Environmental Regulation of Tree Biotechnology for Wood and Bioenergy: Effect of USDA and EPA Regulations on Research, Breeding, and Commercial Products

A proposal for the

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ABSTRACT

Despite great hope for tree biotechnology to contribute toward improved economic and environmental sustainability of tree farms for wood, fiber, and energy products, there have to date been no releases of any genetically engineered (GE)[1] forest trees. In contrast, GE varieties account for a majority of the soy and cotton crop is the USA, and fruit from GE papaya trees have been on the market for more than 10 years. To help understand how regulations have affected development of GE forest trees, we propose to examine the Coordinated Framework for Regulation of Biotechnology that was published on by the Office of Science and Technology Policy on June 26, 1986 (51 FR 23302). Its rules spell out the coordination responsibilities among FDA, USDA, and EPA—operating under their existing statutory authorities—with respect to most types of genetically engineered plants and animals. In the course of implementation, there have also been many rules, guidances, legal actions, and publications that have helped to clarify the detailed activities and information required by regulations. Our goal is to objectively describe—from the viewpoint of a research scientist, breeder, development company, or university that must comply with the regulations—how the implemented regulations at USDA and EPA have affected research and commercialization of GE forest trees. We will also consider several case studies that will include the most widely grown plantation tree species in the USA, and the traits of most promise and interest to growers. Our analysis will be based on detailed reviews of regulations and published literature, court decisions and interviews with several dozen research scientists, research administrators, and regulatory agency professionals. In addition, we will conduct a small, formal survey of researchers to quantify the opinions and issues identified in the literature review and interviews. This work will build upon prior Mellon/RFF-supported work by Sedjo that considered the broad regulatory environment surrounding GE trees, especially economic prospects and trade issues. Our analysis is expected to inform ongoing efforts by USDA to substantially revise its regulations for GE crops and trees.

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[1] Genetically engineered (GE), genetically modified, recombinant DNA modified, and transgenic are terms that are typically used interchangeably and synonymously to identify crops that contain DNA that was modified using recombinant methods and inserted into its chromosomes asexually. Among scientists, the term biotechnology includes a much broader array of methods. However, the public and legislators often use biotechnology and genetic engineering synonymously, as was done in the Coordinated Framework for Regulation of Biotechnology.

BACKGROUND

Genetically engineered soy, corn, canola, and cotton are grown widely, and comprise a substantial portion of these crops in North America (USDA 2006). However, since GE methods were first applied to plants more than two decades ago, only a single GE variety of a tree—virus-resistant papaya that was authorized in the early 1990's—has been approved for commercial use (reviewed in Sedjo 2004). A second horticultural tree variety with a similar trait, virus-resistant plum, is now being considered by USDA for commercial authorization. Outside of China—where there are limited commercial uses of GE poplars—no forest trees appear to be approaching commercial deployment (FAO 2005). This is in spite of a large number of field trials worldwide, a great deal of early optimism about the prospects for biotechnology in non-food crops, the amenability of intensively cultivated trees such as poplars to GE methods, and the large number of field trials (>> 100) that have shown that GE-imparted traits are stable and likely to be useful (Strauss et al. 2004, Poupin and Arce-Johnson 2005, Nehra et al. 2005). In fact, most large forestry and horticultural companies appear to have stopped or restricted their development efforts in GE, which are widely believed to be mainly due to regulations and other social, rather than biological, factors (Nash 2003). Surprisingly, despite renewed interest in trees as biofuels—and some obvious opportunities for GE to increase feedstock yield, cost, or value—there appears to be little commercial efforts to use GE methods in variety development (Herrera 2006). The proposed research will examine the effects of the USDA and EPA regulation from the viewpoint of company and public sector (USDA, academic) developers to document how the regulations have been interpreted and implemented, and survey researchers and regulators to document how they believe this is affecting research and development toward commercial products.

Regulatory Environment

General framework. In 1986, the United States government published the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302). This policy outlined the regulation of products of "modern biotechnology" (i.e., recombinant DNA-derived, GE products) using existing statutes administered by FDA, USDA and EPA. These hot-linked web sites provide up to date, clear summaries of what is regulated by these agencies, new regulatory developments and initiatives, and direct access to the over-arching statues, rules, and guidances each has provided. A Pew Initiative on Food and Biotechnology Proceedings has documented how the Coordinated Framework affects state regulatory options. All of these resources provide direct access to relevant documentation for this project.

