TRANSGENIC HORTICULTURAL CROPS

Challenges and Opportunities

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12 Why Are Regulatory Requirements a Major Impediment to Genetic Engineering of Horticultural Crops?

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Regulations in the United States and in most other countries treat all plants produced using recombinant DNA methods (genetic engineering or genetic modification) as illegal for use in the environment or in commercial products until their safety and acceptability has been specifically authorized. The costs of complying with regulations and the legal risks of not complying place severe constraints on the use of recombinant DNA breeding methods at both research and commercial phases. In particular, the limitations to gene release in the environment pose severe constraints for required field research, development, and commercial applications for most horticultural crops, a problem that is exacerbated in many cases by their incomplete

domestication and wild or feral relatives. This chapter explores the direct and indirect causes for the stringent regulatory system in place, discusses the opportunity costs they impose, and proposes some alternative regulatory concepts. I maintain that until regulatory systems incorporate a tier that provides, at the outset of field research, exemptions or workable tolerances for adventitious presence, the ability to use transgenic approaches for horticultural breeding will be severely limited, thus foreclosing a number of important options for improving pest management, stress tolerance, and product quality.

It is common to see lay discussions of the social controversies and the potential of genetic engineering (GE)* virtually ignore the federal regulatory gauntlet that GE products must get through. Those who tend to be in favor of GE crop solutions often assume that regulations are well-crafted and essential to protect the public safety; their efficacy, cost, and what products might have been discouraged even before they are created are rarely considered. In contrast, those against GE argue that regulations are not strong enough, as evidenced by the very existence of GE products with the absence of full scientific certainty about their effects. Because of the esoteric nature of regulations, it often seems to be only the practitioners of GE who really understand the implications of regulations in practice. Who else would know what it costs in time and labor to conduct a regulated field trial apart from those conducting the trials? Or of what it costs to bring a product to market, other than public sector institutions or companies that have sought to do so? The goal of this chapter is to discuss the costs and impediments to research and development of transgenic horticultural crops from the perspective of a public sector biotechnologist who works on ornamental and forest trees. In addition to my own experience, this article is motivated by the apparent absence of any new horticultural transgenic crops in the public sector pipeline (an observation based on discussions with many colleagues) in spite of a rather large number of field trials that have been conducted during the past two decades (see http://www.isb.vt.edu/cfdocs/fieldtests1.cfm for listings). This suggests that regulatory costs and obstacles, in combination with market risks, are severely impeding transgenic variety development.

NEED FOR BIOTECHNOLOGY SCIENTISTS TO BE INFORMED AND TO INFORM REGULATIONS

Few scientists or students who are drawn to plant science or to its practical applications such as horticulture and forestry like the idea of studying government regulations. It sounds about as exciting as reading the United States Internal Revenue tax code, and about as enticing as a trip to the dentist to have your teeth drilled. As a scientist, I fully share these sentiments, but my work over the years with field trials of genetically modified trees[1,2] (Figure 12.1), and the small part I have played in writing

* Throughout this chapter, which specifically addresses the products of genetic engineering or genetic modification, I use the terms "biotechnology" or "GE" or "GM" as shorthand. I am referring to crops produced using methods where plants are modified by asexually induced, specific genetic modification and regeneration of the modified cells into plants.

