SUSTAINING A REVOLUTION

A Policy Strategy for Crop Engineering

A paper by David G. Victor and C. Ford Runge based on a Council on Foreign Relations
Study Group

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FOREWORD

The United States and the European Union (EU) are edging ever closer to an outright trade dispute over genetically modified foods. Farmers in the United States and several other countries are devoting an increasing fraction of their fields to these crops because they are less costly to grow than conventional varieties. At the same time, however, many European governments have branded genetically modified foods unsafe for humans and dangerous to the environment—despite scientific analysis, though still incomplete, which strongly suggests that these fears are vastly overblown. Meanwhile, the World Trade Organization prohibits governments—which rarely rely solely on scientists when making policy—from barring imports of novel food products without a sound scientific justification for their actions. What is to be done? Two highly respected authors—David G. Victor and C. Ford Runge offer a long-term strategy of political and economic steps that is workable. If their plan or something like it is not followed, the next set of choices for Europeans and Americans will be far more drastic.

Their report is their own responsibility, but it was based on cogent and careful deliberations of a Council on Foreign Relations Study Group. That group was chaired by David L. Aaron, whose experience in business and government and tough-mindedness made him an ideal discussion leader. The Victor-Runge report argues that the dispute over access to the European food market must be seen in a larger context. It is an early skirmish in a revolution that is transforming agriculture. Genetic engineering is not the only important innovation in agriculture today: fertilizer, pesticides, and mechanization are still making significant contributions to the business of farming. But crop engineering opens avenues unavailable with traditional crop breeding techniques. In so doing, it promises to make agriculture more precise and productive.

Dr. Victor and Dr. Runge offer a long-term strategy to ensure that the early skirmishes do not derail this important technological innovation. Prosecuting a formal trade dispute against the European Union, they argue, would only backfire on the United States: the EU is unlikely to change politically popular regulations just because they run afoul of international trade laws, and the acrimony and hype surrounding such a dispute would just make it harder for consumers to understand the real benefits and costs of crop engineering. A better approach, Victor and Runge argue, would sustain the current transatlantic dialogue on these issues. The United States should focus pressure on the few egregious aspects of EU policy—such as proposed labeling requirements for meat produced with engineered feeds—that are particularly harmful to U.S. exports and completely divorced from any sound scientific basis. At the same time, the EU-U.S. dialogue should concentrate on the need for EU government policies that will increase public confidence in food-safety regulation. Europeans' wariness about genetically modified food stems largely from a long history of regulatory failures by their own governments that have made consumers skeptical about ingestible innovations.

A long-term approach is needed. The first generation of engineered food crops that farmers are planting today barely reveals the technology's ultimate potential. Subsequent generations, already developing in laboratories and field trials, will make it possible to grow foods that are more nutritious and have a smaller impact on the environment as compared to traditional crops. Consumers in the advanced industrialized nations are likely to embrace these new foods. But their benefits could be even more significant in rural areas of developing countries, where local populations often suffer from malnutrition and subsistence farmers struggle to get ahead.

The long-term strategy outlined here urges governments to reinvigorate their commitment to public agricultural research as well as practical "extension" activities that help farmers apply innovations in the field. Although the private sector in advanced industrialized countries is already investing in crop engineering, the rural poor in developing countries are not attractive prospects for

private investors. A stronger public role is therefore needed. Inauspiciously, budgets for both international agricultural research and many national agricultural research centers in developing countries have shrunk in recent years. Crop engineering could help researchers and extension workers do more with less, but that promise will not be realized unless governments make a new commitment to public agricultural research and extension by investing heavily in the crop engineering methods that will benefit the world's poorest peoples.

In addition to inadequate public investment, Victor and Runge explore other factors slowing the application of crop engineering for the benefit of low-income farmers and consumers. Today's system of intellectual property, for example, offers ever-stronger patent protections on agricultural innovations. The authors argue that this system has created a congested web of conflicting and complicated patent rights that is impeding innovation and access to the ideas and tools needed to create crops for the world's poorest peoples. So far, intellectual-property owners have kept the crisis at bay by making liberal donations to philanthropic causes. A voluntary approach, however, is not sustainable. Victor and Runge explore several mechanisms that could offer more durable solutions.

I thank the authors, the Study Group members, and Mr. Aaron for their hard work and their commitment to finding facts and solving problems. These are extremely complicated issues. I hope this lucid and scholarly report will help policymakers identify and pursue a sensible long-term strategy.

Leslie H. Gelb President Council on Foreign Relations

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We thank all these colleagues and sponsors for their contributions. But we bear sole responsibility for the final product. This is not intended to be a consensus document; rather, it presents our views as informed, enormously, by the Study Group process and the many colleagues and institutions that have lent support along the way.

David G. Victor Council on Foreign Relations and Stanford University

C. Ford Runge University of Minnesota

CHAIRMAN'S COMMENT

Controversy, even fear, of new foods is not new. The tomato was widely regarded as poisonous in the United States and northern Europe as late as the 1830s, due to its relationship to the night-shade family of plants. There was such concern that in 1820, the state of New York banned their consumption. Tomatoes even had their own "Frankenfood" label: "wolf's peaches."

Then in 1830, Colonel Robert Gibbon Johnson announced that he would prove tomatoes were safe by eating a basket of them on the steps of the courthouse in Salem, New Jersey. At the appointed hour, a crowd of two thousand people had assembled, convinced that they were about to see a man commit suicide. A local band began to play a dirge as Johnson climbed the courthouse steps. He turned and addressed the throng:

The time will come when this delicious scarlet apple...will form the foundation of a great garden industry, and will be eaten and enjoyed as an edible food ... and to help speed that enlightened day, to prove that it will not strike you dead—I'm going to eat one right now!

Johnson then dipped his hand into the basket, brought out a tomato, and consumed it in a few bites while the crowd shouted, "No!" He not only lived, but today New Jersey is called the Garden State largely because of the tomato. Moreover, Americans rate it as their favorite vegetable (although technically it is a fruit).

It is understandable that a species like ours, which foraged for its food through most of its evolution, would have an innate sense of caution when it comes to what it eats. But since the Neolithic revolution more than 10,000 years ago, humans have been creating their own variations of the plants and animals existing in the wild. Are genetically engineered crops substantially different? Do they require special regulation? How can we realize the great

promise they hold for the hungry and poor, and for a world in which the human demand for food is rising rapidly? How can we assure human safety and protect the environment, particularly in nations where regulation is often lax or nonexistent? These are some of the questions that this paper is designed to address.

When Les Gelb asked me to chair a Council on Foreign Relations Study Group on this complex of issues, I jumped at the chance. I first became involved with engineered crops as a trade problem when I was undersecretary of international trade in the Department of Commerce. The Europeans were reacting badly to the idea of such food and were refusing to approve the import of new varieties. They were also demanding labels that would stigmatize genetically modified (GM) products and setting unrealistic standards for GM-free foods. When I pointed out to my European counterparts that engineered crops and foods had been consumed for a decade in the United States and there had not been a cough, a rash, a fever, or any adverse health consequences, my argument fell on deaf ears. No amount of scientific proof would allay popular fears.

There are legitimate questions about the risks of genetic modification technology—and for the most part there are also sensible answers. There is little doubt that the GM foods developed in the United States are safe. They have gone through more testing than any foods in history. Indeed, the public is largely unaware that most new varieties of non-GM crops are not tested by the government at all!

There are potential environmental risks such as resistance to herbicides and pesticides and the unintended spread of modified genes through cross-pollination. It is important to note, however, that we already effectively deal with these problems in the use of traditional weed killers and pest control chemicals and the planting of hybrids.