USDA. USDA regulates biotechnology under the Animal and Plant Health Inspection Services (APHIS), Biotechnology Regulatory Services. It derives its authority to write regulations from provisions of the Plant Protection Act, which is a part of the larger Agriculture Risk Protection Act of 2000, that incorporated and updated a great deal of earlier regulation on plant pest control. It and other relevant USDA regulations can be found at this web site that outlines USDA regulatory authority. USDA has the lead agency role over all field research with GE organisms that stays within prescribed limits in field size, and for which there is no permanent spread into the larger environment or food. They are also the lead agency for authorizing deregulation (unrestricted growth in the environment) for all but the EPA-regulated PIP-containing crops, discussed below. These rules are outlined in the Federal Code of Regulations, Volume 7, Section 340. Technically, USDA has regulated recombinant DNA products because plant pests such as the gene insertion tool *Agrobacterium*, and sections of plant pest genomes such as the cauliflower mosaic virus promoter, have been widely used in their production, thus pathogenic properties might be inadvertently inserted (Medley and McCammon 1995). This pest-focused system has evolved into a system where USDA appears to now be asserting authority over all products of recombinant DNA modifications, an expansion in authority that may be consistent with the expanded definition of a "noxious weed" in the Plant Protection Act (S. McCammon, USDA APHIS, pers. comm.). It now states that a noxious weed is "…any plant or plant product that can directly or indirectly injure or cause damage to crops." Detailed guidelines on the kinds of information researchers would need to provide to USDA are available under "guide for preparing and submitting a petition"—enabling us to assess its likely effects on research and development of GE trees. USDA regulators have also made a number of detailed presentations on information needed for petitions for trees (e.g., Cordts 2006).

EPA. EPA regulates biotechnology under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which covers the domestic manufacture, sale, and use of all pesticides, including those incorporated into plants via genetic engineering (known as PIPs, plant incorporated protectants). Under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA has the authority to ensure that any pesticide residue in or on a food product falls within a safe limit (known as a food tolerance), or an exemption from the requirement of a tolerance is granted. Under this regulation they are responsible for herbicide residues present in GE herbicide tolerant crops and trees. Under the Toxic Substances Control Act (TSCA), EPA tracks all chemical substances or mixtures of chemical substances produced or imported into the USA. Genetically engineered microorganisms and trees engineered for removal of toxins from the environment would fall under this regulation (Bryson et al. 2004). FIFRA and section 408 of FFDCA are administered by the Office of Pesticide Programs (OPP), while TSCA is administered by the Office of Pollution, Prevention, and Toxics (OPPT). With respect to PIPs, a number of key guidances and interpretations of the regulations have been provided in their July 19, 2001 notice in the Federal Register and associated documents, which are available at this hot-linked EPA site: Plant-Incorporated Protectants Rules.

Recent court cases. There have been three recent court cases that have seriously challenged USDA's regulatory scope and actions, and are likely to result in significant changes in regulatory policies that affect forest trees in the near future. In CFS/FOE/PANNA vs. USDA (2006), the USDA was told it must seriously consider effects on endangered species from field trials of GE biopharmaceutical-producing crops—even though the size/scope of research trials would appear to have made such a consideration moot in this case. In Geertson vs. USDA (2006), the USDA was informed that its consideration of the economic impacts of GE alfalfa—which it deregulated in 2005 to allow commercial use—was inconsistent with the National Environmental Policy Act with respect to consideration of possible economic effects of on organic and conventional alfalfa growers. And in ICTA vs. USDA/Scotts, USDA was criticized for allowing a large field trial of GE bentgrass when there were reasons to expect that gene dispersal from the trial could be substantial. Studies have since shown dispersal of the GE grass over many miles, including into a National Grassland (Reichmann et al. 2006). These court cases are likely to result in important changes in regulations of relevance to GE trees as a consequence of their potential for long-distance gene dispersal by pollen and seeds, economic impacts from spread onto conventional and FSC certified forest lands,[2] and their large ecological footprints. The Hawaii ruling on biopharmaceutical-producing crops are likely to affect rules for all bioindustrial crops, as USDA regulates these in the same stringent manner (see USDA Permits for Pharmaceutical and Industrial - Expressing Crops). GE trees for bioenergy under the "biorefinery" (multiple-products) concept of DOE may be designed to produce additional products, such as enzymes to aid in their processing, or co-products such as precursors for bioplastics, and would therefore fall under these regulations.