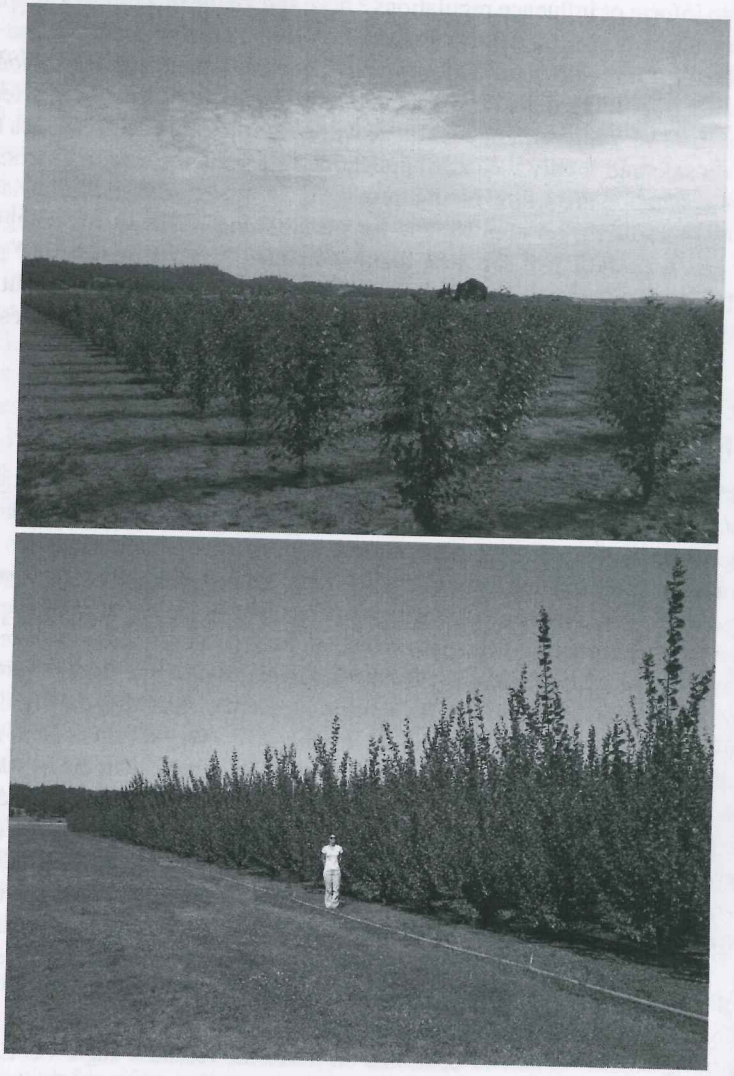

FIGURE 12.1 **(See color insert.)** USDA-APHIS authorized field trial of transgenic poplars in Oregon (United States) during its first (top) and second (bottom) growing seasons. The population, part of a gene discovery program using a method called "activation tagging" (where genes are randomly upregulated by insertion of a gene expression enhancer), was being screened for novel morphologies under field conditions. The trees had to be removed prior to the desired long-term nature of this experiment because of regulatory costs associated with long-term containment, monitoring, reporting, and removal costs for large trees. There is no obvious scientific basis for intensively regulating such trees while interspecies hybrid poplar trees, and those produced through non-transgenic forms of mutagenesis, are essentially unregulated throughout the world.

about regulatory reforms[3,4] and taking part in national and international workshops designed to inform or influence regulations,[5] have shown me how important they are. I now often argue that every plant scientist who works in and understands the potential benefits of transgenic plant biotechnology needs to understand regulations, and play a role in improving them. The goal is to craft regulations that more effectively target and limit very high risk applications, while minimizing encumbrances to field research on safe and highly valuable applications. At least for now, regulations and their implementation are still evolving, providing an opportunity for influence from scientists.[6] In addition, all applications for permits and petitions for deregulation (USDA) and registration of GE pest-tolerant plants (EPA) have required periods of open public comment; the high quality science-based or data-based input that is often received from biotechnology scientists is valued by regulatory agencies.

CONSEQUENCES OF FAILURE TO COMPLY WITH REGULATIONS ARE LARGE

Regulations are informed by science, but mainly they embody the overall "attitude" of a society about a technology.[7] Emotions, perceptions, economics, and politics generally dwarf the influence of science in developing regulatory policies. Regulations can be written with a tone of aversion and extreme caution when society senses risk and harm rather than direct benefit—as we see today with plant biotechnology. Or, they can be written with a sense of optimism and encouragement, as we tend to see today with respect to wind power and related technologies. Because regulations have the force of law behind them, even minor violations can have significant penalties including heavy fines and even imprisonment. Thus, they have a power and gravity very different from research procedures or recommendations, such as those followed in molecular biology laboratories in the United States under the National Institute of Health (NIH) recombinant DNA research guidelines. The risks and costs of complying with regulations—or being unable to comply—often determine, not just inform, scientific and business strategies.

