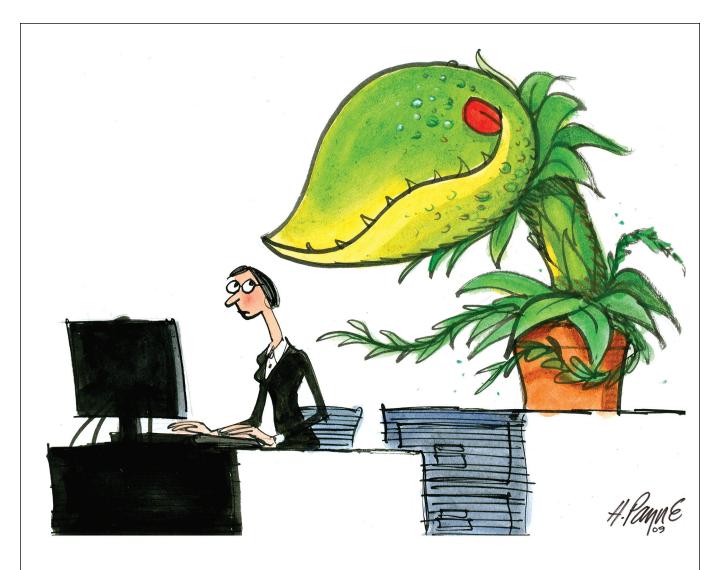
Environmental Protection Through Analysis · Opinion · Debate



Are Current Rules Adequate to Regulate Genetic Engineering?

Water's Worth

The U.S. Faces a Future of Scarcity

Vision Test

Eyeballing IRIS, the Toxics Bible

Regulating Climate

Should Obama Wait for Congress to Act?

The Next Generation

U.S. regulatory agencies have reviewed genetically engineered crops by adapting existing laws to address potential safety questions, but those procedures have not resulted in adequate oversight. With a second generation of GE crops in prospect, the federal government needs to improve its regulation to ensure safe products from a promising technology

Gregory Jaffe



Gregory Jaffe is Director of the Biotechnology Project at the Center for Science in the Public Interest in Washington, D.C.

n the past dozen years, genetically engineered crops have become part of mainstream agriculture in developed and developing countries alike. Farmers have planted GE crops on millions of acres and the majority of the risks raised by critics have not been borne out. While not all the advantages touted by the developers have materialized either, significant benefits have been documented. GE crops are here to stay.

Developers are set to move forward with the second generation of GE products. The first generation mostly benefited farmers and included plants that produce their own pesticides or are resistant to herbicides. The second generation could move far beyond those achievements. For crops, that means traits such as drought-tolerance and enhanced nutrition. Then on to engineered meat and dairy animals and drugproducing biopharming. Are current rules adequate to regulate these activities? It is time to revisit the debate about genetic engineering in agriculture.

To date, GE crops have been managed under the Coordinated Framework for Regulation of Biotechnology, a 1986 federal policy that calls on the Environmental Protection Agency, Food and Drug Administration, and Department of Agriculture to regulate GE products using existing laws. The framework has attempted to ensure the safety of first-generation crops but can it adequately regulate upcoming products? With products looming on the horizon that may be more controversial and raise more potential risks than current ones, public understanding of current GE crops and their regulation as well as the potential for new benefits (and new risks) is critical to U.S. leadership in biotechnology as well as to protecting the environment and public health.

Genetic engineering in agriculture involves taking a gene from one species and introducing it into a cell of another species to produce a desired trait in the resulting organism and its progeny. So far, developers have concentrated on agriculturally important characteristics, chiefly herbicide tolerance and the ability of plants to produce their own pesticides, in four crops: corn, soybeans, cotton, and canola. Those crops have been widely adopted in certain countries, with the United States leading the way. In 2008, some 12 million farmers grew 282 million acres of GE crops in 23 countries. In the United States, 142 million acres of GE crops were planted, which included 80 percent of the corn crop, 92 percent of soybeans, and 86 percent of upland cotton. In developing countries, Chinese and Indian farmers were the most significant adopters, with almost 11 million mostly small-holding farmers

growing 27 million acres of insect-protected cotton.

While many developers and biotech proponents generalize benefits globally for GE crops, in reality, benefits must be analyzed based on the crop, the introduced trait, and the specific location and farming conditions. Adoption of first-generation GE crops has been driven by the benefits that accrue to farmers. In the United States, farmers growing conventional cotton use significant amounts of pesticides to reduce insect damage. Farmers who adopted GE cotton reduce the number of pesticide applications by as much as half. On the other hand, adoption of herbicide-tolerant soybeans by U.S. farmers has not reduced total herbicide use but substituted a herbicide that is believed to be less environmentally harmful. Those herbicide-tolerant soybeans have not increased per-acre yields but they have increased farmers' use of environmentally beneficial no-till farming and reduced their management time.