The most challenging potential problem is in developing countries, where health and environmental safeguards have historically been weak. Allowing engineered crops to fulfill their great potential in the developing world will not only require public support for research and extension services and a clear path through the

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maze of conflicting intellectual-property demands; above all, it calls for help in creating the institutions that will make biotechnology safe.

The debate over genetically engineered foods is just one part of the wider controversy about the consequences of the remarkable advances in biotechnology in recent years. Arguments over stem cells and cloning are other current examples. In the twenty-first century, biotechnology looks likely to be as important and pervasive as technologies involving electricity were in the twentieth century. It is no exaggeration to say that within the next hundred years, humankind will probably acquire the technological capacity to control the future evolution of both the human race and of every other species on earth.

The public is far from ready for the momentous economic, social, and cultural effects of this biotechnology revolution, nor is it prepared for the profound moral, ethical, and philosophical questions that will have to be answered. This paper addresses only one of the early manifestations of the unfolding biotechnology revolution. But it will, we hope, make a contribution to understanding the issues involved and offer an approach to meeting the challenges of genetically engineered agriculture in a way that advances human welfare.

David L. Aaron Washington, D.C.

SUSTAINING A REVOLUTION

Introduction: "Prometheus Entangled"

An agricultural revolution is unfolding. For more than ten thousand years, farmers have improved crops by letting nature do the breeding and then choosing the best offspring. Over the last century, scientists accelerated the improvement of crops by selecting parents and offspring more carefully, while still leaving nature to cross the genes. Today, however, new techniques based on discoveries made in the 1970s but applied commercially in just the last decade make it possible to breed crops with much greater precision and power. The most controversial and pivotal of these techniques are "transgenic": they empower scientists themselves to actually engineer new crops by splicing together particular genes, rather than relying solely on the random and uncertain crosses that are the hallmark of traditional crop breeding.

For some, the transgenic revolution is a horror. Tinkering with nature's order, these detractors argue, is human arrogance and will backfire when spliced genes disrupt the ecosystems on which life depends. For others, plant engineering is a Promethean step in a logical progression of crop breeding techniques, a development that will shrink the time and money needed to develop more nutritious food products and help meet the challenge of global hunger. Optimists also argue that biotechnologies can help lighten the human tread on the environment. More of the Earth's surface is given over to farming than to any other human activity; engineered crops can allow farmers to increase yields, producing more food for a growing world population on a smaller area of farmland and relieving the pressure on natural prairies, forests, and wetlands. Plant engineering can also make it possible to control crop diseases and pests with precision, reducing the need for the blanket-spraying of hazardous and costly pesticides and herbicides that has been the norm in industrial agriculture.

We side with the optimists but are concerned that today's debate over genetically engineered crops has drifted away from

reality, driven by short-sighted tactics rather than strategic thinking. On one side, some advocates of transgenics are so eager to see the method deployed that they pretend engineered crops are no different from earlier agricultural innovations; in fact, differences do exist, and some of them are substantial enough to require new types of regulatory oversight. On the other side, meanwhile, a vocal minority of detractors has amplified hypothetical risks in an allout assault on the very concept of crop engineering. The most disturbing impact of their attack has been hobbling the application of the technology where its contribution to human welfare would be greatest: in publicly funded crop programs that benefit poor farmers and consumers in the developing world.

Advocates of crop engineering have often branded the public as irrational and ignorant of science—and thus reluctant to accept engineered crops. In fact, lay people today are no less informed about transgenics' true risks and benefits than was the public that greeted electricity in the 1880s or personal automobiles in the 1910s. Reluctance to accept engineered crops stems less from ignorance than from the perception that they carry uncertain costs while delivering miniscule benefits to consumers. The engineered crops on the market today were designed to allow farmers to save money by reducing the use of expensive pesticides and herbicides, and this real added value explains why farmers in the United States and a few other countries such as Argentina, Canada, and China have adopted engineered seeds more rapidly than any other innovation in agricultural history. But nearly all the payoff has gone to the seed companies and the farmers themselves; from the consumer's perspective, the first generation of engineered food products is indistinguishable from traditional foods—the new foods look and taste the same yet are no cheaper at the supermarket. And consumers in places where they do not trust public institutions to regulate product safety are understandably wary of ingestible innovations. This is notably true in Europe, where public confidence in national and European Union (EU) regulators has been undermined by past regulatory failures such as "mad cow" disease and HIV-tainted blood.

This report steps into the void in the current transgenics debate by outlining a long-term strategy for managing the agricultural gene revolution, focusing on the implications for U.S. policy. We argue that strategic thinking is needed because markets, by themselves, will not clear the obstacles that currently block crop engineering from reaching its full potential. Active policy reform is essential, as are active efforts by the United States to coordinate policy with other nations, because engineered crops trade globally, and some of the knowledge that allows scientists to create better crops is a global public good. Public officials, firm managers, investors, and leaders of nongovernmental organizations (NGOs) need a strategy that focuses on the crucial actions to be taken while avoiding peripheral debates. Even steadfast opponents of transgenics would gain from strategic thinking. The technology they abhor is already unbound, but a well-reasoned strategy would help ensure that research does not remain disproportionately focused on products that benefit only a very small segment of the world's population.

Our strategy of policy reform is built on three pillars. First, policymakers must ensure that the techniques of crop engineering are applied for the benefit of those who would gain most: the approximately two billion rural poor in developing countries whose livelihoods depend mainly on farming. The current impasse is mainly the byproduct of divergent views in extremely wealthy societies that can afford to be indifferent about agricultural biotechnology. But a growing number of crop biologists and development experts see engineered crops as part of the next frontier for alleviating poverty, a "doubly green" revolution that will allow poor farmers to meet growing demand for food while reducing the impact of farming on the environment. From China to Kenya, field trials of crops engineered for greater nutritional content, improved disease resistance, longer shelf life, and higher yield are confirming such hopes, although practically none of these products have actually been approved for widespread production.

Responding to the needs of the world's poor requires reinvigorating the traditional crop breeding and extension programs that created the first green revolution. The scientific tools for mapping crop genomes and engineering particular traits are not

magic wands—they can work only in concert with both a broader, sustained program of crop breeding and active efforts to train farmers in the proper use of new varieties and farming methods. Yet the countries that have been most generous in funding international agricultural research, notably in Europe, have been least enthused about seeing their euros spent on crop engineering. By contrast, the U.S. government has been much more supportive of biotechnology but has not delivered proportionate backing for international agricultural research. Over the last decade, for example, the United States has cut its support by nearly 30 percent (in constant dollars) for the Consultative Group for International Agricultural Research (CGIAR), a highly effective network of sixteen international agricultural research centers funded by the World Bank and national governments. But it is precisely these advanced industrialized countries that should take the lead in reinvigorating CGIAR as well as national agricultural institutions, first by immediately halting the decline in real spending and then by working to ensure that research and extension budgets for the centers double in the next decade. "Middle-income" countries should also be enlisted in the effort; today, nations such as Colombia and Mexico offer generous support to international agricultural research centers located in their own territory, but few other affluent developing countries contribute substantially to the collective effort of breeding better crops for the world's poorest farmers and consumers.

Building developing countries' capacity to invent and tailor engineered crops to local circumstances is only one aspect of the policy reforms that are needed. The benefits of crop engineering cannot be extended to the neediest peoples without steps to ensure that regulators and farmers manage the risks associated with crop engineering. Substantial progress has been made in the last decade in transferring regulatory rules and procedures to low-income countries, but their implementation has been much more uneven. Without effective regulatory systems, it will be exceedingly difficult for firms and public institutions anywhere in the world to sustain public support for transgenics. Crop engineering will be subject to the same public scrutiny and skepticism as have been other high-technology innovations, such as air travel, and a fail-

ure in one area will undermine public acceptance of the technology in general. Thus, the advanced industrialized countries' collective interest in spreading crop engineering should inspire them to help developing countries adopt the technologies with adequate regulatory oversight. Governments that already fund enhancing regulatory capacity programs through international institutions such as the Global Environment Facility should refocus those programs on implementation. However, effective implementation—like most matters of governance—is ultimately a national responsibility.

