, reliable screening for blight and Phytophthora resistance.

ClonalTesting & Gene Transfer

- Over 170 new embryogenic chestnut cultures initiated for clonal testing and transformation.
- Germplasm agreements allowed initiation of the first ever TACF B3F3 embryogenic cultures for clonal testing.
- Bioreactor technology has accelerated candidate genes through the "pipeline" by 12X.
- 18 candidate genes and 3 reporter genes transformed into multiple chestnut genotypes.
- Chestnut cultures can be screened for stable transformation only 6 weeks after transformation.
- First "southern" field test of transgenic chestnuts established.

Transgenic Testing

- Leaf assays are being developed as an early, non-destructive assay for blight resistance; first transgenic events are looking promising.
- Currently there are over 400 transgenic trees in the field representing 23 events. Will have over 500 trees & more events by end of the year.
- Testing insert copy number, gene expression, & leaf assays.
- Have cloned 20 "cisgenic" candidate genes from Chinese chestnut; 19 for Chestnut Blight and 1 for Ink disease (*Phytophthora* root rot). Most are in the transformation pipelines at SUNY-ESF or UGA.
- Are testing early (continuous) flowering genes to enhance breeding.

II. Social/Environmental Highlights

The Social/Environmental Group (SEG) is comprised of a diverse mix of more than 20 stakeholders including environmental groups, state and federal agencies, landowners, social interest and professional organizations.

Thinking Tree: The October 22, 2010 conference call to discuss comments generated by the review of the documents drafted by the Social/Environmental Group (SEG) attracted broad participation by FHI participants. On the call, FHI participants agreed that it was important to have a definition of "biotechnology" that all participants could agree on for the purposes of internal discussions. Those on the call agreed that the definition of biotechnology is much broader than Genetic Engineering (GE) and is a continuum that includes the use of DNA markers derived from genome sequence as an aid to breeding and selection, to cloning individual trees as an aid to plant material scale-up, to developing a genetically modified tree that could not be produced through traditional breeding. All of these biotechnology tools enable the possible production of well-adapted trees that could potentially be deployed in restoration or mitigation efforts – with the key feature that they are faster and more efficient than non-biotechnology based approaches. However, GE trees generate added scrutiny under the current US regulatory environment.

Those on the call agreed that it would be helpful to develop a series of science-based questions to evaluate the best available options for addressing forest health challenges and if a GE tree turned out to be a logical option, what kind of foreseeable risks needed to be addressed. John Davis and Steve Hamburg, together with FHI staff agreed to develop a discussion paper (attached) to generate FHI participant understanding and agreement on the concept of a decision tree and a process for crafting a "decision tree."

Since then, those who volunteered to participate on a task group to develop a decision tree (Steve Hamburg, John Davis, Faith Campbell, Steve Strauss, Pat Layton, Maud Hinchee, and Kim LaDuke) have agreed that it is more appropriate to view their work as a "thinking tree" as the model to generate discussion within the FHI around all the nuances rather being a strict process for decisions. Attached is the current *DRAFT* version of the thinking tree model. In addition, attached is some of the detailed support documentation the task group is considering. The Thinking Tree Task Group will adjust the model and the detailed support documentation based on input from the June 2011 FHI meeting and a subsequent meeting in September 2011.

FHI Outreach: The FHI Social/Environmental Group (SEG) was organized to ensure that all stakeholder groups had the opportunity to provide guidance on whether and how biotechnology should be deployed to address forest health challenges. Since the SEG was established it has developed draft principles and a draft outreach and communications plan. In October 2010 the full FHI group discussed these materials and suggested to the FHI Steering Committee that a professional communications consulting firm be contracted to refine messages and develop a presentation that could be used by all FHI participants in outreach efforts.

In December 2011 the Steering Committee agreed to engage Burness Communications to develop outreach messages and materials. Since then Burness has reviewed all of the SEG material, developed some key messages and a power point presentation for use by FHI participants (attached). We used the power point presentation for a webinar with USDA Forest Service representatives on May 24.

Representatives from Burness Communications presented their recommendations to our group on June 2. On June 3 we invited stakeholders in the D.C. area to participate in a discussion on the FHI. We will use the presentation developed by Burness Communications, as modified by our discussions during the annual meeting, as a means to introduce the FHI and generate discussion.