In developing countries, small-scale farming conditions are different from U.S.-style industrial agriculture, and so the benefits of GE crops are different. Many farmers in India or China had not sprayed pesticides, so using Bt cotton, which produces its own insect-repelling chemicals, does not significantly reduce pesticide use. Studies show, however, that Bt cotton farmers have higher yields, increased income, and their use of Bt cotton even increases the yields of neighboring non-GE cotton farmers (a spillover effect). For example, one study in India found that farmers

planting Bt cotton had a gross revenue benefit of 162 percent. For farmers who did use pesticides on their crops, another significant benefit has been the reduction in poisonings from the reduced pesticide use. That benefit is not seen in developed countries, with their tougher safety regulations.

s the benefits have varied by location and product, so have the risks. To date, no commercial GE crop has presented any food-safety risk or resulted in a documented human health effect, although each new product still needs to undergo its own individual food-

safety risk assessment. Developers need to ensure — and the government needs to verify — that the introduced gene does not produce an allergen or toxin and that by engineering the plant, there is no reduction in its nutritional profile or the production in any edible portion of harmful substances normally produced elsewhere in the plant.

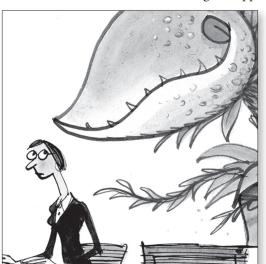
Environmental risk assessment and management of GE crops is complex because the environment is dynamic and agriculture, by its very nature, is usually environmentally detrimental. Some environmental concerns raised by the current GE crops have been whether the plants can transfer the introduced genes to wild relatives and what effect that might have; whether they can transfer the gene to native land races and impact biodiversity; whether the newly produced substances might impact non-target organisms (such as Monarch butterflies, grasshoppers, or deer); and whether pests

might evolve resistance to the incorporated pesticide and return farmers to the pesticide treadmill.

To address any potential environmental risks for GE crops, regulators have requested environmental studies and imposed use restrictions, but the results have been mixed. For example, when there was a concern in 2000 that insect-protected corn might harm Monarch butterflies despite the initial risk assessment's contrary conclusion, additional evidence did find that one variety had such an impact, but, by chance, that particular variety was not fa-

particular variety was not favored by farmers, did not have widespread adoption, and could be easily discontinued. Regulators around the world have imposed refuge requirements (areas of non-insect-protected corn or cotton planted in close proximity to the GE crop) to retard the development of resistant pests and preserve the technology for future generations. While those refuges have been highly effective in the United States, at least one instance of resistant pests has emerged in South Africa. And some engineered DNA did contaminate local corn varieties in Mexico but there was no negative impact on those crops or local biodiversity.

The most significant risks from GE crops, however, have been socioeconomic and commercial. When Star-



Products looming on the horizon may be more controversial than the first generation

link corn, a GE variety only approved for animal feed, got into the food supply, it resulted in a \$1 billion recall. More recently, when rice planted in the United States was found to be contaminated with small amounts of an unapproved, though safe, GE-variety, there was no domestic recall but trade with countries such as Japan was affected, greatly impacting rice farmers. And the growing of GE crops that have been approved in the United States but not in trading countries has reduced U.S. exports of some commodities and forced channeling of exports at lower prices and volumes to specific domestic and international markets.

iotechnology companies plan to commercialize additional herbicide-tolerant and pesticide-producing varieties of commodity crops. In some cases, engineered crops are being "stacked" with multiple genes to increase their utility to farmers. Monsanto and Dow AgroSciences have announced they would jointly market a seed combining eight different herbicide-tolerant and insect-protection genes. It will be available next year.

The next decade could also see the commercialization of second-generation biotech products that could be controversial. Second-generation products include complex input traits helpful to farmers and nutritionally enhanced products beneficial to consumers. Some engineered crops designed to address farm-level production constraints that farmers could be growing soon include drought-tolerant corn and cotton and salt-tolerant corn. Engineered animals and biopharming will come next.

Biotechnology companies and public researchers also have announced plans to commercialize nutritionally enhanced products, a claim heard during the early years of biotechnology that still has not borne fruit. Monsanto is developing GE omega-3-enriched soybeans. Golden rice — a variety engineered years ago to produce beta-carotene and touted as a partial solution to vitamin A deficiency in developing countries — is receiving new funding from the Rockefeller Foundation to move that product from the laboratory to farmers in southeast Asia. Also, the Gates Foundation is funding research on a biofortified sorghum that could improve the nutritional status of millions of Africans who rely on the grain for most of the calories in their diet.