The second pillar of policy reform relates to the protection of intellectual property. The revolution in crop biotechnology, as in much of the "new economy," is based mainly on intellectual innovations—new ideas for gene applications and combinations that are costly to invent but easy to copy. Since 1980, starting in the United States, governments have allowed extensive patenting of life forms; today, patents govern most of the genes and many of the techniques associated with crop engineering. Not only have private firms rushed to claim intellectual-property rights for every patentable innovation, but publicly funded researchers—notably in universities can also seek patent protection for their innovations. In what has become a vicious pattern, the patent rush has, in turn, spurred counterpatenting: firms fear patent-infringement lawsuits, which can cause costly delays in new product launches, so their best defense is an arsenal of conflicting patent claims with which to countersue and settle. Although some protection of intellectual property is essential to encouraging innovation, the race to patent biological discoveries resembles the panicked land rushes of the nineteenth century in the American West. Fragmented and conflicting claims now inhibit innovation, undermining the goal that originally inspired governments and courts when they encouraged inventors to fence in their ideas.

Fixing the intellectual-property system will not be easy. Some of the needed reform is already under way as patent offices, especially in the United States, reverse their earlier zeal and shorten the list of patentable innovations. But the thicket of patent problems will grow denser because crop engineering's greatest poten-

tial lies with products constructed from multiple innovations, rather than the relatively simple products based on single genes or technical procedures that have dominated the market so far. At a minimum, two reforms are needed. One is the creation of a mechanism for pooling patent royalties to reduce the daunting costs that small-scale innovators face when taking products to market. The other is to establish a system for allowing access to intellectual property for inventors of products that are marketed to poor farmers in the least developed countries.

The third pillar of policy action is the containment of conflicts over engineered food, especially between the United States and Europe, and prevention of their spread through trade institutions. Whereas U.S. consumers have largely accepted transgenic foods, a sizeable minority in Europe is steadfastly opposed and unlikely to change its opinion—even though leading European scientists, biotechnology firms, and key EU officials have all argued in favor of policies that would accept crop engineering. Because food products move in global markets, differences among national regulatory approaches are fomenting tensions in international trade institutions. To date, U.S. and European policymakers have contained their differences: the European Union has maintained "temporary" restrictions on imports of some engineered crops, while U.S. trade officials have resisted filing formal trade disputes with the World Trade Organization (WTO). That standoff is coming undone, however, and the two sides are edging ever closer to an outright trade dispute. The costs of the European restrictions on market access are mounting, and EU policymakers are developing additional rules that will make it more cumbersome to market engineered foods.

So far, Washington has followed the right policy: it has avoided launching a formal trade dispute even as it sounds louder alarms about European restrictions. The government, private firms, and NGOs have also wisely supported various transatlantic dialogues to exchange information with their counterparts in Europe (although such forums have only limited leverage on European public attitudes about biotechnology and thus little impact on European policy). We counsel staying this course even if new

European rules harm U.S. exports. At the same time, European policymakers must understand that they are close to exhausting U.S. tolerance. U.S. soybean exporters, in particular, stand to lose significantly from proposed EU rules on labeling animal feed. The rules would require meat producers that use American soybeans to label their meat products to indicate the use of engineered animal feed, while competitors whose animals eat Brazilian soybean exports, which are treated as "engineering free"—despite the fact that about one-third of the Brazilian soybean crop is engineered, produced by farmers who illegally sow engineered seeds—need not use such a label. The European Parliament holds the keys to compromise, which does not bode well—so far, the Parliament has been extremely responsive to vocal opponents of biotechnology but less able to consider the broader foreign policy implications. The United States must actively seek to emphasize that neither side can "win" a formal trade dispute in which the two parties would be forced to defend mutually incompatible positions. The need to avoid food conflicts at the WTO is particularly acute since liberalizing trade in food products is one of the most critical elements of the new round of trade talks launched in Doha, Qatar, in November 2001.

Avoiding a formal WTO trade dispute with the EU over this issue does not mean that the United States should be weakkneed on all differences with its trading partners. There is a premium on avoiding formal disputes with the EU because there is no constructive scenario for winning. In contrast, the United States should move quickly to resolve brewing conflicts with China over approval to export genetically modified (GM) soybeans to the Chinese market and over China's restrictive labeling rules. Fully one-fifth of U.S. soybean exports (about \$1 billion annually) are sent to China. The danger of a conflict that could disrupt this trade stems not from democratic pressure inside China to ban food engineering but from Beijing's temptation to use trade restrictions to protect its own infant industry in creating and growing engineered crops. Indeed, China trails only the United States in the invention of engineered crops. And already in 2001, when China issued a first draft of these restrictive rules, bilater-

al soybean trade was disrupted for several months. Pressure on China has been effective and more pressure will be needed in the future. Failure to address these problems could result in similar restrictions on cotton, corn, or other U.S. exports of GM products, even as Chinese firms develop similar products—some based on their own innovations and others derived from intellectual property acquired from U.S. firms. From the perspective of international trade law, the potential disputes with the EU and China look similar; in terms of strategy for advancing the technology and working within the WTO, the best U.S. responses are quite different.

The furor over food engineering matters not only because it affects the future of agriculture but also because it is emblematic of the fits and starts over globalization. Originating in the basic research of a few countries, crop engineering is now spreading rapidly through both global networks of scientists and the global marketplace. The United States is the leading innovator in crop biotechnology; the fact that China, not the European Union, holds second place indicates an international changing of the guard in terms of technology prowess and politics. Because the first generation of engineered crops trades widely in world markets, the international debate these crops have aroused has also exposed one of the greatest difficulties for globalizers: accommodating differences in national regulations while also opening borders to trade. That tension is most evident in the looming U.S.-EU conflict, but it affects many other countries as well—indeed, the first formal trade dispute over market access for engineered food products concerned Egypt and Thailand and was initiated in September 2000.

The crop engineering issue also resembles the broader globalization debate in that the roles of multinational corporations have been a lightning rod for discontent. During the 1990s, the development of transgenic crops concentrated in the hands of five major corporations: Aventis, Dow Chemical, DuPont, Monsanto, and Syngenta. These firms are still absorbing their smaller rivals and may eventually consume one another. Similar concentrations of power have occurred in other industries, from aerospace to pharmaceuticals, where product development, regulatory approval, and marketing are time-consuming and costly.

In such industries, a few consolidated research and development engines innovate more effectively than do fragmented networks of "boutique firms." But the concentration of power, which in turn enhances these firms' global presence, makes their role controversial. For example, seed companies around the world are lining up to sell cotton that has been engineered to fend off cotton-chewing bugs. The value of this innovation accrues not only to innovators such as the multinational Monsanto, but also to local farmers who can harvest more cotton at lower cost while lessening the impact of pesticides on the environment. Even where Monsanto has set high prices for its cottonseed—thus reaping most of the value from the innovation for itself—farmers have embraced the modified cotton because they, too, capture some of its benefits. In Mexico, modified cotton has spread widely; even in India, where regulatory approval for such cotton has been mired in a gridlock of controversy over multinational corporations, farmers have smuggled in seed at a premium because it offers higher yields and lower production costs. Opponents focus on Monsanto's large slice of the pie that it takes as profits; supporters underscore that without Monsanto's innovations there would be no pie on which to feast.