As seen with the StarLink GE maize debacle[8] and with the ongoing multimillion dollar lawsuits over accidental infusion of USDA-approved GE rice that harmed U.S. exports,[9] the consequences of getting the regulations about gene dispersal (often called adventitious presence [AP] or low-level presence [LLP]) wrong, even in small detail, can be enormous for companies and for the entire agricultural sector. In addition, recent successful lawsuits over USDA decisions on herbicide resistant sugar beets, alfalfa, and creeping bentgrass have set new precedents for use of the National Environmental Protection Act. Its requirement for Environmental Impact Statements in regulatory decisions on crop biotechnologies has brought the courts into the regulation of crop biotechnology in a major way[10] that requires far more work and legal detail to the process in order to increase the likelihood that Animal and Plant Health Inspection Service (APHIS) decisions can withstand legal challenges. In addition, given the broad interpretation of what National Environmental Policy Act (NEPA) covers in these cases—which include economic damages to organic and conventional farmers from AP—it is unclear whether the preparation of Environmental Impact Statement (EISs) will improve the quality of scientific analysis of the underlying biological issues.

A MULTITUDE OF REGULATIONS EXIST AT NATIONAL AND INTERNATIONAL LEVELS

The problems with AP and consequent trade disruptions described above also remind us that we have not one, but a multitude of national regulatory regimes that can vary widely by country, as well as an overarching international regulatory policy in the Cartagena Protocol of the Convention on Biological Diversity (CBD).[11] The CBD's provisions must be addressed if living agricultural products such as seeds are traded, or if pollen, seed or vegetative propagules can move across country boundaries. Such rules are critical for trade in many horticultural crops, where the products are often living (e.g., nuts, fruits, horticultural varieties), and where wind and insect vectors often can move pollen, fruits, and sometimes small seeds many kilometers. This network of regulations means that making changes to regulations is truly a glacial process; it involves seeking coordinated changes in the attitudes of highly diverse societies, as well as through fractious and highly political bureaucracies such as the United Nations. Given the negative attitude inherent in most regulatory regimes concerning crop biotechnology, it is not hyperbole to state that the regulatory challenges facing horticultural biotechnology are both global and monumental.

REGULATORY COMPLIANCE IS ESPECIALLY PROBLEMATIC FOR HORTICULTURAL CROPS

For most horticultural crops,* the implications of the stringent regulatory system are even more grave than for field crops. This is because the high regulatory costs[12] per gene insertion event tend to be spread over a smaller variety base, with a smaller economic return, and with a longer time for the return to be manifest. This results because these crops are far more diverse in their genetics and geography, transferring approved biotech traits into new varieties through breeding is slow due to a longer generation time and biological limits to inbreeding, and because valuable genotypes tend to be cloned rather than sexually propagated. Thus, it is expected that individual transgenic events from elite clones, not progeny from deregulated or registered events, will each require separate regulatory dossiers and decisions.[3]

Moreover, these crops as a category tend to be less domesticated and thus can more readily mate with wild or feral relatives, and spread directly via seed or vegetative propagation in wild or feral environments. Because of their large size and potential for wide pollen or seed dispersal by wind, insect, or animal vectors, containment when plants are old enough to flower and are producing fruit can be very difficult, costly, and often impossible to assure. This creates a situation where gathering needed regulatory data on environmental effects, under the very strong confinement mandated by regulations, poses a kind of "Catch-22" situation (i.e., where the required information, at a high level of scientific rigor and ecological relevance, is nearly impossible to obtain while assuring full containment). Even if the data could be obtained, the required depth of analyses (e.g., of nontarget

* Throughout this chapter my focus is on woody fruit, shade, and ornamental horticulture species.

effects, fitness, potential for spread, effect on endangered species) is very costly and by their nature imprecise, requiring, for reasonable estimates, large experiments and years of study over many environments. For pest-tolerant crops (i.e., those with plant incorporated protectants, [PIPs]), the required analyses by EPA are expected to be even more costly and complex. Rarely are the paybacks to developers from improved horticultural crops sufficient to cover all of these large up-front costs.