Second-generation engineered products will also involve food animals. A Massachusetts company, AquaBounty, has engineered salmon by adding a gene from another fish species so that they reach market size in half the time. That may reduce producer costs and generate an environmental benefit by reducing both the feed that fish-farming operations use and the waste

that the fish produce. Other companies are engineering pigs to produce less polluting waste and engineering cows to be resistant to mad cow disease. Scientists also are engineering pigs so that their meat contains healthy omega-3 fatty acids. However, in addition to potential food-safety and environmental risks, engineering animals raises animal welfare concerns and objections by some people that these activities are unethical or immoral.

Biopharming is also controversial. It is defined as using crops or animals as factories to produce biologically active molecules that are extracted, purified, and then sold as human drugs or biologics. For example, GTS Therapeutics has transplanted genes from humans into goats, which then produce milk containing anticoagulants and other human drugs. Hematech is using engineered cattle to make human polyclonal antibodies. Ventria Biosciences is using rice to produce proteins found in breast milk, and SemBioSys is using safflower to make pharmaceuticals and other high value proteins. Those biopharming developers claim their drugs are cheaper to produce and will improve human health.

Biopharming products are expected to be in the marketplace within the next few years. If this production method is commercially viable, engineered plants and animals must be segregated so that they don't enter our food supply. No one wants their glass of milk to contain dissolved spider silk molecules or for their corn flakes to have even minimal levels of human pharmaceuticals.

lthough GE crops were commercialized in 1996, the federal regulatory system for those products actually started a decade earlier with the Coordinated Framework. That policy focuses on three agencies, EPA, FDA, and USDA, and uses existing statutes that were written before genetic engineering or its products existed. In addition for its assertion that current statutes were sufficient for regulation, the framework stated that the products, not the process by which they are developed, should be the basis of any regulation. Although a creative attempt to regulate an emerging technology using existing laws, because it was stitched together from diverse parts, it resulted in gaps and ambiguities in regulation as agencies applied standards and procedures not designed to address those products.

FDA regulates food under the Food, Drug and Cosmetic Act, which requires pre-market approval only for "food additives." The agency determined in 1992 that added DNA in crops (and its resulting fruit) generally is not a food additive and does not require mandatory pre-market approval. Instead, FDA set up a

voluntary consultation process whereby developers can show the agency their food safety data so it can identify any deficiencies. While such regulation is welcomed by developers (they get to avoid the lengthy food-additive approval process), it puts the burden on the agency to find a product potentially unsafe before it can prevent its introduction into the food supply. It also results in the public relying on the industry's self-interested safety determination, instead of an FDA independent safety assessment. In contrast, every other country with a functional biosafety regulatory system mandates a government approval before a GE crop is marketed. It is also ironic that GE crops need formal approval to be planted outdoors (see below) but no formal approval to enter the food supply. That result is not a policy decision that GE crops are more dangerous to the environment than they are to eat, but solely because the government is trying to fit products made using a new technology into an old regulatory scheme not designed for such applica-

Engineered food crops that produce pharmaceuticals also avoid food regulations at FDA because the law's definition of food is something intended to be eaten by humans or animals. If a developer does not intend its GE biopharming crop to enter the food supply, then FDA has no jurisdiction until and if that crop inadvertently ends up in the food supply (but everyone knows accidents do happen).

FDA announced last September that it will regulate GE animals as "new animal drugs," which requires FDA approval before companies can market those animals and their products. While GE animals clearly are not similar to conventional animal drugs and the public will not understand why they are being treated like drugs, applying those legal provisions does ensure a mandatory pre-market approval process intended to safeguard the animals' welfare along with any food from those animals. The down-

Feeding, Fueling, Healing

Michael Wach

ince biotech products were first commercialized in 1996, the world has embraced this science because of the proven benefits it delivers to growers and consumers. More than 12 million farmers in 23 countries are using agricultural biotechnology today. In other words, ag biotech is agriculture.

Biotech crops help farmers grow heartier and healthier food. A genetically enhanced virus-resistant papaya literally saved the Hawaiian industry for farmers who suffered devastating losses from a pest. Biotechnology also benefits the environment. Because biotech crops

require less cultivation and fewer pesticide applications, farmers save fuel and reduce carbon dioxide emissions.

As we look to the future, we see the promise of crops that are more tolerant of drought and flooding and crops that

use soil nutrients more efficiently. Foods can also be fortified with more nutrients.

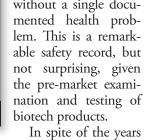
Although animal biotechnology is a much younger segment of this dynamic industry, its promises are equally compelling, and society is just beginning to learn of its benefits. Research with genetically engineered animals has yielded a variety of breakthroughs that can help advance human health, enhance food production, mitigate environmental impact, and optimize animal welfare. In January, the Food and Drug Administration issued the first regulatory guidance governing GE animals. This system ensures the products made available through this science will go through a rigorous and transparent review process before being approved for the marketplace.

