The Biggest Pest of All

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THE U.S. DEPARTMENT OF AGRICULTURE'S biotechnology regulations have been a shambles for more than 15 years. Its compulsory case-by-case review, costly field test design, and other requirements have made gene-spliced plants disproportionately — and unnecessarily — expensive to develop and test. A field trial with a gene-spliced plant may be 10–20 times more expensive than the same experiment performed with a plant that has identical traits but that was modified with less precise genetic techniques.

The USDA's approach to biotechnology regulation is internally inconsistent and contradicts official federal policy (developed during the previous Bush administration with the explicit concurrence of USDA), which stipulates that oversight of biotechnology products should be "risk-based," "scientifically sound," and focused on "the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created." The USDA has crafted exactly the opposite: regulation that arguably has an *inverse* relationship to risk and is triggered by the use of gene-splicing techniques.

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USDA regulators announced last January 23 that they plan to revise their approach to oversight of gene-spliced plants. Is that good news? Not really. Their plan ensures that they will get the scope of what they regulate wrong yet again, and that they will spend years and tens of millions of dollars on a gratuitous environmental impact statement.

BETTER APPROACH The USDA's strategy is unconscionable, an example of a flawed, unnecessarily complex government solution to a problem that regulators created in the first place. Ironically, a scientifically sound and risk-based regulatory approach, grounded on the well-established model of the USDA's own plant quarantine regulations, has already been proposed by several academics, including this author.

Almost a decade ago, the Stanford University Project on Regulation of Agricultural Introductions began work on a widely applicable regulatory model for the field-testing of any organism, whatever the method or methods employed in its construction. It is patterned after national quarantine systems, including the long-standing USDA Plant Pest Act regulations, the approach of which is essentially binary: A plant that a researcher might wish to introduce into the field is either on the proscribed list of plants pests — and therefore requires a permit — or is exempt.

The more quantitative and nuanced "Stanford Model" is based on the ability of experts to stratify organisms into several risk categories. It closely resembles the approach described in the federal government's handbook *Biosafety in Microbiological and Biomedical Laboratories*, which specifies the procedures and physical containment that are appropriate for research with various microorganisms, including the most dangerous pathogens known. The microorganisms were stratified into risk categories by panels of scientists. Interestingly, and in contrast to the USDA's approach to gene-spliced organisms, the handbook does not — even for the most dangerous pathogens — dictate mandatory requirements, but only offers guidance to researchers.

EVALUATION The Stanford Model was validated in a proof-of-principle project in 1997. (That demonstration applied only to plants, but the model can be readily applied to accommodate other kinds of organisms, as well as regional and local preferences for greater or less stringent regulation.) The project assembled a group of approximately 20 agricultural scientists from five nations at a workshop held at the International Rice Research Institute (IRRI) in Los Baños, Philippines. The goal was to develop a risk-based, scientifically defensible approach that would evaluate all biological introductions, not just those that involved gene-spliced organisms. The need for such a broad approach was self-evident: There was already abundant evidence that severe ecological risks can be associated with plant pests and "exotic," or non-coevolved, organisms.

As part of the pilot project, the IRRI conference participants evaluated and then, based on certain risk-related traits, stratified a variety of crops into risk categories. Such traits included the ability to colonize, ecological relationships, effects on human health, potential for genetic change, and ease or difficulty of risk management. Consensus was reached without difficulty, suggesting that it would be similarly possible to categorize other organisms as well.

Each of the organisms evaluated during the conference was assessed for all five factors, which enabled the group to come to unanimous agreement about the organism's risk cat-

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egory. Most of the common crop plants addressed were found to be of negligible risk, while a few were judged to be of low but non-negligible risk. One plant (cotton) was judged to be of negligible risk if it were field tested outside its historical center of origin, but of low (but not negligible) risk if tested in the vicinity of its center of origin.

In the evolution of this Stanford Model, the factors taken into account were indifferent to any genetic modification techniques employed, or to the source(s) of the introduced genetic material. The participants agreed that the use of conventional breeding techniques or gene-splicing methods to modify an organism was irrelevant to risk. They also agreed that whether DNAs were combined from distantly related organisms — that is, organisms from different genera, families, orders, classes, phyla, or kingdoms — was irrelevant to the risk of an organism.

In other words, the group's analysis supported the consensus view of the wider scientific community that the risks associated with field-testing a genetically altered organism are independent of the process by which it was modified and the movement of genetic material between "unrelated" organisms. The Stanford Model proves the utility and practicality of an approach in which the degree of regulatory scrutiny over field trials is commensurate with the risks — independent of whether the organisms introduced are "natural," "exotic," or have been genetically improved by conventional methods or gene-splicing techniques.

OPERATION What are the practical implications of an organism being assigned to a given "risk category"? The level of regulatory oversight faced by a field trial investigator could include complete exemption, a simple "postcard notification" to a regulatory authority (without affirmative prior approval required), case-by-case review and required assent by regulators, or even prohibition (as is the current case of experiments with the Foot and Mouth Disease virus in the continental United States).

A key feature of the Stanford Model is that it is sufficiently flexible to accommodate differences in regulatory authorities' preferences for greater or lesser regulatory stringency. Various national regulatory authorities can choose the level of risk-aversion that best suits them by selecting different regulatory requirements that correspond to the various risk categories, some leaning more toward exemption and notification, others toward case-by-case review. However, as long as regulatory requirements match the relative risk of each category and do not discriminate by treating organisms of equivalent risk differently, the regulatory methodology will make scientific (and common) sense.