Relation to Previous RFF-Supported Research

In 2002 Roger Sedjo received a Mellon RFF Fellowship in Environmental Regulatory Implementation for a project entitled "A Systematic Examination of Environmental Regulations Related to the Commercialization of Transgenic Trees for the Production of Timber and Industrial Wood." That effort resulted in a Final Report to Mellon in 2004 which laid out the standards and procedures necessary for the deregulation of a transgenic tree. Twelve papers published in peer reviewed professional journals, chapters in scholarly books, and reports, have resulted (abbreviated resume attached). This report sets the stage for our current proposal, which will take a detailed look at how the regulations, and their

[2] The Forest Stewardship Council (FSC) forbids any use of GE trees, even for research, on certified lands (Strauss et al. 2001). It is unclear what impact on certification, or marketing, the unintended spread of GE propagules onto FSC certified lands might have.

interpretation by regulators at USDA and EPA, affect the capacity of public and private research organizations to conduct research and produce tree varieties.

Our proposed work will be substantially aided by having an active biotechnology researcher, PI Strauss, leading on the report. Strauss has given many invited lectures on GE regulatory issues (CV attached), conducted GE research with trees for more than 20 years, and has interacted intensively during that time with forest and agricultural biotechnology industries, and regulators at USDA, EPA, and FDA. The proposed research will also differ from the prior study by Sedjo in its intense focus on the research community, conduct of a survey to quantify regulatory implementation effects, and its consideration of EPA as well as USDA regulations. As discussed above, EPA has oversight responsibilities for regulation of pest resistant and phytoremediation-active GE trees. These kinds of trees may be important for managing exotic pests that are damaging wild forests (Bauer 1997, Adams et al. 2002, Mann and Plummer 2002, Strauss et al. 2001a), and for removal of industrial and agricultural pollutants from soils (e.g., Doty et al. 2000), respectively. The White Office of Science and Technology Policy conducted a number of case studies of regulation of new kinds of GE crops, including one on "bioremediation using poplar trees." This analysis, and the review by Bryson et al. (2004), will facilitate our analysis of how the several kinds of EPA regulations pertaining biotechnology affect development of commercial products.

Rationales and Issues Motivating this Study

Bioenergy. There is growing interest in the use of lignocellulosic energy crops in the USA as a result of rising energy costs, security risks from the use of imported fuels, and greenhouse gases that are leading to global climate change. In addition to maize, the two major types of dedicated crops proposed for use are perennial grasses such as switchgrass, and fast growing trees such as poplars. GE methods are of considerable interest for these crops (AC21 2006) due to the complex genetics of the grasses and the long generation times of trees, both of which retard breeding progress. Traits of considerable environmental and agronomic value include herbicide tolerance to facilitate weed control and promote conservation tillage (Cerdeira and Duke 2006, Strauss et al. 1997), pest tolerance to improve yield and reduce pesticide usage, and drought tolerance to reduce irrigation and related energy costs. In addition, there is interest in production of coproducts such as enzyme or bioplastics, or modifications to chemistry to promote processing, that would benefit from GE methods (e.g., Herrera 2005 & 2006, Kinitisch 2007). However, for all species gene dispersal to wild or feral relatives are major concerns—both in research and commercial stages—as a result of their long-distance pollen and/or seed movement, and presence of fertile relatives. USDA, and especially EPA regulations, due to their requirement for a complete absence of gene dispersal, may make the required research and breeding to develop these products very costly or impossible to conduct.

Containment. One way to reduce the issues of gene dispersal is to insert genes that impart infertility, either by acting on the male or female reproductive mechanisms, or both. GE methods are widely recognized to have great potential for creating and inserting genes for sterility. These would also reduce the large impacts from spread of exotic, weedy trees (Richardson and Petit 2005, Hoenicka and Fladung 2006, Brunner et al. 2006). Without such mechanisms, there is certain to be extensive "contamination" of wild species—both from pollen and seed spread—which some scientists and many members of the public find noxious almost regardless of benefits (e.g., Williams 2005). The same restrictions to transgene dispersal during research that are imposed by regulations appear to also apply to infertility genes, which may make the research needed to identify the best and most stable methods for containment very costly or impossible to conduct.

