Transgenic Trees: Implementation and Outcomes of the Plant Protection Act

Roger A. Sedjo

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Resources for the Future
1616 P Street, NW
Washington, D.C. 20036
Telephone: 202–328–5000
Fax: 202–939–3460
Internet: http://www.rff.org

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Abstract

The responsibility for protecting U.S. agriculture from pests and diseases is assigned by the Federal Plant Pest Act (FPPA) to the Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture. The Plant Protection Act (Title 7 U.S.C. Sections 7701 *et seq.*) gives Aphis statutory authority over genetically modified organisms (GMO), in effect assigning to APHIS a related responsibility of determining whether a genetically altered plant, crop, or tree is likely to pose unacceptable risks to the environment. Although APHIS has considerable experience with crop plants, it has only limited experience with trees. Yet the possible benefits of applying genetic engineering to trees are substantial and include industrial wood production and environmental uses, such as toxic remediation and species restoration. This report focuses on the Plant Protection Act (PPA) and related regulations as they have been applied to timber transgenic trees.

Key Words: Forestry, biotechnology, transgenic, tree plantations, timber supply, genes, GMOs, industrial wood, economics, regulations, costs, benefits, conservation.

JEL Classification Numbers: JEL Q21, QW23, Q16, O32, L73

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I. Introduction

The responsibility for protecting U.S. agriculture from pests and diseases is assigned by the Federal Plant Pest Act to the Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture. In addition, the Plant Protection Act (Title 7 U.S.C. Sections 7701 *et seq.*) provides a related statutory authority to APHIS to regulate a genetically altered plant, crop, or tree on its potential to become a plant pest or pose unacceptable risks to the environment. Although APHIS has considerable experience with crop plants, it has only limited experience with trees.

APHIS administers regulations for most genetically engineered plant organisms, which are initially classified as "regulated articles." Developers of regulated articles must obtain prior authorization from APHIS for the importation, interstate transport, and field-testing of these plants. Field-testing is a precondition of deregulation, which in turn is necessary for the transgenic to be commercialized without restrictions. Based upon the results of field tests and other information, an APHIS scientific committee determines whether to deregulate specific transgenic plants. Once a determination of nonregulated status is made, the product and its offspring no longer require APHIS authorization for movement, release, or commercialization in the United States.

To date, APHIS has authorized thousands of field tests for more than 50 plant species, mostly agricultural crops, and many of these have achieved deregulated status. However, as recently as 2000, only 124 field tests of genetically altered trees have been authorized (McLean and Charest, 2000), including transgenic spruce, pine, poplar, walnut, citrus, cherry, apple, pear,

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* Roger A. Sedjo is a Senior Fellow and Director of the Forest Economics and Policy Program, Resources for the Future, 1616 P St. NW, Washington, DC 20036. He can be reached at sedjo@rff.org.

plum, papaya, and persimmon. Only one tree—the orchard tree, the papaya—has achieved deregulated status.

This report describes and examines the implementation and outcomes of procedures for the deregulation of transgenics with a focus on transgenic trees. It further details the process of the developer obtaining an acknowledgement from APHIS to field test, the provision of the results of the fields tests to APHIS (in support of a petition), and the various other types of information and testing required to deregulate a plant. Since the experience with transgenic trees is limited, much of the report examines unique issues related to tree deregulation, including issues raised by various users, environmental advocates, and transgenic tree developers. Actual experience is cited including the reaction to regulations of various groups and actual outcomes. The report describes the existing regulatory system[1], identifies issues commonly raised among interested parties, and discusses regulatory systems in countries other than the United States, including Canada, the European Union, and China.

Finally, the reactions and attitudes toward the regulatory process by involved participants—including biotechnology developers and users (which may be the same group but often will be different), environmentalists, regulators and ultimate consumers—are noted, and the actual outcome of the regulatory process described.

II. Background

The domestication of a small number of plants, particularly wheat, rice, and maize, is among the most significant accomplishments in human history. Modern civilization would be impossible without this innovation. Common features associated with plant domestication include high yields, large seeds, soft seed coats, nonshattering seed heads that prevent seed dispersal and thus facilitate harvesting, and a flowering time that is determined by planting date rather than by natural day length (Bradshaw 1999).

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[1] It should be noted that APHIS began a process of updating biotechnology regulations in January 2004 (USDA 2004). As of the writing of this report, the updating is still in process. The updating will likely include preparation of an Environmental Impact Statement followed by publication of proposed rules and ultimately the final revised regulations.

Biotechnology and Genetic Modification

Biotechnology has been defined as having five major categories. These are: 1) markers; 2) propagation and multiplication; 3) functional genomics; 4) marker-aided selection/breeding; and 5) genetic modification (El-Kassaby 2003). This report focuses largely on 5) genetic modification, with some discussion of 2) propagation and multiplication as applied to trees. The role of 2) propagation and multiplication as enabling technology to 5) genetic modification is the main reason for its inclusion in this report. A genetically modified plant that involves the alteration of the genome by the insertion of a gene using a nonsexual approach is considered a bioengineered plant and defined as transgenic. In the United States a transgenic is subject to regulation if it has the potential to be a plant pest. As practiced in the United States, essentially all transgenics are automatically subject to regulation. Transgenic plants have already had an important impact on agriculture. Genetically modified (GM) plants were grown on more than 145 million acres worldwide, 100 million in the United States; 81% of U.S. soybeans, 40% of U.S. corn, and 73% of all U.S. cotton are GM crops (Pew 2003).

Benefits and concerns around transgenic trees share similarities with agricultural crops. Much of the biotechnology already developed for agriculture has direct applications for forestry. However, there are also major differences originating from the fundamental characteristics of trees, for example, their being long-lived, outcrossing organisms that can disperse pollen and seed across long distances. Additionally, in many cases trees are likely to be planted within potential mating proximity of wild, compatible populations of related species (DiFazio et al. 1999).