This regulatory model makes it possible to perform accurate, scientific determinations of the risks posed by the introduction of an organism into the field — and to match regulatory requirements to those risks. Consequently, it fosters enhanced agricultural productivity and innovation while protecting valuable ecosystems. It offers regulatory bodies a highly adaptable, scientific paradigm for the oversight of plants, microorganisms, and other organisms, whether they are "naturally occurring," non-indigenous, or have been genetically improved by either old or new techniques.

Under such a system, some currently unregulated introductions of traditionally bred cultivars and exotic organisms considered to be of moderate or greater risk would likely become subject to regulatory review, whereas many gene-spliced organisms that now require case-by-case review would likely be regulated less stringently. The introduction of such a risk-based system would streamline the regulation of field trials and would reduce the regulatory disincentives to the use of gene-splicing techniques that currently exist.

The Stanford model is ready to roll. But the USDA's roadmap makes it clear that regulators intend to continue to single out gene-splicing for discriminatory regulation. When it comes to regulatory reform, the USDA cannot seem to find the onramp. The feds who regulate plant pests are still the biggest pests of all. R

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Reactionary Regulation

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Well-publicized business scandals often result in the enactment of new government regulation. Policymakers and industry leaders worry that if they do not enact new laws and rules, the public might confuse them with the unethical actors, regardless of whether or not the enacted regulations actually protect consumers in any meaningful way. Thus, worthless or counterproductive regulation usually follows corporate scandals.

Since 1988, the accounting industry has advocated a 30-hour increase in the traditional 120-semester hour baccalaureate degree required to sit for the Uniform Certified Public Accountant exam. Although states initially responded gradually to this push, the Arthur Andersen and Enron scandals changed that dynamic. Now, 45 states have adopted the increase, thus requiring accountants to pursue the equivalent of five years of college rather than the traditional four.

CENTENNIAL STATE OPPOSITION Colorado has resisted that change. In response, proponents of the 30-hour increase claim the state is not protecting consumers. Is Colorado's resistance to more credit hours a careless disregard for consumer protection?

There are two points that, *prima facie*, argue against increasing the credit-hour requirement. First, there is no evidence that consumers have been harmed by the 120-hour requirement. Second, increasing the required semester hours will increase the barriers to entry and thus reduce the supply of accountants. In light of those two points, it is difficult to argue that Colorado officials are somehow being derelict in their duty if they do not adopt the 150-hour standard.

Colorado is one of the least regulated states in the nation, and also one of the most prosperous. Offices within the Colorado Department of Regulatory Agencies review proposed rules to protect small businesses from potentially onerous new regulations and perform sunset reviews to evaluate the necessity of existing programs.

In 1997, the Colorado Legislature adopted the 150-semester hour requirement, but the provision was subsequently repealed in 2000. The increase never went into effect because the 1997 law included a five-year transition period. The repeal occurred in response to the 1999 sunset review of the Colorado Board of Accountancy, which determined that it was not in the public interest to mandate an increase in semester hours for accountants. In the words of Gov. Bill Owens, "Colorado CPAs aren't suffering with only four years of college. It's just a way to protect current CPAs. It's just a needless expense."

RACE TO THE BOTTOM? Critics claimed that Colorado would become a diploma mill and that the quality of the accounting profession in the state would suffer. There is no residency requirement to sit for Colorado's CPA exam, and the state has seen a slight increase in the number of international applicants for the test. Consequently, the accounting industry will likely renew its efforts to change Colorado's requirements when the Accountancy Board is up for its next sunset review in 2005.

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Is Colorado experiencing a "race to the bottom"? In the years since most states increased their semester hour requirement, Colorado has not seen a disproportionate increase in accounting industry problems relative to other states. In fact, no evidence from either the state or independent groups suggests that Colorado's resistance to increasing the 120-hour requirement harms consumers at all. Colorado has not become a wasteland of undereducated, unscrupulous accountants, and there is no indication that it ever will.

CONCLUSION A simple increase in educational requirements will not solve ethical problems in the accounting industry. The accountants involved in the Enron scandal were well edu-

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cated and unethical. The accountants working for Arthur Andersen were some of the most highly educated accountants in the world. Competition for positions in top accounting firms is fierce, and only the "best and brightest" receive job offers. Many top accountants obtain graduate degrees; thus they have more than the proposed 150 semester hours. Requiring 30 additional undergraduate semester hours will not rid the accounting industry of all its potential "bad apples."

Critics argue that educational requirements must be increased to reflect changes in the accounting industry. However, colleges and universities have always updated coursework to reflect industry changes without increasing the semester hours required for a degree. If new information did not replace obsolete coursework, earning a degree in most fields could take decades to complete. Updating the curriculum can and should be done within the bounds of established timeframes.

Students and parents who pay for school want to maximize the benefits that flow from their tuition dollar. If a student can obtain a finance or general business degree in four years versus an accounting degree in five, financial considerations may drive them to do so. While the increased requirements may keep some unscrupulous accountants out of the industry, the requirements would also discourage potentially first-rate accountants from entering the industry. This outcome does not protect consumers. It only raises their costs and protects the income of current accountants. R