Integration with breeding. Even in the absence of regulations, there are considerable biological and business obstacles to use of transgenes in breeding of forest trees (Cheliak and Rogers 1990, Sedjo 2006). It is important to understand these complex, and often interactive, issues so that the additional effect of regulations on research and development are not inflated. The key issues are likely to include: 1) whether use of GE methods requires clonal propagation and deployment, and if such cost-effective methods are in place. For conifers, for example, such methods rely on somatic embryogenesis, which are generally not cost-effective, though research on them continues at a rapid pace. GE benefits might have to be high enough to warrant a major change in genetic deployment method. 2) The added costs and delays from adding transgenes to elite genotypes, and then needing to field test the GE-versions of these genotypes for several years to verify their new properties and retention of basic elite breeding value, would occur while breeding for new varieties continues in the base, non-GE breeding program. This would result in a lag where the GE varieties are a generation behind the non-GE, conventionally bred trees, making it difficult to compete unless the transgenes deliver extremely high value. The lag would be especially great if, in addition to GE-specific trait and field testing, an array of longer-term ecological research (e.g., Farnum et al. 2006) is also required due to regulations. Thus, the interactive effect of breeding lag, and the high costs and further delays from regulatory requirements, may make use of transgenes in tree breeding too costly for operational programs to consider. 3) The requirements for strict containment and monitoring of field trial sites—which are often remote and difficult to travel to, and numerous, in forestry programs—may make the multiple-year, multiple-site field trials that are a routine and essential part of breeding difficult to afford (Valenzuela and Strauss 2005). Companies may not be able to bear the expense or liability risk if trees "escape" from the site by biological means (flowering, vegetative propagation), via theft, or via lapses in control due to financial and management changes (e.g., from the commonplace changes in ownership of forest lands in the USA).

Input to fast changing regulations. A major usefulness of this project would be the help it would provide regulatory agencies in determining whether to revise their regulations so they are more appropriate for "specialty crops" generally, of which forest trees are one type. Specialty crops include all of the non-commodity agricultural crops, for which the diversity of varieties and products is usually far higher, and total value of each variety lower, making the costs of regulations a major issue (Bradford et al. 2005). USDA has held two meetings and funded a pilot "Specialty Crops Research Initiative," and the Pew Initiative on Food and Biotechnology has held two national workshops on the topic, one in June 2004 and one in January 2007 (not yet published online). PI Strauss was an invited participant and speaker at these two meetings, respectively. They have also held a tree GE workshop, and are planning another in April 2007. APHIS is seeking to revise their regulations, and is conducting a general environmental impact statement of their regulations for GE crops to help in identifying desirable changes. The kinds of changes under consideration based on the USDA web site are described below:

> "*Revision of APHIS Biotechnology Regulations*
> APHIS is currently developing an Environmental Impact Statement in association with its proposed biotechnology regulatory revisions. APHIS is considering revising its regulations to better position the Agency to meet the challenges that will be posed by the next generation of biotechnology products. In the EIS, BRS is exploring the environmental impacts of a wide range of regulatory options. Among other changes, APHIS BRS is considering: expansion of the scope of regulation to include the noxious weed authority given by the Plant Protection Act of 2000, development of a multi-tiered risk-based system for field trials, use of compliance agreements, between APHIS and producer, for commercial production of plants not intended for food or feed. The DRAFT EIS is currently undergoing internal review and clearance, and APHIS anticipates making the draft EIS available for public comment in 2007. A proposed rule will follow."

These changes could have strong effects on regulation of tree biotechnology, possibly by increasing stringency and costs—which the recent court cases discussed above provide new impetus for. They might also reduce stringency for some kinds of traits if the "multi-tiered, risk based system" cited above is put in place, perhaps enabling high benefit and low risk traits like tree sterility and modified wood properties to be employed in routine field trials during breeding (Strauss 2003). In addition, a move away from gene insertion "event" based regulation is under consideration—which would significantly reduce regulatory burden for GE trees and other vegetatively propagated crops (Bradford et al. 2005). Alternatively, a new definition of "noxious weed," as discussed above, may make *all* GMO releases problematic if USDA concludes that all releases of transgenes are potential economic harms to agriculture, as the GE alfalfa case (Geertson vs. USDA 2006) might suggest. Fortunately, these changes are expected to occur within the period of the proposed study—making this an opportune time to carry out the work.