Technology in various forms has increased food production in the past. Hayami and Ruttan (1985) point out that land productivity in grain production in the United States showed little increase over the two centuries before 1930. Most of the gains in production were due to innovations that allowed more land to come into production, such as new equipment and mechanization. By contrast, over the same period, increased productivity in Japan was a function of biotechnological improvements in the form of better seed and higher crop yields. Similarly, the improvements seen in maize and potatoes in pre-Columbian American reflect human selection and breeding practices oriented toward enhancing productivity and the expression of other desired traits.

In the United States after the 1930s, when most of the highly productive agricultural land was already in use, the focus of innovation was redirected to plant improvement, which increased land productivity through higher yields. Until recently these improvements were achieved through the use of traditional plant-breeding techniques, which rather substantially increased agricultural yields. The past decade has seen continuing increases in biological productivity, driven at least in part by genetically modified crops.

In many cases genetic modification augments traditional breeding methods. For example, the increased productivity of soybeans has been achieved through traditional breeding, while its resistance to herbicides, a characteristic that allows the more efficient and effective application of herbicides, is the result of bioengineered genetic modifications, which imparted herbicide resistance. A similar pattern involving both traditional breeding and genetic engineering is emerging for trees.

Timber Crops

High-yield plantation forestry has the potential to meet the world's industrial wood needs while simultaneously protecting existing natural forests and thereby conserving their environmental values. The continuation of the shift toward intensively managed planted forests opens up the possibility of stabilizing the area of the world's natural forest at roughly current levels (Victor and Ausubel 2000).

Traditionally, society's demand for wood products such as timber and pulp was met through harvesting trees from natural forests—in effect, collecting or foraging from the bounty of nature. This approach, however, is gradually being replaced by a crop-growing mode of forestry. Only recently did forestry begin to follow the pattern established in agriculture over ten millennia ago, when humans made the transition from gathering to growing crops. Although many orchard and ornamental trees have been manipulated by humans for hundreds, if not thousands of years, planting trees for future timber harvests began in earnest only a few decades ago (with some notable exceptions in parts of Europe and Asia). It was only after trees were being planted for commercial purposes that serious efforts began to increase their productivity through selection of superior trees using traditional breeding. Thus, unlike many agricultural crops, trees have only been partly domesticated in the last half-century (El-Kassaby 2003).

The foraging approach to forestry, for example, logging on natural forests, is gradually being replaced by "cropping," or plantation forestry. Today, intensively managed planted forests, which have substantially higher biological yields, are becoming an important source of timber and have the potential to dominate industrial wood production (Sedjo and Botkin 1997). It is estimated that roughly one-third of today's timber comes from planted forests, compared with essentially a negligible portion 50 years ago (FAO 2001). In addition to providing wood at a lower cost, high-yield planted forests have the desirable environmental side effect of drawing timber harvests away from natural and old-growth forests, which can then be used for nontimber purposes, including conservation and environmental objectives.

The Potential for Transgenic Trees

High productivity plantation forestry, with control from seedling to harvest, has created the preconditions necessary to financially justify tree improvement through both traditional and modern transgenic breeding. As with agriculture, forest cropping involves intensive management and control over the inputs, including the choice of the germ plasm to be planted. Over the past 30 years considerable improvements have been made in forest stock using traditional breeding approaches. Forest biotechnology, including genetic modification, is in its infancy and offers incentives for the improvement of planting stock through the addition of desired traits. Introducing these genes in transgenic trees gives great promise of providing for the expression of desired traits thereby increasing productivity, increasing product quality, and expanding the range and types of land and climatic conditions under which production forests can thrive. Additionally, gene transfer offers a potential means of recovering some of our lost forests (Smith 1997). Thus, tree biotechnology offers a number of opportunities for achieving environmental goals.

The introduction of a herbicide-tolerant gene into tree seed stock, for example, follows directly from the success of the introduction of the same herbicide-tolerant gene in agriculture. Research similar to that in agriculture is also being undertaken with disease and pest-resistant genes, as well as other gene-altering modifications. It is anticipated that these innovations could result in substantially reduced wood costs, through increased productivity and the reduction of plantation establishment costs and reduced tree losses through the growing cycle. Also, biotechnological research in forestry is moving in the direction whereby genetic alterations would enhance wood quality by desired modifications in fiber characteristics and other tree characteristics, such as, lignin content or limb thickness, in a manner that would reduce processing costs. All of these modifications have the potential to generate financial benefits through reduced production costs and enhanced productivity.

Some Concerns

Although the potential benefits of transgenic trees appear great and transgenic food crops are widely planted and have gained wide acceptance, the subject remains controversial. As the regulatory structure suggests, the primary reason for regulation of transgenics is concern that there may be health, safety, or environmental risks. The issues related to transgenic trees are somewhat different from those of much of agriculture, however. Traditional health and safety issues related to food ingestion are largely absent with wood fiber (although cellulose is sometimes used as a food filler). The problem areas for trees are largely in the environmental realm with concerns about whether transgenics introduce new environmental risks.

More broadly, there are concerns that environmental disruptions could result from the effects of “gene flow” or “gene escape,” that is, genetically modified plants might interbreed with wild plants and thus the altered gene would escape into the natural environment. While in most cases this need not generate damages or disruptions, under certain conditions there may be ways that escape could alter wild plants such that disruption of the environment might occur (DiFazio et al. 1999). Concern about gene flow is somewhat greater in forestry than in agriculture because of the longevity of trees and the likelihood that a similar species of wild tree may be growing nearby. Furthermore, trees take years to mature. Delayed flowering generally makes the examination of the impacts of the introduced genes over generations more difficult but not impossible, since certain tissue culture approaches may be helpful in reducing the intergenerational delays.