DEREGULATED HORTICULTURAL VARIETIES DO NOT PROVIDE GENERAL MODELS

The very few woody horticultural crops that appear to have successfully navigated the regulatory maze have special characteristics, and thus provide few general lessons. They are trees that have genes that protect against a major viral pest and make no actual novel pest-toxic compound (papaya and plum: they invoke the natural RNA interference mechanism), and also cannot spread in the wild to any significant degree. The GE cold-tolerant and male-sterile eucalypt, now in extensive field trials and part of a petition for deregulation, is also dependent for its approval to allow flowering and commercial planting on its presumed sterility or inability to spread.[13] It is as yet unclear if, in a practical and affordable way, normally fertile horticultural varieties that have wild or feral relatives can comply with regulations and obtain regulatory approval for commercialization.

CAUSES OF OUR STRINGENT REGULATORY SYSTEM

How have we, in the Unites States, produced a regulatory environment that appears so hostile to transgenic innovation in horticultural crops? The political and legal history of our regulatory framework is well known,[6,14] and there are a number of very significant political issues[15] that appear to have played a major role in shaping the negative, or at least highly divided, public view of crop biotechnology. Major sources of controversy include:

1. The relatively new and major roles for strong patents in crop breeding, which provide no breeder's rights to the use of genetic material and no limits on ownership of genes and transgenic plants when they move in the environment. This appears to be considered an overstep or an outright ethical transgression to many.
2. The growing role of multinational corporations in biotechnology. This is in no small part due to the costly intellectual patent and regulatory landscapes discussed above. Negative attitudes toward these corporations and their dominance in the development of commercial biotech crops are also a result of the legacy of the production and marketing of pesticides, and of divisive products such as recombinant bovine somatotropin (rBST), by these companies or their predecessors.
3. The lack of direct benefits to consumers and food production/service companies, in the face of perceived risks to people or retail chains, from use of herbicides and pesticidal molecules in the current major transgenic varieties.

4. Divided scientific advice on the risks versus benefits of GE in relation to the stringency of regulations. The large majority of ecologists I have met with, including during services on National Research Council panels, show a strong negative attitude toward GE of crops, whereas most breeders, agronomists, and biotechnologists seem to view them positively. The concern expressed by ecologists is prompted in no small part by the commonly made analogy between transgenic and invasive exotic species. Moreover, many serious invasive plant species are the result of intentional introductions from the horticulture industry. Thus, although there is only limited biological homology between a novel invasive organism and introduction or modification of one or a few genes in a familiar organism, the legacy of exotic species problems creates a climate that dictates extreme precaution and concern.
5. The growing popularity of organically certified forms of agriculture and its strong direct and indirect campaigns against transgenic breeding methods and varieties as dangerous and "unnatural."
6. Waning trust in government and government organized science panels to make wise judgments about the safety of novel genes in foods and environment.
7. The strong political and legal pressures for stringent regulations from well-funded nongovernmental organizations that are opposed to, or highly concerned about, GE crops.

All of these are clearly major problems for any efforts to produce what GE crop developers would view as more balanced science-based regulations. However, I will discuss what I see as deeper, more foundational issues that I believe have contributed to making the regulatory system such a difficult barrier to progress in horticultural biotechnology.

Presumption of Harm from Transgenic Methods

Thomas Jefferson is widely quoted as having said that "the greatest service which can be rendered any country is to add a useful plant to its culture."* Clearly, something has changed since the era of transgenic biotechnology began. Whereas all products of traditional breeding are considered generally regarded as safe (GRAS), all varieties produced using transgenic methods are in effect considered the opposite, that is, hazardous until "proven" safe.† This is despite the common scientific knowledge, and FDA rulings, that the transgenic method per se is not more risky than conventional breeding methods such as inbreeding, wide hybridization, and mutagenesis. Moreover, the established legacy of plant breeding includes importations of exotic plants that can spread widely; enabling agriculture and humans—arguably the

* Thomas Jefferson, "A Memorandum of Services to My Country," September 2, 1800 (*PTJ*, 32:124). Polygraph copy at the Library of Congress. http://wiki.monticello.org/mediawiki/index.php/Useful_plant_%28Quotation%29

† It is not in fact possible to prove the absence of any risk.