Regulatory costs and comparative advantage. It is widely acknowledged that the costs and data required by regulations are major impediments to release of GE crops of any kind. This is true for major players such as Monsanto and DuPont, as well as for breeders in small companies and land grant universities. The same perception is strong among tree biotechnologists (Strauss and Bradshaw 2004, preface). It is also well-known that foreign producers of wood, especially those growing plantations in the southern hemisphere, are likely to have fewer constraints and other economic advantages from use of GE (Sedjo 2005). This trend that has also been accelerated by changes in forest ownership in the USA toward organizations such as TIMOs and REITs[3] that are generally less willing to invest in research. This means that the strength of regulations in the USA may have important economic effects in making US producers less able to take advantage of the US's superior scientific and technological capital. The net result may be an accelerated loss of economic competitiveness by the US forest and renewable energy industries.

Regulations for 'adventitious presence' are critical for trees. It is widely recognized that genes are hard to contain, whether bred via GE or conventional methods. The unintended presence of regulated genes is known as 'AP' or 'adventitious presence.' The promiscuity of genes in the environment has become a major legal issue in agricultural crops (AC21 2006) and will be even more difficult in trees. This outcome is a result of strict regulations surrounding GE, the highly variable patchwork of national approvals and bans around the world, and the existence of marketing systems such as organic certification of food and green certification of forests (Strauss et al. 2001b) that discriminate against GE presence. Trees such as conifers are particularly problematic because of the ability of their pollen and seed to move over large distances, and because of their ability to establish progeny in the wild (Williams 2005). The legal settlements over AP have cost hundreds of millions of dollars in some cases, raising questions as to whether *any* kind of GE tree can be affordably produced under the current regulatory regimes (Bryson et al. 2004). Thus, a detailed consideration of regulations surrounding AP and how its management, its attendant liability risks, and its effects on research and breeding (discussed above), are central considerations for this project.

RESEARCH PLAN

Methodology and Objectives

1) **Analysis of relevant legislation, regulations, guidance, perspectives, and legal actions administered by the USDA and EPA.** The PIs will ensure that they are thoroughly up to date in their knowledge of current regulations and guidance, legal rulings, and scholarly interpretations of regulations and trends. Rachel Lattimore, Esq. (letter attached), a legal expert in the U.S. regulation of bioengineered crops and plants, has agreed to provide *pro bono* legal advice for this project, should it be needed to help understand the regulatory implications of recent court rulings.
2) **A description of the likely implications of these rules for developers of biotech products, both at field research and commercial development stages, and for specific case studies.** Our interpretations will also be tested in our contacts with officials at regulatory agencies and researchers that have active notifications or permits from USA or EPA (discussed below). What are the kinds of data needed, and how much time, effort, and cost are likely to be required? Is the work in fact possible to carry out given the constraints on field studies and environmental releases? Have these costs driven, or are they threatening, to drive developers/researchers out of the field? We will consider several case studies in detail that are likely to include pines, poplars, and eucalypts grown for bioenergy, fiber, and/or wood products. GE traits under consideration are likely to include growth enhancement, wood property modification, infertility, cold tolerance, disease resistance, insect resistance, and phytoremediation.
3) **Formal interviews with a wide range of public sector and company scientists, research administrators, and regulators about the requirements for GE tree research and product development.** Learn how the implemented regulations and guidance is understood by researchers and developers, obtain their evaluation of results from the case studies, and assess their views of the

[3] TIMO: Timber investment and management organization; REIT: real estate investment trust.

effects of regulations on research and commercial development of GE trees. For the researchers, we will seek to understand their product goals, and the extent to which they believe the regulations provide manageable or insurmountable requirements for research and commercial release. We will assess the extent to which they believe they are able to cope with regulations given costs and risks, and the degree to which they and their institutions are able to accept the apparent risks and liabilities associated with research on trees in the field over multiple years, and in commercial releases. Strauss maintains a large network of colleagues, and many more will be identified via literature searches, studies of recent conference participants, and analysis of GE field test databases, such as that maintained for USDA at Virginia Tech (ISB). The status of all active notifications and permits, organized by applicant, can be accessed via USDA APHIS.

4) **A quantitative survey of affected researchers and companies, as well as the experiences of regulators, to quantify the views and actual impacts of regulations expressed in the interviews**. These will be formulated and reviewed by a statistician familiar with survey methods (e.g., available from the Survey Research Center at Oregon State University), and conducted by a student research assistant. This will cover research and development decisions; perceptions of cost and liability; views of regulatory soundness and workability; related marketplace and social issues, such as intellectual property and green certification/labeling (which may interact with regulatory requirements); and capacity for integration of GE trees into ongoing breeding programs and practices. The survey will be oriented toward determining the extent to which the regulations are viewed as manageable and therefore result in additional research, and the extent to which the regulations associated with GE tree development and deregulation are viewed as so onerous so as to skew researcher efforts to other endeavors.