Botkin (2003) has likened transgenics to exotic species, some of which have become invasive. However, other ecologists have argued that the risks of a transgenic are generally lower and more predictable than for an exotic because the plant has a limited number of introduced genes and their general expression is usually known. Thus any problems associated with transgenics should be easier to identify.

III. Regulation of Transgenic Trees

U.S. Regulatory Framework

A consistent principle of health and environmental law in the United States is that products introduced into commerce should either be safe or present no unreasonable risk to humans or the environment. How this principle is applied varies, depending on which law is applicable, which agency has jurisdiction, and the social perception of risk.

Products of biotechnology do not always fit comfortably within the lines the law has drawn, which are based on the historical function and intended use of products. In 1986 the Coordinated Framework for the Regulation of Biotechnology was adopted by federal agencies (51 Fed. Reg. 23302; June 26, 1986) to provide a coordinated regulatory approach. Products of biotechnology are regulated according to their intended use, with some products being regulated under more than one agency.

Three main agencies are involved in regulating transgenics. The Food and Drug Administration (FDA) of the Department of Agriculture is concerned with food safety. The Environmental Protection Agency (EPA) regulates toxics and pesticides (under the Toxic Substances Control Act of 1976 and the Federal Insecticide, Fungicide, and Rodenticide Act of 1996) and overall environmental safety (under the National Environmental Policy Act of 1969).

Separate from questions about human health and safety is whether a gene-altered plant, crop, or tree is likely to be a plant pest that could harm U.S. agriculture. This question is examined by the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) under the Plant Protection Act, (especially Title 7 U.S.C. Sections 7701 *et seq.*). This Act is the new statutory authority under which APHIS regulates genetically engineered (GE) organisms. This authority supersedes their authority under some of the earlier acts such as the Federal Plant Pest Act (PPA), which mandates monitoring of plants that offer potential pest risks. In particular, the PPA includes a broader definition of a noxious weed to include native plants (previously the definition was limited to nonnative plants). It is under this broader definition that APHIS is regulating genetically modified organisms (GMOs). The Plant Protection Act is generally applied to all genetically modified plants, including trees.

As the regulatory structure suggests, the primary reason for regulation of transgenics is the potential for health, safety, or environmental risks. The problem area for trees is largely environmental (see Mullin and Bertrand 1998): regulators must presume that transgenics pose new risks of environmental damages.

The Deregulation Process

The deregulation process is designed to assess a transgenic plant to determine whether it is harmful; if not, it can be deregulated. The process involves *permitting, notification*, and *petition*. For regulated articles, such as transgenic plants, a *permit* must be obtained from APHIS for the importation, interstate movement, or release of the article into the environment. The implementation of the assessment related to transgenic plants is centered on determining the safety and environmental implications of the modified plant. The criterion is to ensure that new varieties are as safe to use as traditional varieties.

To achieve deregulation requires field-testing. When undertaking field-testing, *notification* of APHIS that the process is about to begin is imperative. Next, deregulation requires that a *petition* for deregulation be submitted to APHIS detailing the field-testing results, providing a literature review and any other relevant information and or experience. Upon receipt and evaluation of the petition, APHIS, using a scientific committee, makes a determination of whether to deregulate. Once a determination of nonregulation status is made, the product and its offspring no longer require APHIS authorization for transport, release or communication in the United States.

The implementation of the PPA related to transgenics is centered on assessing the safety and environmental implications of the modified plant. Field-testing is one of the major sources of information. It is usually undertaken by the developer and occurs under controlled conditions for most genetically engineered organisms, particularly new or genetically modified plant varieties. It is designed to ensure that the new variety is as safe to use as traditional varieties.

APHIS testing proceeds as follows: The developer is authorized by APHIS to gather information through field trials including statistical analysis, laboratory tests, literature reviews, and other approaches to confirm that the product has the new intended property and is as safe to the environment as traditional varieties. When enough information is gathered, the developer can *petition* APHIS to make a "Determination of Non-regulated Status."

When APHIS receives a petition, a team of agency scientists begins the review, and the agency announces to the public that the petition has been received, and the completed petition is made available for public review and comment. In these reviews, the APHIS standard is that an organism must not directly or indirectly cause disease or damage to plant, plant parts, or processed products of plants and that the risks are not greater than those for traditional plants. Upon receipt and evaluation of the petition, APHIS, using a scientific committee, makes a determination of whether to deregulate.

Once the agency determines that the plant variety or line has met all the requirements and standards, it makes a "Determination of Non-regulated Status" and the product and its offspring are deregulated. In this case developers no longer need APHIS authorization to transport or release the new variety in the United States. Often, however, the petition is neither accepted nor rejected, but returned to the developer with requests for additional information. Currently, each transgenic application is required to undergo the full deregulatory process.

The overall assessment by APHIS includes a consideration of the potential effects on the "wider" surroundings to ensure that any environmental impacts are not likely to be significant. Broader considerations are mandated under the National Environmental Policy Act of 1969 (Title 42, U.S.C. sections 4321 *et seq.*). In addition, EPA is directly involved in the deregulation process for any transgenic plant that has pesticidal or toxic properties under TSCA and FIFRA, as well as for overall environmental safety under NEPA.

IV. APHIS Performance

Deregulation, as noted, is based on assessment of the results of field-testing, statistical analyses, literature review, and so forth. AHPIS reviews about 1,000 applications for field-testing transgenics each year. Only about 59 transgenics, representing 13 species, have been deregulated over the past 15 years. APHIS has received some 89 applications for deregulation of GM crops and has overseen several thousand field trials of GM crops (NRC 2002). APHIS has now approved more than 40 applications, and several more are under review or pending (USDA 2003).