The key to success with this technology, we argue, is binding together a set of interlocking interests. Public interest groups should accept the inevitable concentration of the ideas that underpin the gene revolution in the hands of major corporations, in exchange for hard evidence that the benefits of crop innovation are flowing to the least advantaged. Public research institutions and private firms should forge partnerships to help channel private innovations to public purposes, but only if governments reinvigorate their investment in international agricultural research. In trade policy, exporters must accept that democratically elected governments in many countries face strong public pressure to restrict engineered crops from the food supply, whereas importing governments must take care as they respond to public concerns not to adopt arbitrary rules that have no relationship to the underlying fears. At the same time, governments under the strongest pressure to curtail the use of crop engineering must themselves invest in public campaigns to illuminate the real dangers while eclips-

ing imaginary fears. Public interest groups should isolate those who fan public unease with baseless dangers, but advocates of the technology must not pretend that engineered foods are identical twins of traditionally bred crops. Finally, to ensure that the practice of crop engineering is safe, governments must invest in proper oversight of these new techniques.

The challenge for analysts and policymakers is how to sustain all these quid pro quos simultaneously in several different policy dimensions: in commercial agriculture, development policy, environmental policy, and trade. The choices in each area require a delicate, dynamic balancing of interests, since no single best solution will emerge. Moreover, it is impossible to bind these many interests into a single "deal" that advances the technology and distributes the benefits, because no single forum or mechanism exists for ensuring that all sides keep their part of the bargain. Instead of a formal contract or agreement, progress will come from high-profile, symbolic actions by each side as it attempts to signal its intentions to others. And throughout this delicate dance, the chances of disruption will remain high because each dancer depends critically on the others for success. Sustaining the engine of innovation depends on private firms and their investors; access to markets for those firms' products, in turn, depends on reputations forged by public interest groups. And most of the public policies that will be needed to sustain the quid pro quos depend on actions by governments whose leaders often behave as if they have little influence over the decisions they adopt because elected leaders must respond to domestic opinion first. Sustaining this revolution will require greater public funding, but often governments are strongly tempted to cut programs that supply global public goods, the benefits of which accrue mainly to foreigners. Overall, therefore, no single group of actors has much leverage on the outcome and all face tactical pressure to abandon course.

Again, these challenges mirror a larger globalization conundrum: how to assure global benefits of new technologies when spreading those benefits requires such complex coordination of diffuse actors. Previously clear lines between public and private responsibility are erased, as evident in the "global compact" agreed upon

by U.N. Secretary-General Kofi Annan and business leaders in July 2000 and the burgeoning effort by firms around the world to embrace "corporate social responsibility." For the topic of engineered food, we suggest a path that responds to these pressures. We begin with an overview of the business of crop breeding and the innovations of agricultural biotechnology. We then concentrate on public and private incentives to invest in crop engineering and the rules and funding mechanisms that determine which products attract investment. Finally, we examine the implications of these products and the controversies they have spawned for the international trading system.

Gene Machines in the Garden

Agriculture emerged about fourteen thousand years ago when nomadic, foraging humans gradually settled in areas rich with wild plants and animals. The earliest evidence of plant domestication dates to about eleven thousand years ago in the Jordan River valley; these first crops—probably seed grasses such as barley and wheat were similar to the wild plants that were already part of the foraging diet. These ancient foragers-turned-farmers began selecting seeds that yielded heavier grains, greater resistance to pests, and other easily recognizable beneficial properties. Ever since, humans have been deliberately altering the genetic code of plants; today's domesticated plants bear little resemblance to their wild ancestors and most could no longer survive in the wild at all. Domesticated corn is radically different from its short-stalked and scrawnyeared wild relatives; modern tomatoes, resplendently plump and uniform on the supermarket shelf, seem alien next to their multicolored, grape-sized ancestors; sorghum, wild only in the tropics, is so transformed today that some varieties thrive even in the frigid Dakotas.

Until barely a century ago, crop improvement proceeded through the instinct and experience of farmers who, after nature had done the breeding, eyeballed the offspring and selected the best. Each farm was an individual research lab, and innovations came mainly from lucky pollinating breezes and chance encounters. The discovery of crop genetics—technically introduced by ama-

teur scientist Gregor Mendel in the 1860s but not permanently taking root until after Mendel's work was "rediscovered" in 1900 made it possible to decipher the genes that caused particular traits. At the same time, the new field of statistics made it possible to relate pedigrees to outcomes and to select the plants with the best genetic codes. Equipped with theory and method, scientists could systematically develop new crop varieties. Creating a superior plant often required, for example, propagating many wild varieties as "pure lines" through self-pollination, observing which were most hardy and high yielding, and then cross-breeding their picks to produce hybrid progeny. The armies of scientists deployed in experimental fields could control breeding to a limited extent by covering flowers with bags and clipping pollen-laden stamens to ensure that only the best pollen found a mate—a method of scientific breeding that, although more precise than hit-or-miss crossing, was labor-intensive and clumsy. Still, it delivered impressive results.

Among the first successes was hybrid corn, first applied widely in the United States starting in the 1920s by private seed companies that bred high-yielding hybrids and sold them to farmers. At the time, no legal institutions were in place that could give private firms an incentive to invest in new seed by allowing them to claim sole ownership over the intellectual property in their products. Patent rights existed but did not extend to plants. Hybrid corn, however, fortuitously had a built-in mechanism for property protection: it lost its vigor with each planting generation, leaving farmers obliged to return to the seed company for fresh, potent batches. The success of hybrid corn as both a crop and a business model created a wave of private investment and innovation in crop engineering. Until that time, nearly all scientific research on improving crops—including the basic discoveries that led to hybrid corn—had been done in publicly funded universities and research stations. But the enormous profits that flowed to innovations in hybrid corn encouraged similar private investments in hybrid cotton, tomatoes, and sundry other agricultural products. The potential for private innovation forced governments to change intellectualproperty laws so that private firms could reap a larger fraction of

the benefits from their inventions. The United States allowed patenting of plant varieties created through asexual breeding as early as 1930, but it took another 40 years before U.S. law extended patenting to varieties produced through normal sexual breeding. Until very recently, most seed companies protected their new varieties through a much weaker form of intellectual-property protection known as a "plant breeder's right," which allowed plant breeders exclusive marketing rights for new varieties that they created but did not give them the right to charge royalties to other plant breeders who applied their innovation to yet further improved seeds; nor did plant breeder's rights bar farmers from saving seed from one year for planting the next year's crop.

Better seeds—along with tractors, irrigation, fertilizer, pesticides, knowledge, and other factors—helped lift farm productivity in the twentieth century. Indeed, by 1997, average U.S. corn yields—composed almost entirely of hybrid corn—had reached eight tons per hectare, compared with one ton per hectare in 1930. In the 1950s, the obvious potential of hybrids and other agricultural innovations inspired plant breeder Norman Borlaug and the Rockefeller Foundation to create a program that would diffuse these discoveries to developing countries, initially Mexico and then throughout Latin America and worldwide. The innovations, first in corn and wheat and later extended to nearly all major staple crops, allowed developing countries such as India to increase crop production so rapidly that they nourished their ever-increasing populations even as they switched from being net importers of food to net exporters. Other foundations and governments joined the effort, which is famously remembered as the "green revolution" (and later earned Borlaug a Nobel Peace Prize). Many of the same controversies that befall crop engineering today were played out in the 1960s and 1970s with the diffusion of high-yielding seeds, fertilizers, and agricultural techniques of the green revolution. The technologies were essential to providing nutrition to a rapidly growing population, but the benefits of the technology accrued mainly to the firms and farmers best able to adapt to technological change. The success of the green revolution was institutionalized in 1971 with the creation of the CGIAR network of international agricultural research centers.