Projected Outputs

The purpose of the proposed research is to systematically examine the implementation of the Coordinated Framework for Regulation of Biotechnology by USDA and EPA under their existing statutory authorities. Specially, the research and projected outputs will focus on an assessment of how the laws and regulations of the various agencies have affected GE tree developers and scientific research. The research outputs will include case studies that are likely to include the most widely grown plantation tree species in the USA, and the traits of most promise and interest to growers. Through and interview and survey data, the completed study will objectively describe how the regulation was promulgated and implemented, the reactions to the regulation(s) by various developers and researchers, without arguing in favor of any particular policy or result.

Publication Plans

The output of this research will be published as a monograph or book. Additionally, a number of published papers and book chapters are expected to result; the results of the case studies, interviews, and survey may provide the focus for different publications.

SCHEDULE

Duration of 24 months (begin summer/fall 2007, completed summer/fall 2009). Strauss plans to travel to RFF in fall 2007 for first 1 week consultation, then spend winter 2008 or 2009 in residence for 4 months, then spend one additional week in spring to summer 2009 to finalize reports.

PRIOR EXPERIENCE OF APPLICANTS (CVS attached)

Steve Strauss: Professor of Forest Science and Director of Biotechnology Outreach, Oregon State University; Leopold Leadership Fellow, Stanford Institute for the Environment; CV: 150 publications; one RFF book on forest biotechnology; $13.9 million research grants. More than 150 invited lectures, many in ecological and regulatory aspects of tree biotechnology.

Roger Sedjo: Currently Senior Fellow and Director of the Forest Economics and Policy Program at RFF. Author of 15 books and hundreds of published papers on forest and natural resources, including on biotechnology in forestry.

REFERENCES

AC21. 2006. Opportunities and Challenges in Agricultural Biotechnology: The Decade Ahead. USDA Advisory Committee on 21st century agriculture.

Adams, J.M., G. Piovesan, S.H. Strauss, and S. Brown. 2002. Genetic engineering of forest trees against introduced pests and diseases. Conserv. Biol. 16:874-879.

Bauer, L. 1997. Fiber farming with insecticidal trees. J. Forestry 95(3):20-23.

Bradford, K., N. Gutterson, A. Van Deynze, W. Parrott, and S.H. Strauss. 2005. Regulating biotech crops sensibly: Lessons from plant breeding, biotechnology and genomics. Nature Biotechnol. 23:439-444.

Brunner, A., J. Li, S. DiFazio, O. Shevchenko, R. Mohamed, B. Montgomery, A. Elias, K. Van Wormer, S.P. DiFazio, & S.H. Strauss. 2006. Genetic containment of forest plantations. Tree Genet. Genomes (Strauss is co-senior author) (online)

Bryson, N.S., S.P. Quarles, and R.J. Mannix. 2004. Have you got a license for that tree (and can you afford to use it?), Chapter 10 *In* S. Strauss and H. Bradshaw (eds.), The Bioengineered Forest: Challenges for Science and Society, Resources For The Future, Washington, DC.

Cerdeira, A.L. and S.O. Duke. 2006. The current status and environmental impacts of glyphosate-resistant crops: A review. J. Environ. Qual. 35:1633-1658

CFS/FOE/PANNA vs. USDA. 2006. United States District Court for the District of Hawaii, CIV. No. 03-00621 JMS/BMK.

Cheliak, W.M. and D.L. Rogers 1990. Integrating biotechnology into tree improvement programs. Can. J. Forest Res. 20:452-463.

Cordts, J. 2006. Identifying scientific issues to address regulatory requirements. Presentation in “Growing trees and stemming risks,” Institute of Forest Biotechnology Conference, Vancouver, BC (March 20).

Doty, S., T.Q. Shang, A.M. Wilson, J. Tangen, A.D. Westergreen, L.A. Newman, S.E. Strand, and M.P. Gordon. 2000. Enhanced metabolism of halogenated hydrocarbons in transgenic plants containing mammalian cytochrome P450 2E1. Proc. Natl. Acad. Sci. USA 97:6287-6291.