To date, most of the field tests have been agricultural crops; as of 2000 only 124 field tests of genetically altered trees have been authorized (McLean and Charest, 2000), including transgenic spruce, pine, poplar, walnut, citrus, cherry, apple, pear, plum, papaya and persimmon. Only one tree—the orchard tree, the papaya—has achieved deregulated status.

Tree Deregulation

Trees make up only a small portion of the plants tested. However, the number of trees tested has increased dramatically in recent years, as has the total number of plants of all types.

Trees can be classified as orchard, ornamental, and wood (that is) timber. The experience with timber trees is presented in Table 1. From 1987 to 2001, timber trees were involved in only 1.2 percent of the total number of field tests, for both agricultural and forest crops, and 91% of those occurred in the latest reported period (1997–2001). A total of 90 timber tree field tests were undertaken representing four tree genera between 1987 and 2001, with the poplar genus being involved in well over one-half of the trials. The number of trees tested has increased dramatically in recent years. About 57% of the trees tested are timber trees.

Table 1. Field Tests for Transgenic Timber Trees, 1987–2001

	Poplar	*Pine*	*Walnut*	*Cotton-wood*	*Total tree tests*	*Total APHIS-approved crop tests*	*Percentage timber trees of total crop tests*
1987–1991	1	0	2	0	3	181	1.7
1992–1996	3	0	2	0	5	2,354	.2
1997–2001	52	15	8	7	82	4,804	1.7
Total	*56*	*15*	*12*	*7*	*90*	*7,339*	*1.2*

Source: http://www.isb.vt.edu/cfdocs/fieldtests1.cfm.

Table 2 provides information about duration and size of the trails. The average tests have lasted from one to almost seven years on fields, with the field size per test ranging between 0.25 and 2.6 acres.

Table 2. Characteristics of APHIS-Approved Transgenic Tree Trials

Tree	*APHIS-approved tests, 1987 to July 2002*	*Average duration (months)*	*Average size (acres)*
Poplar	65	14	1.5
Pine	17	56	0.25
Walnut	12	55	1.9
Cottonwood	7	45	2.6

Source: http://www.isb.vt.edu/cfdocs/fieldtests2.cfm

The United States accounts for an estimated 61% of worldwide tree trials. Other countries undertaking field trials include Australia, Canada, Chile, France, Italy, Japan, New Zealand, and South Africa.

Tree Deregulation

With the exception of the transgenic papaya, APHIS has received no petitions for the deregulation of a transgenic timber tree. Worldwide, there are no documented transgenic timber trees that have been commercially released, although there are rumors that transgenic trees are being planted commercially in China.[2]

Case Study: Papaya

Thus far APHIS has deregulated only one tree, the papaya. However, that experience is instructive and provides insights into the types of problems transgenics can address, the process of deregulation, and some of the difficulties likely to be encountered in the deregulation of trees in the future.

In the 1940s the papaya crop in Oahu was devastated by a new insect-borne virus—the papaya ring spot virus (PRSV). In a mature plant, the virus caused the leaves began to wilt, and fruit had little sugar and mottled skins. Young infected plants died. The virus spread slowly until all of the papaya orchards were infected. To escape the virus, the papaya industry moved to the island of Hawaii, but by the 1970s the virus had followed. Plant breeders crossed wild papaya with commercial species and achieved resistance, but the papaya fruit was of low quality.

The technology for a disease-resistant papaya was developed by Dennis Gonsalves of Cornell University, in cooperation with researchers in Hawaii. The team used a viral coated protein, developed from other plants (watermelon, cucumber, zucchini, and winter squashes). They inserted the viral genes into the papaya and found a papaya strain that was resistant to PRSV. The team had discovered a natural plant mechanism that recognized the messages from foreign DNA to protect foreign protein and destroyed those messages before the protein could be made. The gene inserted into the transgenic papaya set this immunity mechanism into play.

In 1994 a larger field trial was started that proved very successful. Control plants all became infected within 11 months, but after 35 months the transgenic plants remained healthy (Pew 2002). Subsequently the disease-resistant papaya was approved by APHIS as it was determined that it met the requirements for deregulation. However, the actual planting of the trees was prevented because the developers needed to gain approval for the various patented technologies that had been used in the development of the disease-resistant tree. Use of these technologies in a commercial product without the approval of the patent owner makes the user subject to an injunction preventing the use of the technology and/or liable for damages. In this

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[2] At a November 2003 meeting of the FAO Panel of Experts on Forest Gene Resources, a Principal Research Scientist at the Research Institute of Forestry reported on the establishment of close to 300 Ha of transgenic poplar in China. (Personal communication, Yousry El-Kassaby, January 20, 2004)

case the legal use of the patents for the transgenic papaya was provided gratis by the various patent holders, since the innovation had limited applicability and was viewed as socially desirable. Most of the papaya growers are small family-run operations. The legal background and activities necessary to obtain legal use of the patents are discussed in Goldman (2003). However, for more commercially viable operations, the purchase of the rights to use patents required for the development of a transgenic tree could be both costly and time consuming.

V. Some Regulatory Issues

Risk and Coverage

The U.S. Approach: Two major issues in the regulation of plants are the level of acceptable risk and the types of plants covered. That is, should the regulation apply on the basis of the genetic modification process or on the basis of attributes of the plant that may pose risks? The formal U.S. decision criteria are that the product presents "no significant or unreasonable adverse risks." Note that some "reasonable risk" is allowed. Currently, under the U.S. approach, all transgenic plants and trees are automatically classified as regulated articles that must go through the deregulation process to be eligible for commercialization. Alternatively expressed, any plant that involves the insert of a gene using a nonsexual approach is defined as a transgenic and is automatically regulated.

Some biologists have argued that regulation would better be applied to plants on the basis of the plant attributes, rather than simply on the basis of the genetic engineering process. The decision would be based on the "novelty" of the plant independent of the process used in its development. This criterion would be applied, in principle, to all "novel" plants, including genetically modified plants, whether the modification occurred by traditional breeding or genetic engineering.