III. Regulatory/Policy Highlights

The Regulatory/Policy Committee is overseen by the Institute of Forest Biotechnology with input from the three US regulatory agencies with oversight of GE trees: USDA APHIS, EPA, and FDA. Other members include experts in intellectual property law and NEPA law.

General Policy Response Plan

The following 8 components are integral to a policy plan that quickly responds to forest health threats with biotechnology tools. The left column shows the relative order of components grouped into phases, and how early to start working on them. Relative timing of phases is important, but there is overlap and many components can happen concurrently.

Phase 1

Start 5 years prior to possible deregulation and use

1. **Open lines of communication with policy stakeholders**
   Objective: Foster open discussions to guide biotechnology efforts
   Communicating with key policy stakeholders is a critical step because it will help guide all of the following steps that have regulatory implications. In general, the earlier an initial communication is made the better. However, planning for a product that is more than five years away will make the discussion less concrete to regulating agencies.

2. **Engage a wide spectrum of additional stakeholders**
   Objective: Increase understanding between FHI participants and stakeholders
   Creating a positive, collaborative dialogue with many types of stakeholders is critical because healthy forests are a social good. Topics should include the environmental and economic impact of the forest health threat and the corrective options available.

Phase 2

Start 3-5 years prior to possible deregulation and use

3. **Review intellectual property**
   Objective: Understand which biotechnology options are available
   Intellectual Property (IP) holders are stakeholders with legal recourse based on patents they own. IP reviews, also referred to as patent landscapes, help researchers determine what direction research is moving in the field, can help identify competitors, and identify the geographic areas where research is occurring. More specifically, a detailed review of patents can be used as an examination of potential patent problems that may interfere with future research in an area and commercialization of discoveries. However, a patent landscape is not a legal opinion on freedom to operate. Costs vary, but initial, overview IP reviews cost about $15,000.

4. **Assemble a biological dossier**
   Objective: Provide stakeholders a single biological information resource
   A detailed document covering both the forest health threat and the tree species in danger helps regulating agencies, stakeholders, and research scientists communicate more effectively by referring to common information. This information is very useful in making regulatory decisions and environmental assessments. Costs vary, but an initial, overview biological dossier costs about $15,000.

5. **Review the regulatory landscape**
   Objective: Understand the framework that regulatory agencies work within
   A review of the current state of regulations and related lawsuits that control or influence the use of biotech trees for forest health is necessary before a regulatory course can be planned. This step also helps guide scientific efforts and public interactions. In the U.S., there are three government agencies that can have jurisdiction over the development and deployment of biotech trees:
   - U.S. Department of Agriculture's (USDA) Animal Plant Health Inspection Service (APHIS)
   - U.S. Environmental Protection Agency (EPA)
   - U.S. Department of Health and Human Services' Food and Drug Administration (FDA)

   Regulatory landscape reviews vary in cost, but a basic review costs about $15,000.

Phase 3

Start 3-1 years prior to possible deregulation and use

6. **Query agencies to define a regulatory course**
   Objective: Gather specific information about the regulatory process
   In order to develop a concrete plan to use a biotech tree for forest health, routine interactions with regulatory agencies are necessary. Since regulators are mandated to respond to discrete requests, this step will involve a number of iterative questions and answers to and from the agency.

7. **Prepare an environmental report**
   Objective: Assess the risks and benefits of using the biotech tree
   The U.S. National Environmental Policy Act (NEPA) applies to all three agencies in situations that could potentially have a large effect on the environment. It is likely that NEPA will play an increasingly large role in the regulation of biotech trees in the future. Preparing an environmental report is a major step in addressing NEPA issues. In addition, this document is a useful tool to further engage regulatory and public stakeholders on project details. Costs vary, but basic environmental reports start at about $100,000

8. **Interact with agencies on future regulations**
   Objective: Increase the effectiveness of regulations that deal with biotech trees
   Regulations change slowly over time while forest health threats move quickly. By and large, environmentally focused stakeholders believe that helping agencies evolve their regulations is critically important to ensure that the risks of using advanced biotechnologies are reduced, while the benefits from these technologies are increased.

This generalized policy rapid response plan was synthesized during the FHI's policy work, which is ongoing, and will likely evolve as the FHI's efforts progress. To date the process has been very iterative and is a result of many collaborators from academia, industry, government, and non-profit organizations.