FAO. 2005. Preliminary Review of Biotechnology in Forestry. Forestry Dept., Food and Agricul. Dept. of the United Nations, Rome, Italy. 118 p.

Farnum, P., A. Lucier and R. Meilan. 2006. Ecological and population genetics research imperatives for transgenic trees. Tree Genet. Genomes (online)

Geertson vs. USDA. 2006. United States District Court for the Northern District of California, No. C 06-01075 CRB.

Herrera, S. 2005. Struggling to see the forest through the trees. Nature Biotechnol. 23:165-167.

Herrera 2006. J. Wood-based ethanol advances on international front. Industrial Biotechnology 2(2):101-107.

Hoenicka, H. and M. Fladung. 2006. Biosafety in *Populus* spp. And other forest trees: from non-native species to taxa derived from tradional breeding and genetic engineering. 20:131-144.

ICTA vs. USDA/Scotts. 2006. United States District Court for The District of Columbia, Civil Action 03-00020 (HHK).

Kinitisch, E. 2007. How to make biofuels poplar. Science 315:786.

Mann, C., and M. Plummer. 2002. Can genetic engineering help restore 'heritage' trees? Science 295:1628.

Medley, T., and S. McCammon. 1995. Strategic regulations for safe development of transgenic plants. Chap. 6 In: H.-J. Reim, G. Ree, A. Puhler, and P. Stadler (eds.), Biotechnology Vol. 12: Legal, Economic, and Ethical Dimensions, Weinheim, Germany.

Nash, S. 2003. The phantom forest: Research on gene-altered trees leaps ahead, into a regulatory limbo. BioScience 462-467.

Nehra, N.S. et al. 2005. Invited review: Forest biotechnology: Innovative methods, emerging opportunities. In Vitro Cell Dev. Biol.—Plant 41:701-717.

Poupin, M.J., and P Arce-Johnson. 2005. Transgenic trees for a new era. In Vitro Cell Dev. Biol.—Plant 41:91-101.

Reichmann, J., L. Watrud, E.H. Lee, C.A. Burdick, M. Bollman, M.J. Storm, G.A. King, and C. M.-Smith. 2006. Establishment of transgenic herbicide-resistant creeping bentgrass (*Agrostis stolonifera* L.) in nonagronomic habitats. Molec. Ecol. 15:4243–4255.

Richardson, D.M., and R.J. Petit. 2005. Pines as invasive aliens: Outlook on transgenic pine plantations in the southern hemisphere. Ch. 10 *In* C.G. Williams (ed.), Landscapes, Genomics, and Transgenic Conifer Forests. Springer, Netherlands.

Sedjo, R. 2004. Transgenic trees: Implementation and outcomes of the Plant Protection Act. Resources for the Future Discussion Paper 04-10.

Sedjo, R. 2005. Will the developing countries be the early adopters of genetically engineered forests? AgBioForum *8: 205-212.*

Sedjo, R. 2006. GMO Trees: Substantial promise but serious obstacles to commercialization. Silvae Genet. 55:241-292.

Strauss, S.H. 2003. Genomics, genetic engineering, and domestication of crops. Science 300:61-62.

Strauss, S.H., and H.D. Bradshaw (Editors). 2004. The Bioengineered Forest: Challenges to Science and Society. Resources for the Future, Washington, D.C. 245 pp.

Strauss, S.H., S.A. Knowe, and J. Jenkins. 1997. Benefits and risk of transgenic, Roundup Ready® cottonwoods. J. Forestry 95(5):12-19.

Strauss, S.H., S. DiFazio, and R. Meilan. 2001a. Genetically modified poplars in context. Forestry Chron. 77(2):1-9.

Strauss, S.H., P. Coventry, M.M. Campbell, S.N. Pryor, and J. Burley. 2001b. Certification of genetically modified forest plantations. Internat. Forestry Rev. 3(2):87-104.

Strauss, S.H., A.M. Brunner, V. Busov, C. Ma, and R. Meilan. 2004. Ten lessons from 15 years of transgenic *Populus* research. Forestry 77:455-465.

USDA. 2006. The first decade of genetically engineered crops in the USA. Fernandez-Cornejo, J. and M. Caswell. USDA Economic Information Bulletin No. EIB-11, 36pp.

Valenzuela, S., and S.H. Strauss. 2005. Lost in the woods. Nature Biotechnol. 23:532-533.

Williams, C. 2005. Framing the issues on transgenic forests. Nature Biotechnol. 23:530-532.