Approaches of Some Other Countries: The argument of those suggesting regulatory change is that the transgenic process does not inherently lead to more risky products. Rather, they say, regulators should focus on the changes and the attributes, whether generated by traditional or transgenic approaches, which could present a social or environmental risk. That is, the risks are associated with particular attributes, and it is the products with these attributes that ought to be regulated. This is the approach used in Canada, which applies the "novelty" criterion to both traditionally modified and genetically engineered varieties. However, thus far in Canada, no tree modified by traditional methods has yet been required to go through formal deregulation, whereas almost all transgenic plants and trees require deregulation (McDonald personal communication, Quebec City, October 2003).

Another approach is that of China. That country has a risk scale that ranges from no risk to low, medium, and high risk. A preliminary appraisal places a new plant in one of these categories. Those in the no-risk or low-risk classes are automatically deregulated; those given a higher risk rating go through a more extensive deregulation protocol.

The European Union's decision criteria are particularly averse to risk and require that GM plants present no additional or increased risks—that is, zero risk. This is stricter than the U.S. and Canadian standards, which accept some level of risk.

Although most countries agree on the need for some type of risk assessment for transgenic plants, there is as yet no global consensus on the degree of potential harm that will be tolerated and the degree of severity of the risk (Pachico 2003).

In summary, the formal decision criteria regarding the level of acceptable risk vary by country, from zero risk in the European Union to "reasonable," "low," and "acceptable" risk in other countries. The formal criteria of the United States, China, and the European Union focus regulation on transgenics. Only Canada seeks to regulate on the basis of the novelty of new plants, however those new attributes have been achieved, but in effect, only transgenic plants have been regulated.

Conditional Release

Another outstanding issue is the question of conditional release. Under the current system, a plant is either regulated or nonregulated. The concept of conditional release that would enable the developers to answer questions related to the development and us of a GMO prior to its unconditional release. The purpose of conditional release would be to allow movement towards unconditional release in a step-by-step process. Restrictive conditions could be altered as the relevant evidence becomes available.

Gene Escape

Gene escape involves the possibility that a transferred gene in a transgenic tree will be passed from a plantation forest to trees in adjacent plantations or in the natural system. If the gene is wholly benign, no damages would occur and the issue is moot. Thus, gene escape is only an issue if the gene presents a risk to other trees or to the environment. The concern focuses on under what circumstances such a transfer of genes cause damage to other domesticated trees, to wild species, or to the balance in the natural ecosystem. A separate concern relates to commercial marketing. For example, the transfer of a gene from a transgenic crop to non-transgenic crops could disqualify the "tainted" crops from nontransgenic status and hence preclude them from sale in certain markets. Elements of this issue have been under discussion at the World Trade Organization.

The issue involves potential ecological damages. In part, the question is one of "flow versus fate." In the absence of containment or remedial actions, there is broad consensus that some degree of gene flow will almost certainly occur. Pollen will be transported, seed may be released, and with some plants, including trees, vegetative propagation may occur. In trees, however, the gene flow could be minimized by additional genetic modifications that delay flowering, impart terminator genes, or create sterility.

The concerns with gene flow in trees are generally related to the effect on the ecosystem of the transfer of a gene from a planted transgenic tree to wild trees with which they could hybridize. One example is the risk of transgenic tree invasiveness at the interface of private industrial forests and public lands. Potential risks associated with transgenic pine escape and colonization include species displacement and ecosystem disruption (Williams 2004).

Another concern in forestry is the effect of *Bacillus thuringiensis* (Bt) genes, which are used to impart pest-resistance properties to plants. When applied to planted trees, under some circumstances these traits could escape to wild trees of the same species, which would then gain a competitive advantage over other forest species, in the extreme disrupting the vegetative balance in the natural system. However, as yet there is little if any research proceeding on Bt genes for trees.

An additional question is whether the gene might have detrimental effects on the environment if, say, the trait might give an advantage to some wild plants, and not others, thereby creating a pest—a plant that could now become an invasive in the wild. A related problem might occur if, for example, herbicide resistance is transmitted to wild poplar, which then became an uncontrollable weed in Douglas-fir trial where weed control was a goal. However, since herbicide resistance is typically provided for a specific herbicide, other herbicides could be used to control the herbicide-resistant wild poplar.

Gene escape will not occur if the transgenic is an exotic species and there are no compatible wild relatives in the natural environment. For example, conifers are not indigenous to South America, so the problem of gene transfer from a planted pine to a native tree is nonexistent.

The question of whether a trait that escapes through gene flow will persist is an important. In general, for the trait to persist, it must impart fitness. Fitness is defined as the relative success with which a genotype transmits its genes to the next generation. Major components of fitness in perennial plants are survival, vegetative growth, and reproduction through pollen and seeds. Many domestication genes do not impart fitness in the wild, and such traits generally disappear from the gene pool through time. For example, it is unlikely that a low-lignin transgenic tree will have improved fitness in a wild environment. However, fitness is dependent on the environment and a trait that might not impart fitness in one environment can impart fitness in another.

Often, there may be fitness “costs” associated with transferred genes, but other transferred genes can have positive or neutral effects on fitness. According to Snow (2003), transferred genes that are not deleterious to fitness are likely to persist in wild populations. That raises the question whether plants with positive or neutral effects on fitness should be released in the wild. The consensus among scientists appears to be, “it depends” (see Snow 2003). If a transgenic tree with enhanced fitness is introduced as an exotic where there are no wild relatives that could be genetically tainted, the problem is minimal. If specific genetic change enhances a desired commercial trait, such as cellulose production, but has a neutral effect on the tree’s fitness in the wild, there is little reason to expect that the transgenic tree could become a pest or significantly modify the ecosystem. In many cases, developers argue, a sound scientific assessment would conclude that the transgenic is not truly “novel” and hence poses no more risk of damage than would a plant modified through traditional breeding. In this case regulation might be uncalled for.