By and large, as farmers have more fully understood and manipulated crop genomes and ecology, they have served consumers better while treading more lightly on nature. In the United States and later in Europe and Japan, the percentage of land devoted to farming has shrunk consistently ever since the introduction of higher-yielding varieties in the early twentieth century made it possible to grow more food on less land. Paul Waggoner at the Connecticut Agricultural Experiment Station and Jesse Ausubel at Rockefeller University predict that cropland worldwide could shrink by another one-third in the next half-century if farmers continue to increase their yields at a rate that has been sustainable in the past. Best farming practices still far exceed the average, which indicates a large untapped potential to lift average performance. Many analysts warn, however, that the potential for improving seeds through traditional breeding is diminishing.

Over the past thirty years, a cluster of biological technologies, known broadly as "genomics" and "transgenics," have laid the foundation for a new green revolution. The hallmark of these technologies is precision. Traditional breeding swaps dozens of genes from parent plants, some with unknown properties, to yield new varieties. The process requires painstaking control and selection of parents, and the range of potential offspring is severely restricted by the range of naturally available genes. Genomics is the application of new statistical and computational methods to the problems of mapping plant genomes and discerning the functions of individual genes and gene clusters. The resulting gene maps, which are rapidly becoming less expensive to compile, can guide the creation of new plants. By far the most controversial of the new biotechnology techniques are "transgenic"—tools that make it possible to alter ("engineer") the genetic code, inserting genes that code for particular properties such as resistance to pests or tolerance of salt and trace metals that are prevalent in many soils and make it hard to grow hearty plants. Genomics and transgenics are each powerful tools on their own, but each can reach its full potential only when advances on both fronts are applied in tandem.

The biotechnology revolution has been controversial for many reasons, but four stand out. One rallying cry is that manipulating

plant genomes is unnatural. In fact, however, humans have been intervening for millennia, and a shift "back to nature" would be extremely costly. Much larger land areas would be required for food production and in many ways the food produced would be less safe for human consumption. Even the genome of organic produce reflects the heavy hand of human selection.

Another fear often voiced but easy to dismiss is the worry that "marker genes" used during the production of transgenic crops will cause harm to humans or the environment. Researchers use various techniques for splicing genes, but typically only a tiny fraction of the genetic "packages" actually lands inside the target plant cells. Thus, a scientist will include in the "package" a marker gene, often one that confers antibiotic resistance. Only the cells that have successfully incorporated the antibiotic marker—along with the rest of the "package"—will survive when submerged in an antibiotic bath. But the marker gene remains in the plant's genome after it has served its duty, and some analysts have warned that proteins created by such genes could cause harm to humans who eat the engineered product or might encourage resistance to antibiotics in such crops when they are grown in large quantities. This potential problem is disappearing rapidly, in part because the original fears have proved incorrect and in part because the European Union and some non-EU countries are banning the use of marker genes. The controversy has thus forced scientists to invent alternatives.

Two other fears about the biotech revolution must be taken more seriously. One is that engineered foods may cause harm to the people who eat them or to the environments where they are tested in field trials and grown on a commercial scale. The regulatory systems already in place and charged with assuring food safety and environmental protection have long dealt with such risks involving non-engineered foods. (To name just a few traditional concerns: food allergies, harmful pesticide residues, and the environmental costs of large-scale cropping, such as runoff of fertilizers and the vulnerability of monocultures, have been around for a while.) Yet some of the risks associated with engineered foods are distinct, such as the danger that novel genes could carry new allergies, or the risks

of "gene flow" as engineered crops in cultivated fields breed with wild relatives nearby. But all the countries that have active foodengineering research programs have also established mechanisms for screening the results (just as breeders screen the output from traditional breeding) and for regulating field trials and commercial planting. Whether those mechanisms are adequate is another question.

The other fear that also merits scrutiny is that the innovations of biotechnology will alter the economics of agricultural production in ways that harm poor farmers. This critique is partly based on the observation that the benefits of the green revolution accrued mainly to farmers who were able to embrace new technologies and techniques—often educated, larger-scale farmers—at the expense of those already living on the edge and least able to adopt to technological change. Insofar as farming is the main occupation of the rural poor living at subsistence levels in developing countries, these incidental costs of innovation must be considered.

Addressing both of these issues—the environmental effects, the health-related consequences for consumers, and the impact on agricultural producers—requires looking closely at the incentives for firms and public institutions to invest in biotechnology innovations. It also requires a careful investigation of the relationship between investment and the mechanisms for regulating the safety of agricultural research. The following sections shall address those issues.

The First Generation

Although the genetic revolution offers great promise, its actual impact on food supply has barely been felt. Only a very limited number of engineered foods and other crops are grown in commercial quantities, nearly all of which emerge from innovations with one of two types of genes.

One successful cluster of plants has been genetically engineered to produce the bacterium *bacillus thuringiensis* (Bt), a naturally occurring pesticide that kills the European corn borer and other hungry insects. Cotton, corn, tobacco, and potatoes account for nearly all plantings of Bt-engineered crops—indeed, two-thirds of the

U.S. land areas in cotton production and about one-third of U.S. corn are Bt engineered. These transgenic crops can theoretically be grown with lower quantities of pesticides, making it possible to lift yields while cutting costs and lightening the detrimental effect on the environment and on the health of farm workers. The actual impact of Bt crops on the consumption of pesticides, however, is hotly contested. For at least one crop—cotton, which sees the largest use of agricultural pesticides in the United States and in most other countries where cotton is grown in large quantities—Bt engineering has indeed reduced sharply the volume and frequency of insecticide applications.

The other successful cluster of genetically modified plants is engineered with a gene that confers tolerance to the herbicide glyphosate. Having sown a field with these hardy plants, a farmer can spray this single herbicide on top of the growing plants; in contrast, growing conventional soybeans, for example, often entails spraying smaller quantities of a dozen or more herbicides at carefully timed intervals to kill the weeds. Engineered seeds are more expensive than conventional seeds, but the simpler and more effective weed-control program reduces production costs—typically by about 10 percent. This 10 percent savings actually allows much higher profit potential, since the farming industry depends on high volumes to squeeze profits out of thin margins and volatile commodity prices. U.S. farmers harvested the first commercial crop of soybeans engineered with this gene in 1996. Only five years later, more than 60 percent of the U.S. soybean crop was glyphosate-tolerant. In Argentina, the world's second-largest grower of engineered soybeans, 90 percent of the soybeans grown are glyphosate-tolerant. Even in Brazil, where it is still illegal to grow engineered crops commercially, perhaps one-third of the soybean crop is engineered (sown with seed smuggled in from Argentina). Surveys suggest that farmers will continue to plant large quantities of these beans even though many could earn slightly higher prices if they sold soybeans certified free of genetic engineering. Similar economics explain the rapid adoption of rapeseed (an oilseed known as "canola" in the United States) engineered for glyphosate tolerance.

This first generation of engineered crops arrived quickly and widely on the markets in part because the engineering was relatively simple—it involved single packages of genes that had no other plant properties. The puzzle is not why these innovations were moved quickly from testing to commercial availability but, rather, why it took so long from the invention of the basic techniques for recombining DNA in the early 1970s to the application of those techniques to simple engineered crops two decades later. Traditional breeding companies that dominated the seed business are one reason for the delay—they needed to develop new business models that combined their own gene libraries with gene-engineering talents in order to apply this technology to commercially viable products. Public policy can do little to speed this process, so patience is needed to wait for the most innovative products to find markets—just as decades passed from the invention of the Internet to its widespread commercial application.