most environmentally destructive forces on the planet—to migrate around the globe as plants have been and are bred for adaptation to new regions. Clearly, the distinct regulatory treatments, which impose such a striking double standard of strong regulation versus the absence of regulation, are a legacy of history. It is fair to say that if conventional breeding were forced to undergo the same scrutiny as does GE, much of it would not be legally permissible today. At a minimum, conventional breeding would all be subject to much higher costs and long delays, with inestimable penalties for yield and product quality improvement. It is also very likely that environmental impacts of agriculture would be far greater, as the amount of output per unit area of land, water, and fertilizer would certainly be far lower in the absence of vigorous plant breeding programs.

Environmental Concerns Prompt Strong Regulations

The pressing environmental problems facing society are another motivation for strong regulations of this new agricultural technology. Whether one considers climate change, non-point-source pollution, soil erosion, or water quality, there is clearly a pressing need to reduce the environmental footprint of agriculture. However, is the intensive regulation of all forms of transgenic biotechnology, and only transgenic biotechnology among breeding methods, a sensible means for doing this? Such a practice seems especially specious in that the environmental benefits of transgenic crops have, on the whole, been strongly positive to date (primarily in the form of tillage and pesticide ecotoxicity reductions),[16] yet many crops with similar expected benefits have not made it to market at all.[12] Some of the most notable examples of transgenic crops that, though developed and field proven, have not made it to market, are horticultural crops. These include virus-resistant berries, disease-resistant apples, and disease- and insect-resistant potatoes. All of these would have reduced pesticide applications. Although business and market factors also contributed, sometimes substantially, to decisions not to commercialize such varieties, the overarching hostile regulatory environment made the business proposition marginal at the outset, especially for public sector breeders and smaller companies. It is not difficult to argue that the stringent regulation of plant biotechnology has had the opposite environmental consequence of what was intended.

Familiar Genes Meet Same Regulatory Review

Unfortunately, the "guilty until proven innocent" framework applies not just to biotechnologies that impart novel properties, such as new kinds of pest resistance proteins or metabolites, but it applies to all cases where a transgenic method is used. Thus, it is the method, not the actual biological novelty of the new gene that triggers the regulatory system. As a result, we scrutinize all changes from the method, not just the novel property imparted, presuming all changes are hazardous until "proven" otherwise. This means that mutagenesis due to the gene insertion process is intensely scrutinized—though mutagenesis in various forms has been long applied in conventional breeding. The nature of the insertion site and any changes in general plant chemistry are studied in detail, not just transgene expression and its associated phenotypes. Regulatory agencies apply similar scrutiny even where genes from sexually compatible or closely related species are transferred, or normally expressed genes are attenuated, shut down, or mutated (often called cisgenics or intragenics). Incremental changes to existing phenotypes such as cold hardiness, reduced rate of ripening, and pest resistance—even when due to modified expression of native genes—are treated as ecologically novel traits if GE is involved. Canada has attempted to put in place a method-neutral regulatory system that covers GE as well as conventional breeding, called the "plants with novel traits" system (http://www.inspection.gc.ca/english/sci/biotech/gen/terexpe.shtml). In practice, however, it appears to regulate all forms of GE crops similarly to method-based systems in the United States, while upsetting conventional breeders when their new varieties come under regulation for the first time.

The intense scrutiny compelled by the GE method creates serious legal and epistemic problems. How can we prove safety when the variances for the system we regard as GRAS are so extraordinarily wide? Food is known to contain "toxins" and contaminants whose concentrations vary widely and can cause adverse effects in high dosage tests, and breeders often make crosses with wild relatives that have not been widely consumed for food and may even be poisonous. For example, if a modified crop has chemical components whose levels are elevated but are still within the enormous range of variation seen among conventional varieties, hybrids, and environments (e.g., of a natural alkaloid or terpenoid), such changes might not be considered safe or desirable from a toxicological viewpoint (i.e., in light of the known biochemical actions of those compounds). How such cases would fare under legal scrutiny in the EU where the Precautionary Principle prevails, or under legal challenge in the United States where FDA could declare such changes as adulteration if supported by toxicological science, is unclear. In addition, because it is logically impossible to prove the absence of a risk, it is very difficult to scientifically declare safety for the whole organism, especially for crops or where gene products that do not fit the standard toxicology model (i.e., where they have complex phenotypic changes, and thus simple dose–response tests performed in the laboratory are not meaningful). This has led to continued political debate over how safe is safe enough, including over whether "substantial equivalence" is a satisfactory regulatory attribute.