VI. Attitudes toward Transgenic Trees and Regulations

In this section I characterize the attitudes of various groups toward transgenic trees and the regulatory structure. These characterizations are not based on scientific sampling procedures but rather reflect my impressions based on conversations with members of the various groups.

Numerous groups have an interest in transgenic trees. These include tree growers, tree processors, tree developers, direct and indirect consumers of forest products, and environmentalists. Not surprisingly, attitudes toward transgenic trees vary substantially among these groups and, as has been shown in various surveys of attitudes towards transgenic foods (Pew 2003), also vary considerably across countries.

Tree Breeders and Developers

As could have been expected, among transgenic tree developers, whether in the private sector or public, the attitude toward transgenics is basically positive. These groups generally believe that there is a place for some type of regulation, but criticize the U.S. approach of requiring all transgenics to go through the deregulation process. A common view among research biologists is that for certain types of predictable transgenic changes, a formal deregulation approach is not required. Such an approach would, obviously, require some preliminary assessment to determine which transgenics require a more comprehensive assessment.

Tree Planters and Growers

Although many forest-based firms engage in tree improvement and some conduct research to improve cloning techniques, especially for pine, few are directly engaged in tree genetic-engineering research and development. In the industry structure that has emerged in the past decade in North America, work on transgenics is undertaken largely by universities and specialized research firms. Most firms no longer conduct work on transgenics as part of their overall tree improvement programs. There are almost surely economies of scale in concentrating research efforts in a few places rather than fragmenting the efforts.

Another explanation is, at least in part, the desire of forest-based firms to distance themselves from the activity of genetic engineering during the current period of questionable public acceptance. Transgenics are attractive in concept because they present opportunities to reduce costs and increase productivity, but tree growers are very sensitive to actual and expected behavior of markets and, given the controversies over genetically modified products, are somewhat wary.

Environmentalists

A systematic inquiry at the booths at the World Forestry Congress in Quebec City (September 2003) found a range of views among environmentalists from extremely hostile to skeptical toward transgenic trees. Representatives of green organizations, such as Greenpeace, exhibited great hostility and made ominous predictions of how transgenic trees would damage the natural environment. The guidelines of Forest Stewardship Council, a certifier of acceptable forestry practices, specifically prohibit the certification of forests of transgenic trees. At the other end of the spectrum are organizations, such as the Nature Conservancy, that have no institutional position on transgenics. In conversations some staff professionals acknowledge that transgenic trees may have some role in forestry's future. They note, however, that this issue is generally out of the mainstream of their organization's direct concerns. However, some individuals with generally negative views toward transgenic were neutral to positive in their reaction to benefits, such as the restoration of the American chestnut, that might be provided to the natural environment through genetic modification.

Consumers

Industrial consumers of wood products—those for whom wood is an input to production, such as pulp mills—are generally enthusiastic about transgenic trees with certain characteristics that improve the economics of production and/or improve ensuing products. Trees with more fiber, less juvenile wood (which is low in cellulose), and less or more easily removable lignin will reduce processing costs and are therefore, in principle, desirable. The proviso is that such products must be acceptable to consumers.

The attitudes of consumers of final products—paper, lumber, panels—made from transgenic wood are problematic. Although transgenic wood products are unlikely to be in markets for another 20 to 30 years, the anticipated attitude of consumers is important for developers. Without an expectation of a viable market, the developments and investments are unlikely to be forthcoming. As with food crops, in many cases GM products could be better in quality or lower in cost, or both. With wood products, however, generally no food safety issues are involved (although cellulose is sometimes used a filler in foods). Thus, the extent to which retail consumers might resist transgenic wood products would appear to depend largely on whether they have environmental and/or philosophical concerns.

The experience with certified and eco-labeled wood products offers some insights: although there is little evidence that consumers are willing to pay a price premium for certified wood, some firms find that certification imparts a competitive advantage, even if not a price advantage (Sedjo and Swallow 2001). How these attitudes may translate to a transgenic wood market remains to be determined.

VII. The Biotech Industry

The transgenic tree industry comprises several types of organizations: universities, biotech firms, conventional tree-improvement-program delivery systems, and forest-based companies. As in agriculture, conventional tree-breeding programs gradually incorporated biotechnology and transgenic techniques, including those first used in agriculture. For example, Monsanto, an early leader in the biotech industry known primarily for its innovations in crops, developed technologies that also have applications for trees (see Sedjo 2001) and has, in the past, worked on developing low-cost means to introduce the herbicide-resistance gene into trees.

Until recently, many of the large North American forest products companies conducted transgenic research, in some cases in collaboration with a major biotech gene developer, such as Monsanto; the results could then be introduced into a forest company's improved tree lines. Today, however, most research on the application of herbicide resistance in trees appears to be undertaken by universities; the tree improvement research programs of most firms apply traditional tree-breeding techniques.

Recently, several forest products firms have formed a joint company, ArborGen, which specializes in the development of transgenic genes and techniques for the participating firms, and perhaps for the market more generally. Considerable research effort is directed to increasing and improving wood fiber and its utilization through modifications that will, for example, reduce the costs of extracting lignin from the wood in the pulping process. Meanwhile, the forest-based firms are typically continuing their traditional breeding programs, but not their genetic engineering research, with the view to eventually introducing the selected genes into the individual company's elite seed stock.