The experience with the first two commercially successful clusters of engineered food products approved for commercial sale reveals the long road that innovators must travel and the challenges they will face in linking engineering skills with traditional practices of breeding and marketing. One of the earliest engineered food products was the Flavr Savr tomato engineered by the biotech upstart Calgene, which altered a gene to slow the softening that occurs as tomatoes ripen. Approved by the U.S. Food and Drug Administration in 1994, it was the first engineered food product sold in the United States and a resounding commercial failure the gene engineering had worked, but Calgene could not combine its substantial genetic talents with adequate traditional breeding skills needed to cross the novel genes into varieties of the Flavr Savr that farmers could grow profitably. Nor was Calgene able to build an efficient supply chain to move its tomato from the field into the hands of consumers, despite a clear customer willingness to pay a premium for the tastier fruit.

Around the same time, a similar innovation—a slow-softening tomato—developed by a research laboratory in the United Kingdom using a different method seemed to break the barrier to commercial success that Calgene could not. The lab licensed

its tomato to the company Zeneca for use in tomato purees and sauces. (Tomato processors dream of tasty but firm fruits exactly what the engineered tomato delivered—because mealy tomatoes make bad sauces.) Zeneca ran trials at several dozen Safeway and Sainsbury stores in Britain—starting in 1996 they sold tomato puree in cans that, for the same price to the consumer, contained 20 percent more puree. They voluntarily labeled the cans as genetically modified and distributed pamphlets that explained the gene engineering and why it made the Zeneca product superior and cheaper. Head-to-head with its competitors, Zeneca's trial sold well. Three years later, the unfolding scandal over "mad cow" disease tarnished all food novelties and gave new breath to the winds of opposition to genetically modified foods. Then, as now, the British government claimed that any engineered foods it approved were safe, but by that point the government's word meant little—as the public learned the full dangers of mad cow disease, it had become clear that the government had hidden the dangers and buried the facts. Indeed, the government's own official report on the mad cow debacle branded it complicit in the deaths and the resulting hysteria and loss of confidence in public institutions. By the end of 1999, Zeneca's trial was over, having proved that consumers would purchase better and cheaper foods that were genetically engineered but only if the public remained confident in the ability of governments to regulate food safety.

These two commercial failures fanned the gale winds of creative destruction. Calgene's stock plummeted and the firm was bought by Monsanto; Zeneca's leadership unloaded its seed business into a new firm, Syngenta. Crop engineering is concentrated in the hands of few companies in large part because it has been a terrible business that, so far, offers few rewards even to patient investors. Only the big firms with extensive accumulated experience and distance vision have stayed the course.

A second reason for the rapid introduction of these firstgeneration of products is that their properties are nearly indistinguishable from those of traditional agricultural crops, which has eased the process of regulatory approval. The Calgene tomato was a tomato in all respects but for its longer shelf life; glyphosate tol-

erance did not alter other properties of soybeans. Bt has long been used as a natural pesticide, especially in production of organic foods, and thus it was easy for regulators to approve Bt-producing plants as pesticides. None of these new genes was known to cause food allergies that would have triggered the need for extensive screening. Even the normally wary EU governments approved more than a dozen varieties of corn, soybean, and rapeseed for production and sale in Europe. Those approvals, however, ceased in 1998, when political pressure to halt consumption of engineered foods had grown so strong in a few countries that the EU had little choice but to impose a "temporary" moratorium on approving engineered products while it tried to find a new way to muddle through the conflict. It is thus important to note that the hiatus in approvals did not occur because the EU's regulatory process had discovered any new dangers in the foods that were also being approved in the United States or in other markets.

A third reason for success with these crops is found in the structure and economics of agricultural production. Farming involves a long value chain, spanning from seed companies and suppliers of herbicides and pesticides, to farmers, grain handlers, and traders, on to food processors, and finally to retailers. The first generation has been relatively easy to diffuse along this chain because the costs and benefits are exchanged between agents that are already closely integrated: seed and chemical companies on the one hand and farmers on the other. Monsanto sells both glyphosate (Roundup) and glyphosate-tolerant (Roundup-ready) seeds. The close links between innovators such as Monsanto and their customers (farmers) have made it possible to evolve a pricing model in which most of the benefits from the innovation flow to the actors who can most influence its adoption. The innovators are able to reap large rewards by selling seeds that they price at a premium, and farmers benefit from lower overall production costs. Indeed, a recent study by agricultural economists Jose Falck-Zepeda, Greg Traxler, and Robert Nelson found that more than half the value created worldwide by the innovation of glyphosate-tolerant soybeans flowed to seed and chemical companies (mainly Monsanto) and farmers (mainly in the United States). Actors further

down the value chain also gained—consumers benefited from lower soybean prices, for example, but they did not notice because few eat soybeans straight from the farm. Instead, they consume the product after it has been processed into a form, such as salad dressing, in which the raw soybeans and oilseeds account for only a tiny fraction of the final cost. When the differences in production costs are relatively small, as with engineered crops, this approach is sustainable only when firms downstream in the value chain and final consumers have no preference as to whether the commodities they eat are engineered or not. Indeed, few of the hundreds of millions of consumers who eat genetically modified food do so because they *want* to. The technology diffuses into markets because producers are enthusiastic and consumers are mostly indifferent.

As the product moves along the value chain, firms add value through processing and marketing and they create brands and reputations to distinguish their products from others. Opponents of the technology attempt to do the reverse—to dissuade innovation and the application of crop engineering, they focus on brands and points of final retail sale, where reputations are both essential and easily tarnished. Where they have found a receptive public—notably in Europe—this strategy has succeeded. (Similar efforts to brand engineered cotton as unsafe have been less successful; people do not eat cotton, although a few firms, such as the U.S.-based outdoor-clothing retailer Patagonia, have eschewed engineered cotton and require all their source cotton to be grown organically.)

Just as small differences in cost explain the rapid embrace of engineered seeds by farmers, other small changes have the potential to send retailers fleeing. The looming danger for producers is not that consumers worldwide will oppose biotech foods en masse but that even a fraction of consumers—perhaps as few as 10 percent—in major markets will demand food free of engineered crops. For processors and retailers, who add value that far exceeds the difference in cost between engineered and traditional commodities, it may be cheaper to produce a single line of products that is entirely free of engineered food than to offer parallel, segregated lines or to lose market share to those who certify their products to be

GM-free. For example, General Mills markets several varieties of Cheerios, but all are branded by differences in the taste of the final product; a line of GM-free Cheerios would be harder to position without tarnishing the mainstream brand. Producers and sellers of final goods will drop engineered inputs even if they perceive consumer sentiment to be tipping. U.S. food processors have been supportive of the innovation of engineered foods, but they will jump ship if public opposition grows, even at the margin. Glimpses of discontent are already evident in the United States, where Trader Joe's, a quality-branded large-volume retailer, has pledged to certify that all its food products are free of food engineering in 2002. For the first generation of engineered crops, a very narrow segment of the agricultural system (in very few countries) has had a strong incentive to embrace the innovation and most of the rest of the world has been indifferent or opposed.

The Next Generation

The next generation of products, which are marching through the research and development pipeline already, will create a very different context for adoption. Whereas the first generation was distinguished by its ability to allow farmers to alter their inputs such as pesticides, herbicides, and time spent applying these chemicals in the fields—the next generation of engineered products will be noted for various "output traits" that yield direct benefits, such as better nutrition, to consumers. Nearly every study that explores the long-term potential of engineered foods arrives at the conclusion that these products are the key to the viability of the technology. They offer the potential to deliver nutrition, such as vitamins or other micronutrients, in novel quantities and forms. They also promise the creation of new foods that have lower levels of pesticide residue and better taste. Consumers will seek them out, and firms far down the value chain will have a strong incentive to link brands with these output traits.