This indiscriminant system also means that gene transfers from related species, such as the transfer of a pest resistance gene from a wild relative, faces the same regulatory system. Why should a gene introduced through hybridization from a wild relative, with its usual linkage drag, be considered less risky than the same gene isolated and introduced using GE methods and accompanied by a well-studied vector and associated sequences? In other words, why are they regulated at all, when the same or a similar result can be produced with conventional breeding, though with less precision? Although it seems likely that regulators will require less data for low novelty transfers compared to wide phylogenetic transfers or newly synthesized genes, just by entering the highly politicized regulatory arena—where agencies simply respond to each case as they come in the door—the costs, delays, and outcomes are unpredictable, and thus can result in costly delays or roadblocks. The unpredictability of the regulatory process is a very serious problem for companies, investors,

and grant agencies choosing among research and technology transfer options. They have little idea what the cost and time delays will really be, and agencies provide no guarantees up front.

ENVIRONMENTAL STUDIES ARE SERIOUSLY COMPROMISED BY REGULATIONS

From an environmental viewpoint, the presumption of harm creates even larger problems and regulatory obstacles. As discussed above, it is very difficult to predict ecological impact from small studies that are performed under containment. Although simple extrapolations are possible when the toxicology model applies (as with a pest toxin whose effects on wild species can be roughly estimated in the greenhouse or short-term field study), even this simple case is fraught with difficulty. Such studies say little about the effect of such genes under varying abiotic and biotic environments in the field, and they cannot predict in any meaningful way what might happen in a future dominated by climate change, nor can assess how biological communities will adapt and evolve in response to the new gene product and phenotype.

In other words, under current regulatory constraints we are unable to adequately answer any of the big questions about transgene impacts. For example, how will the myriad species that might be exposed to a naturalized transgene-expressing plant be affected over time? Can the novel gene/toxin have so strong an effect as to drive an herbivorous species to extinction, or will most species, or other ecosystem adjustments, attenuate such effects over evolutionary time? Do the perturbations matter given the very large effects of agriculture, breeding, climate-induced variation, anthropogenic change, and exotic species in general? How often will genes of value in the management of simple agricultural systems, or as a result of crop domestication for human tastes in food and fiber, be ecologically powerful in diverse wild or feral systems? The point is that while the goal of regulations is to force informed and wise decisions, the reality is that the *process* imposed, with its high costs and legal risks, appears to do more harm than good by impeding most forms of transgenic research and development with horticultural crops. A more efficient option might be to exempt the transgenic method and small or contained field trials from regulation, but require substantially novel gene products—such as phylogenetically novel and broadly effective toxins, or pharmacologically active molecules that result from synthetic biology or long distance phylogenetic transfers—to undergo regulatory review prior to large scale, uncontained field research or commercial use. We have provided more specific recommendations for regulatory reform elsewhere.[3,4,14]

PRESUMPTION THAT STASIS IS DESIRABLE

The USDA regulations for transgenic biotechnology treat all transgenic innovations as risks. The benefits of transgenic plants are not formally considered. This framework is not surprising given the evolution of the current regulatory scheme from a plant pest oriented system.[17] The framework therefore implicitly assumes that crop species and their wild relatives that might receive transgenes via gene flow

are superior in their present form to what they would be with the modified genes—unless a strong case can be made otherwise. This presumption (and the underlying conservation-oriented value that supports it) seems reasonable, until one considers the very strong barrier it also poses to the transgenic use of pest or stress resistance genes to promote the health of horticultural woody plants in cases where they have wild or feral relatives (as nearly all do). If the gene disperses, the genetic diversity and fitness of wild relatives might be increased to some degree. This might in fact be beneficial because woody horticultural and forest species are often foundational members of terrestrial ecosystems, providing much of the structural habitat and primary productivity. Thus, some increased vigor and adaptability would generally be expected to be ecologically advantageous, not disadvantageous. In addition, many woody species are under serious threat from climate change and the emergence or invasion of newly epidemic and/or exotic pests,[18] and thus could benefit from genes that increased their resilience or pest/stress tolerance. Of course, in cases where a wild relative is already a problematic exotic species that is having a strong negative environmental impact, such improvements of vigor would not be considered desirable. Such cases could be specially identified and disallowed (e.g., by presence on a noxious weed list), rather than imposing a blanket preclusion to gene flow to wild relatives as a result of the transgenic method.