Case Study: ArborGen

ArborGen is a joint venture formed in 2000 by companies focused on research and development technologies associated with the modification of trees. The group has more than 90 scientists working in New Zealand and the United States. The company seeks to develop transgenic processes that can be commercialized to create transgenic trees on a commercial and profitable scale. Most of its future products—trees with fiber modification and lignin modification, including reduced juvenile wood, to improve pulpability—would need approval only from APHIS (not EPA or FDA). Such trees could be harvested in a shortened rotation, a very desirable feature. Bt and herbicide-resistance projects are less attractive because first, they would require approval from EPA (viewed as a more difficult regulator) as well as APHIS, and second, they would have less market potential. Herbicide resistance could be more valuable in hardwood plantation establishment than in pines, but since traditional herbicides already work well, this becomes less of a priority. An herbicide-resistant eucalyptus could find a large foreign market, but would need approval in the various other countries even if it were deregulated in the United States. Thus, the costs of deregulation and market size become important.

Thus far, ArborGen has concentrated on loblolly pine, which is extensively planted in the United States, where most of the parent companies are located and have property. ArborGen believes its loblolly pine transgenics have a potential worldwide market as well, since it is a premier species in much of South America as well as parts of China.

In ArborGen's cost–benefit analysis, the costs of development plus the costs of deregulation must be weighed against the anticipated benefits—the financial gain from the increased productivity and quality of the forest, as captured in price premiums received for transgenic seedlings. The higher and more variable the costs of deregulation, the lower the net returns to the firm for a given innovation, and the less likely a firm will be to undertake the investments. Another element in the costs of development is the purchase of intellectual property rights, which are required to successfully develop any innovative transgenic product. ArborGen is working to obtain the rights it will need to pursue the selected projects.

Finally, it is well recognized within ArborGen, as well as the industry generally, that transgenic innovations will work best in concert with traditional tree improvement approaches so that the transgenic innovation is applied to the very best traditionally improved trees.

Clonal Development

Plantation forestry depends on the development of elite planting stock that can consist of seedlings or materials appropriate for vegetative propagation. The procedure for obtaining seedlings, particularly in conifers, is through a seed orchard program where the improved trees are cross-pollinated to produce improved seed, which are mass-produced into seedlings for planting. Although this approach is common, it has the disadvantage of diluting the desired trait since both parents are genetically represented in the seedling due to 1) gene segregation during meiosis and 2) the presence of a significant cross-pollination from unimproved trees outside the orchard population.

The other approach is that of vegetative or clonal propagation. Vegetative propagation has been practiced for centuries in many plants, including grapes, potatoes, and many deciduous trees. The simple form of vegetative propagation involves taking cuttings from a plant, for example, a branch or root, which are then planted. Fences consisting of live trees, common in much of the tropics, are created in this fashion. When vegetatively regenerated, the plant is a "clone" having the same genetic composition as the original plant.

Cuttings and propagules (rooted plantlets from tissue culture, embryogenesis, and so forth) are the planting stock for clones. The development of clonal trees typically takes the following form. First, trees with superior traits are developed through traditional breeding approaches. For trees that can propagate vegetatively, generally deciduous trees, cuttings from the most outstanding parent trees (ortets) provide clonal material, cuttings, for planting. This approach has the advantage of capturing all the genetic superiority for the donor plant because the process relies on mitosis cell division does not impart any gene segregation, unlike sexual reproduction that relies on meiosis and hence some dilution of the positive attributes due to gene segregation. Also, the cost of the cuttings tends to be modest thereby reducing plantation establishment costs. The rooted plantlets can be planted en mass and the beneficial traits of the single tree duplicated in each new tree. This approach has commonly been used for poplar, eucalyptus, and other nonconiferous trees.

Vegetative propagation, however, has not been an effective technique for most conifers —genera in which vegetative propagation is extremely rare. Thus, for conifers the approach also first involves tree improvement through traditional breeding approaches. Embryos from superior trees are then used to create multiple clones. The approach requires the development of sophisticated techniques, such as tissue culture and embryogenesis, which allow for the reproduction of embryo of the superior tree in the form of rooted plantlets. The reproduced materials, propagules, become the material that then is planted to become a clonal tree.

Various approaches to replicating conifer materials are now under development, with the view to achieving mass propagation at low cost. As with vegetative propagation, an advantage of cloning is that all of the genetic gain in an improved tree can be captured without diluting that gain through sexual reproduction. This approach allows for large-scale planting of plantlets with the desired genetic makeup.

It should be noted that sophisticated cloning is not genetic engineering and that such activities are not regulated and do not require that a plant be deregulated. Even in the absence of any genetic engineering, however, the technique would allow forest industry to take more complete advantage of traditional tree-breeding improvements.

While cloning provides distinct growing advantages in itself, a cloning approach also provides an excellent platform for the application of genetic engineering. Cloning can be viewed as an enabling technology that will facilitate the transgenic transformation of conifer trees. Through the cloning process the selected genes, which have been inserted into a particular plant to create a transgenic, can subsequently be transferred to produce transgenic propagules en masse. Each one of these would be identical and have the same externally introduced genes. It is generally recognized that to introduce transgenic conifer trees on a commercial scale will require an efficient low-cost approach to reproducing transgenic clones.

The ideal transgenic plantation technology would also include the ability to cryopreserve —preserve for a period of years a set of potentially productive clones from which the most productive will ultimately be chosen after the transgenic innovation has been assessed and deregulated. The procedure involves propagation of young trees produced from tissue culture or embryogenesis generated propagules. Genetic testing and field-testing must be done to determine which of the clones are best. If portions of each of the propagules are preserved in freezers until the best material is determined, the desired material can be removed from the freezers and used to mass-produce the desired seedlings.

A leader in the development of conifer clones is Cellfor, which is developing the technology and production procedures that will allow it to produce low-cost clones, particularly of pine. With low-cost cloning techniques, the firm could clone elite materials developed using traditional breeding methods by forest products companies for the company's own use. Development of low-cost pine cloning techniques and procedures would also provide a platform for the low-cost replication of transgenic clones for large-scale commercial operations. It would be an "enabling technology" for the commercialization of transgenic conifer trees. Currently, there are still substantial hurdles before low-cost conifer clones become generally available.