What can policymakers do to encourage sustainable development of this next generation of engineered crops? The answers to this question depend on which one of the two distinct markets will be served. One is what we will call the "ordinary market," and it serves about half the world's population; there, farmers purchase

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seeds and consumers buy food products that largely reflect the cost of innovation and the need for suppliers to make a profit. In this market, the proper role of policy is to encourage the private sector to invest in innovation and diffusion of new seeds and products. (In other markets, where poverty and market failure are endemic, a more activist role for government is needed. We examine that context later.)

In this ordinary market, the pivotal issue is the commercial incentive for private firms to invest in innovation. Typically, investors decide whether to back a new technology by probing four links in the chain from invention to profits: Is the technology ripe for advance? Will successful inventors be able to protect their intellectual property? Will the products they create gain regulatory approval? And will consumers want to purchase those products?

The potential of the technology is enormous, as we have already indicated, and has barely been revealed in the first generation of engineered products. Nor will it emerge in the immediate future, since the complex gene combinations required in the next generations will slow the products' appearance in commercial markets. The more innovative and unfamiliar the product, the more careful regulatory scrutiny and longer innovation cycle it will require. When these new generations of products do appear, however, they will likely find a willing market of consumers, despite the current brouhaha over the first generation, because the new products will offer tangible consumer benefits. Indeed, consumers already favor engineered pharmaceuticals, such as insulin, because they are less costly and of higher quality than nonengineered competitors. And consumer response to the two "output trait" products that have already come to commercial markets—Calgene's Flavr Savr and Zeneca's tomato puree were exactly in line with expectations. Consumers, able to see a personal benefit, embraced the genetically engineered product.

The real barriers to innovation lie not with the potential of the technology or with consumer acceptance but with the rules that govern intellectual property and the regulatory environment. The danger is that in both these areas, the pressures for policy reform are mostly pointing in the wrong direction. Vigilance is therefore

needed to ensure that most of today's policy proposals are not adopted.

Regarding intellectual property, innovative firms already have on hand more than adequate tools for protecting their innovations. By the 1990s, all the major industrialized countries had changed their patent rules to allow patenting of innovations in crop engineering. However, most developing countries, many of which are poor protectors of intellectual property, are struggling to implement similar patent rules—forced by the WTO's 1995 Agreement on Trade-Related Intellectual Property Rights (TRIPs), which requires that all WTO members tighten their protections of intellectual property to minimum world standards. Reform in the developing world will be slow because it requires nothing less than reform of these countries' entire legal systems. There are, however, signs of progress in the developing countries with the largest markets—notably Brazil, China, India, and Mexico.

The staunchest opponents of engineered foods have launched two lines of attack on intellectual-property protections for food innovations, neither of which has merit. The first takes on the entire system—food ideas should not be owned, these assailants charge, especially by multinational corporations. But this charge is blind to the fact that the most important innovations in crop engineering are like pharmaceuticals—extremely complex and risky to develop, and requiring extensive public disclosure to ensure that they are safe (but which then makes them easy to copy). The products that offer the greatest promise are probably those that are most complex to develop and thus most costly—they are least likely to emerge as a fortuitous byproduct of work by commercially disinterested public-sector researchers. The profit motive is necessary to attract and focus investment on the most promising avenues, and investors need the exclusive ownership offered by patents to justify the cost. Patents, of course, are not the only factor—firms also need patience, marketing skills, and strong legal talents to navigate the many obstacles to novel products—but secure intellectual property is a critical resource.

The other attack on intellectual property has focused on tools that could be used to prevent copying of genetic technology—in

particular a cluster of techniques that allow scientists to create infertile crops, which prevents copying of seeds. Opponents have dubbed these "Terminator" genes and mobilized to block them as an alleged affront to the traditional method of farming, which relies on farmers' keeping seed from one year's harvest for planting the next. This debate has thrived on a confusion of ends and means. Opponents of crop sterilization claim that their goal is to make agricultural innovations more widely available, especially to the poorest farmers. But they wrongly assume that bans on copy protectors will ease access to useful innovations. These techniques are probably irrelevant to the larger question of whether the benefits from gene engineering will accrue to poor farmers—the key obstacles, as we argue later, relate to inadequate funding of public agricultural research, not to private firms' protections against copying. If these techniques do affect access to intellectual property they will probably exert an influence exactly the opposite of what the critics charge. Terminator technologies offer innovators a way to assert exclusive rights (which are the bedrock of intellectual property) to products that contain the particular genes. With these mechanisms on hand, it could be easier for firms to participate in mechanisms that fine-tune access to intellectual property. We return to this problem of intellectual property later.

Governments have thus far resisted pressure to ban terminator technologies—and rightly so. Not only are they crucial tools for protecting and allocating intellectual-property rights, which in turn could help spur innovation, but mechanisms for sterilizing seeds offer an elegant way to protect "biosafety," ensuring that new genes do not breed with wild relatives during field trials or in commercial-scale planting. However, governments are not the only agents that set policies that affect how firms behave. Pressure groups also hold sway. In the late 1990s, several such groups active in rural development pressured Monsanto, which shares the patent for one type of "terminator" technology, to forswear its use. They also sent warning shots across the bows of other companies and governments (including the U.S. government, which shares the patent with Monsanto) that were contemplating sterile-seed production. For now, the damage from this misdirected campaign has been limited; several other seed-sterilization techniques

have emerged and NGO pressure to abandon these methods remains isolated. But the issue could resurface, causing harm to the whole system of innovation in crop biotechnology with neither firms nor governments able to fully influence the outcome. The NGOs themselves must ensure that their campaigns have proper targets, but the NGO community does not speak with a unified voice. A small minority, tilting at its own windmills, could send the entire system astray.

Our conclusion is that the fundamental elements of intellectual-property policy are sound. The countries that are the major centers of innovation were right to extend patent protection to crops and other plants. Patent offices, notably in the United States, initially granted some patents on biotechnology innovations that were excessively broad—as they did in many areas of high technology, such as the "one click" Internet shopping patent awarded to Amazon.com. Moreover, patents of crop innovations became entangled in a debate over patent rights for "traditional knowledge." Some multinational firms had claimed patent rights on products—such as therapeutic medicines based on the Indian neem tree—the functions of which had actually been discovered lifetimes earlier by indigenous peoples, refined over the generations, and held as communal knowledge. These errors are, we think, the normal byproduct of patent offices' attempts to delineate boundaries around property in novel territory. Some of the early patents have been challenged and a few wisely reversed by the courts; through practice and challenge, the system is settling in.

That leaves regulation of new products. The development of engineered foods is one of the best examples of how product regulation affects the geography of innovation. The United States is the leading center for crop innovation, not only because it has a strong national system for innovation in this area—universities and industrial laboratories that perform basic research, start-ups as well as large corporations that nuture novel ideas into commercial products, and seed companies that breed engineered innovations into new seed varieties—but also because its regulatory environment has welcomed field testing and commercialization of new products. Some other countries, notably China, also combine

propitious conditions for innovation with a welcoming regulatory environment. Europe, on the other hand, represents a striking contrast. There, especially in France, Germany, the United Kingdom, and Switzerland, world-class capacity for research and commercialization of engineered crops has been held captive to a regulatory environment more hostile to new products, especially since the EU imposed its moratorium on approval of engineered crops. The United Kingdom, in particular, was a decade ago a leader in the development of engineered crops; today, European firms have consolidated their operations and, even where they remain in European hands, key laboratories and trial facilities have moved overseas. Switzerland has been more immune to the shifting winds of public discontent—not a member of the EU, the Swiss government was not required to halt approvals for engineered crops along with its European neighbors. The Swiss public narrowly decided in a national referendum to keep approving engineered crops, because failure to do so would hurt Swiss competitiveness.