The core regulatory and ecological problem is the extreme difficulty in predicting the outcome of transgene introductions in terms of their ultimate ecological impact in advance, without actual field releases and monitoring over many years and sites. This, however, is very costly, especially where strong containment must be imposed during these trials. As stated above, this is a reasonable requirement for species with high risk relatives such as a Johnson grass or a scotch broom, but unfortunately under the current operational "presumption of harm" such precaution is applied to all transgenes and species. This makes commercialization of each transgenic product a multidecade and multimillion dollar undertaking, even when pest resistance genes from related plant species are used, and appears to make transgenic solutions prohibitive except in special cases (e.g., American Chestnut, a dominant tree that was driven near to extinction and has strong private and public foundation support for the use of biotechnology for its restoration).[19] Given the growing pace of such serious threats to wild and cultivated trees, it would appear that new, expedited regulatory options—such as exemptions for species in crisis and/or genes from related species—are critically needed.

CONSEQUENCES OF SIMPLE DEFINITIONS OF CLEAN AND GREEN

Finally, a major impediment to the use of transgenic methods appears to reside in the blanket manner with which society seems to categorize technologies as good or bad. Organically certified food is currently considered by much of the public to be greener, safer, and thus superior to conventionally produced food. Yet when scrutinized it has not shown any consistent advantages for food safety or nutrition, and its net environmental benefits are also questionable (e.g., when full life cycle studies of nitrogen, land use, runoff, soil erosion, transport, and energy consumption—and even pesticide ecotoxicity in some cases—are considered).[20–22] Nonetheless,

perceived economic harms to marketing organic products as a result of "contamination" of organic food by GE, even when at very low levels, have prompted successful lawsuits. The courts have viewed organic agriculture as an environmental good, whose possible harm thus requires careful consideration via an environmental impact statement. Such a ruling for alfalfa has resulted in its withdrawal from the marketplace,[23] and a similar case is pending for sugar beet. These legal precedents and the high costs they impose are likely to continue to slow, and in many cases will prevent development of GE crops. Unfortunately, these legal decisions appear to be informed by a popular, rather than a scientific, view of the relative environmental value of GE versus organically certified food. Simple green labels that presume GE is bad and any GE "contamination" of "green" products is bad—when uncritically accepted by courts and a large section of the public—pose considerable challenges to revision of the current regulatory system.

CONCLUSIONS

Regulatory change that would decriminalize the GE process is needed to move forward. But how can that happen? It could be motivated by growing urgency for improved food production, as expanded uses of crops for bioenergy, and climate change-induced crop losses, continue to drive up food prices. Change may also be motivated by the many humanitarian GE projects underway for the developing world, of which Golden Rice is the best known. A single major, highly publicized success could shift public opinion substantially. Change may also be motivated by informed, popular, and powerful thought and environmental leaders, such as Stewart Brand and Michael Specter, who have embraced the benefits and debunked the myths surrounding GE crops and other environmental and scientific technologies.[22,24] However, as discussed above, due to the many layers of national and global regulations, and the strong political influences on them, the timescale of change may be on the order of decades or more.

For change to ultimately occur scientists must play a key role. By educating decision makers and the public in understandable, contextually relevant, and generationally appropriate forms, and by taking an active part in providing public input to regulatory decisions, biotechnologists can help to craft a new era of intelligent, discriminating, science-based regulations. Transgenic biotechnology is too powerful a tool to surrender. Our precarious world, the billions of needy people, and threatened nonhuman species need it to become a potent and central part of the crop technology toolkit.

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