VIII. Issues for Tree Developers

Regulatory Procedures

There appears to be general agreement that the existing APHIS procedures provide the basis for deregulation of transgenic trees but that the specific protocol needs to be worked out. This understanding was reflected in the meetings in July 2003 organized by APHIS to consider the regulatory problems unique to transgenic trees. There remains the question of whether regulation should focus on the process, transgenics, or on the attributes of the plant, irrespective of the process. Also discussed was the requirement that each gene must be separately field-tested. Developers are hoping to test several genes in one trial, an approach that would probably require some change in the existing regulatory protocol.

The longevity of trees makes monitoring for potential problems more difficult than with annual plants. Most tree improvement programs try to identify superior trees early in the cycle, so that the superior stock can be deployed quickly, but "surprises" in the tree's performance may appear as it approaches maturity. There is a fair degree of support in the industry for a “conditional” deregulation by APHIS, whereby distribution would be limited and monitoring continues until any outstanding uncertainties are resolved.

Costs of Deregulation

The costs of deregulation are high and affect decisions about the types of transgenic traits to develop (or avoid). These costs create an incentive to focus on traditional breeding, which requires no deregulation, even though the development costs can be greater. The biotech industry (Maul Hinchee, personal communication, May 2003) estimates that the costs of deregulation account for roughly one-third of the total development costs but are highly variable and uncertain. The uncertainty is not so much in the regulation per se but in the time and costs of achieving deregulation. When a transgenic plant gets to a certain development stage, its developers can be confident about clearing the remaining hurdles of the deregulation process. But at the outset, they cannot know how many tests will need to be undertaken to demonstrate to the regulators that deregulation is justified.

The costs of deregulation increase if more than one agency is involved. APHIS has responsibility for all transgenic plants, but if a transgenic plant has pesticidal properties, such as a Bt gene, EPA becomes involved as well. Going through the process with two agencies undoubtedly raises the costs to the developer, perhaps very substantially. An emerging strategy appears to be to undertake developments that will be assessed by only one agency, APHIS, thereby reducing the costs and the uncertainties. Hence the focus on improving the quality and quantity of the fiber for pulping and decreasing the costs of pulping; a transgenic with such properties would require only APHIS oversight.

The industry appears to have a preference for a two-step regulatory system, in which a preliminary assessment by the regulatory authority would provide a preliminary determination of the nature of the transgenic plants’ characteristics. Plants whose attributes were associated with environmental problems would then undergo through a more intensive (and costly) assessment and review, and other plants could be deregulated through a less rigorous system. Additionally, the industry wants to test several genes in one trial to reduce the costs of deregulation.

International Markets

Deregulation of a transgenic tree in the United States does not guarantee that the transgenic tree can be planted in foreign countries. As discussed above, many other countries have their own transgenic regulatory systems, including prohibitions on planting them at all. Brazil's prohibition on transgenic crops was widely violated, and the Brazilian restrictions may be lifted for some transgenics, including trees. Chile also has a prohibition on the commercial use of transgenics, although it does allow regulated field-testing of some GM plants.

Such a fragmentation of the worldwide market limits the potential for developers of transgenic trees. A recent study (Sedjo 1998) estimated that the potential market for an herbicide-resistant transgenic is large, but regulations abroad severely constrict the accessible market and thus the potential financial returns to the innovation. At the current time there appears to be relatively little research on applying the herbicide-resistance gene in trees, most of it at universities.

Given the problems in international markets for commercial transgenic seedlings, developers appear to be focusing on specific country markets. For example, much of the research by ArborGen focuses on loblolly pine, which is the dominant tree planted in the United States. Similarly, Cellfor, although not constrained by transgenic considerations, is focusing its cloning procedures on pine, an area that offers a large U.S. market as well as substantial foreign potential. New Zealand transgenic tree developers are focusing on *radiata* pine, which is the dominant planted tree in that country. Additionally, there appears to be a substantial amount of research outside the United States on developing transgenic eucalyptus with enhanced fiber content; the intended markets are the large-scale eucalyptus plantations of Brazil and elsewhere.

IX. Summary and Conclusions

As demonstrated in this paper, transgenics in forestry have substantial potential to increase the productivity of industrial wood. Transgenics in forestry also have potential environmental benefits both by taking harvesting pressure off of old growth and nature forests, which are desired for environmental values, as well as for assisting in the restoration of certain diseased species. As in agriculture, biotechnology and transgenics in forestry are controversial. A regulatory system exists in the United States for assessing the safety and environmental impacts of transgenics, including trees. This system has a substantial history with crops, but a much shorter history with trees. Additionally, trees have some features that are different from most crops. A greater understanding of the operation of the regulatory system as applied to trees under the Plant Protection Act promises to increase social acceptance of the system. The outputs of this research project should be useful to assist policy makers in assessing the adequacy of the current PPA and the regulatory processes that come out of the Act, as applied to transgenic trees.

Additionally, this paper should provide insights as to the confidence and attitudes of various involved groups towards the regulatory system and the PPA as practiced.

Forestry will undoubtedly continue its transition from harvesting natural forests to tree cropping. As it does the potential of plant improvements to generate social and economic benefits increases. Transgenics appear to offer opportunities to increase productivity in forestry through innovations like those already developed for crops—herbicide and pest resistance—and through innovations involving trees' form and fiber characteristics. Although the economics of tree improvement must account for long delays between innovation and the realization of financial benefits, genetic modification also promises the early capture of some benefits. Thus far, however, there have been no completed petitions for deregulation and, thus, the regulatory system has not yet been asked to be fully applied on a transgenic timber trees.

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