All of these societal benefits can be realized with next-generation biotechnologies. But they must first work their way through a complex, rigorous regulatory system.

Rules must keep pace with the technology they regulate. But years of experience with the successful and safe deployment of biotechnology indicate that the amount of regulatory oversight in the United States is adequate. U.S.-developed biotech products are so well adopted precisely because our regulatory system results in safe, high-quality products.

The fact is, products derived from biotechnology have been consumed by billions of people

for more than 15 years without a single docubiotech products.



of costly research needed to bring these products to market, developers want the regulatory scrutiny that provides safety for humans and the environment. The reality of modern agriculture dictates that this scrutiny makes not for just good science, but also good business.

Thoughtful commercial development, with appropriate regulatory oversight, is the best way to continue to bring these valuable products to market, well into the future. Now more than ever, we should embrace the technologies that help us be better stewards of the land, while feeding, fueling, and healing our growing world.

Dr. Michael Wach is Managing Director of Science and Regulatory Affairs for Food and Agriculture at the Biotechnology Industry Organization in Washington, D.C.

side is that new animal drug applications and the approval process are shrouded in secrecy, with no opportunity for public comment before FDA approves the product. Such a closed process will not instill consumer confidence. In addition, GE animals may raise environmental issues, such as potential effects of the fast-growing salmon escaping and mating with wild salmon populations (although the developer says it intends to sterilize the fish). FDA will assess environmental issues in compliance with the National Environmental Policy Act but has no legal authority to deny approval of that animal due to an environmental concern. It also does not have adequate recall authority if a problem arises after commercialization.

USDA regulates the import, interstate movement, transport, or release into the environment of GE crops under the Plant Protection Act. Under current regulations, regulated GE crops must submit to one of three oversight processes before release into the environment. Under notification, if the GE crop meets eligibility criteria and the field trial meets established containment standards, the applicant provides the agency with a notification detailing the release; USDA has 30 days to respond. As many as 1,000 field trials are authorized each year using this procedure. The second process is permitting, which requires a more detailed application and a longer review time at USDA before the release is authorized. GE plants that must be permitted include biopharm crops and those that could affect non-target species. Permitting is not as common as the notification process, although hundreds of permits have been issued since USDA began regulating GE crops. The third process is a petition for non-regulated status, where a developer requests USDA to determine that there is no plant pest risk and that the crop no longer needs regulation. The petition process is the primary path to commercialization. Over 60 crops have been deregulated.

While the USDA regulatory system for GE crops is extensive, it has a number of deficiencies. It does not necessarily capture all GE crops, only those with the potential to be plant pests. Also, it does not conduct a thorough environmental assessment for all GE crops, and when it does, those assessments have been criticized as not analyzing all relevant concerns. When GE crops are deregulated, USDA has no means for enforcement if a problem arises. And the department's enforcement to ensure compliance with issued permits has not been effective. Virtually all violations to date have been identified through industry self-reporting, not agency inspections.

EPA regulates GE crops that have been engineered to express a pesticide (called plant-incorporated protectants or "PIPs") under the Federal Insecticide, Fun-

gicide, and Rodenticide Act. A developer must register the GE crop, which requires EPA to determine that the PIP will not cause "unreasonable adverse effects on the environment" and that it does not raise any foodsafety concerns for edible portions of the crop. While EPA's regulation of PIPs has not been perfect (its regulation of StarLink corn led to massive food recalls), the agency's procedures are thorough and transparent and the result has generally been protective of both humans and the environment.

While regulation for the most part has worked in the dozen years since GE crops were commercialized, until the deficiencies are eliminated, the federal government will not be adequately ensuring that GE crops are safe to agriculture interests, humans, and the environment. This past October, USDA published proposed revisions to its regulations that may be an improvement but it will depend on what the agency finally enacts and how the rules are implemented.

enetically engineered crops have become part of mainstream agriculture in developed and developing countries. U.S regulatory agencies have reviewed those crops by adapting existing laws to address potential safety questions, but those procedures have not resulted in adequate oversight that will safeguard our food supply, protect our environment, and lead to widespread consumer acceptance of safe products as the second generation comes online.

In the future, GE crops developed to help farmers should continue to prosper and new crops that benefit their health and nutrition should be available to consumers. Products involving biopharming and engineered animals, however, may not reach commercialization unless developers demonstrate benefits and convince independent regulators that those products can be produced while ensuring food and environmental safety. But can oversight be improved to protect the industry, its customers, and the environment?

Future actions of developers and regulators will determine whether the industry continues to mature and advance new products around the world. The federal government should continue revising its regulations based on its experience to date and the new products on the horizon. Congress should step in and give regulatory agencies additional authority to do their job better. If a strong, but not stifling, regulatory system can be implemented, there will be continued investment in this promising technology, consumers will have confidence in new products, and benefits will continue to be realized. •