Later we will examine the implications for the world trading system of markedly different regulatory rules among countries. In our view, the greatest danger is not that most countries will become hostile to crop engineering; rather, our concern is that some countries will be too permissive and will fail to establish a regulatory system that responds to legitimate concerns about the food and environmental safety of engineered products. We focus first on the United States.

The first generation of products has posed few difficulties for the U.S. regulatory system. The innovation process is replete with screening by food-safety regulators, looking for telltale signs that food innovations might cause dangers. Opponents of crop engineering often cite efforts by Pioneer Hi-Bred (a seed company now owned by Monsanto) to splice a gene from Brazil nuts into soybeans, which would raise the level of amino acids in the soybeans and make them more nutritious feed for animals. Pioneer's own testing revealed that the protein created by this gene was the same one that caused some people to be allergic to Brazil nuts, and the company stopped the program. The case reveals both the dagers that are a normal part of food innovation—even with conventional

breeding—and the critical role of rigorous testing. None of the first generation of crops failed such tests or had any of the alarming signs that would prompt further inquiry. Indeed, the modifications were so small that regulators in the United States treated the first generation of commodity crops, such as glyphosate-tolerant soybeans and Bt corn, as "substantially equivalent" to existing food commodities (although opponents objected to the concept of "substantial equivalence"). No special food-safety approvals were needed.

Nor did the first generation of products pose much difficulty for environmental regulation. Broadly, environmental concerns have been threefold. One worry is "gene flow"—the spread of engineered genes outside the boundaries of field trials and commercial crops as engineered plants breed with their neighbors. If the neighbors are organic farms, then such cross-breeding could undermine the "no-GM" choice that consumers of organic foods often seek. If neighboring plants are weeds, the transfer of genes that create herbicide resistance, for example, might yield a superweed that is hard to kill. If wild relatives of the crop inherit new genes, the vital raw material from which new plant varieties are created could be contaminated. That issue has not been centrally important in the United States, but it has prompted Mexico—home to many wild varieties of corn and the country that hosts international corn seed banks—to prohibit the growing of engineered corn. (In November 2001, a report published in the scientific journal *Nature* claimed that tests at Mexican seed banks revealed genetic contamination; other recent studies suggest otherwise and some of the results from the original *Nature* paper have been discredited due to methodological flows; new rounds of testing are under way to resolve the controversy.)

A second environmental concern is that engineered crops may encourage resistance in pests and weeds. Crops engineered to produce Bt toxins that kill bugs will accelerate the emergence of Bt-resistant bugs; liberal use of glyphosate herbicide to kill weeds around glyphosate-tolerant crops will accelerate the evolution of weeds that are less sensitive to glyphosate. As a result of such effects, Charles Benbrook at the Northwest Science and Environmental

Policy Center has argued that the emergence of herbicidetolerant weeds is undercutting the supposed economic advantages of engineered soybeans.

The third environmental danger is that engineered traits could be harmful not only to bugs and weeds but also to various "nontarget" species. In May 1999, for example, a Cornell University study claimed that Monarch butterflies would die en masse as they migrated across America's corn belt and ate Bt-laced pollen. More recent studies, however, have rejected these findings.

All of these concerns—food hazards, genetic pollution, pest resistance, and harm to nontarget species—are long-standing dangers in agricultural systems. Gene flow is a worry in any active breeding program because breeding requires raw stock; the need to protect that stock is why nations and seed companies invest in gene banks. Natural fertilizers, such as cow manure, are a threat to the safety of organic foods even as residues from pesticides and herbicides are a constant worry for regulators of industrial food production. Pest and weed resistance are well-documented byproducts of intensive agriculture. Addressing these problems requires a debate that focuses on the full range of dangers from each agricultural method, rather than one that highlights the dangers of engineered foods while ignoring the risks of conventional foods that engineering can replace. For regulators, addressing these problems requires managing tradeoffs. To address many of the concerns about environmental safety, for example, regulators and seed companies require farmers to limit the fraction of their plots that they sow with engineered seed, reserving some fields as "refugia" for the very pests they seek to control, so that resistance does not increase too quickly.

The greatest difficulties for the regulatory system have not yet become evident. The products most likely to deliver benefits to consumers, such as vitamin-enriched "nutriceutical" foods engineered to deliver vaccines in easy-to-digest formats, are the most difficult for mature regulatory systems to handle precisely because of their novelty. Advanced food-safety systems all operate on the principle of precaution: regulators tend to err, albeit to different degrees, on the side of safety and extensive testing. Few of the prod-

ucts that are likely to constitute the second generation will be essential therapeutic foods, and thus it will be hard to justify field trials on the model of those done with novel pharmaceuticals. Regulators will need to rely on rules of thumb and the normal, telltale signs of food risks.

We fear that impatience with the slow pace at which the next generation of engineered products is appearing will generate pressure on regulators to treat the newest products much as they have approached the current generation of foods. Already, serious questions have been raised about the wisdom of the "substantial equivalence" approach to food safety taken for the first generation of products. Such doubts have not stuck because the alterations made in the first generation were quite evidently not foodsafety threats. Indeed, there is no credible evidence revealing food-safety dangers in this first generation of products. The most commonly cited accusation against one of these products is a series of studies by Arpad Pusztai published in the British journal *The Lancet* in October 1999 that purported to show that rats fed genetically modified potatoes developed tumors. Those studies were so poorly conducted that they failed peer review. When their existence leaked and critics of food engineering howled of cover-ups, *The Lancet* published the studies under a disclaimer stating that the article was scientifically unsound. The attacks will be louder with the next generation of products and probably harder to refute because the products are much more complex.

We do not fear that unsafe foods will be knowingly approved. Rather, our concern is that the hubris of policymakers, especially in the United States, will lead them to forget that the public imagination sees engineered foods as a quantum leap from traditional breeding—even though, objectively, the risks may be a simple extension of the risks that the regulatory system is already accustomed to handling. The experience with genetically modified Starlink corn (a Bt variety) is sobering. The U.S. Environmental Protection Agency approved Starlink for use in animal feed but rejected it for human consumption because a protein in Starlink had characteristics that could cause allergic reactions. (Allergy science is far from exact, and thus regulators balk at products that

have the look and feel of allergens even when there is no evidence that they actually cause any allergic reaction.) Consumers in the United States and importers (specifically, Japan and South Korea) cancelled orders for U.S. corn when Starlink showed up in products destined for human consumption. Ultra-sensitive testing equipment made it possible to detect even minute contamination throughout the U.S. corn conveyance system, where animal feed often commingles with the human supply (as do beetles, rat excrement, and other fellow-travelers of farming). Human food safety was never in danger—indeed, the U.S. government considered, but rejected, giving Starlink's manufacturer a temporary approval for human consumption so that the commingled crop could travel legally in the United States, which would have reduced the disruption to the U.S. food supply and also reduced the firm's exposure to lawsuits.

The damage from Starlink then crossed over into the public acceptance of engineered foods in general. The effect did not last long in the United States, where the public has been confident of food safety and largely indifferent to the brouhaha about food engineering, but in Europe and Japan the episode was viewed as proof that the system has run amuck. Imagine the scandal and damage to consumer acceptance of engineered foods if "contraceptive corn" engineered to produce antibodies that attack human sperm commingled with the sweet corn on its way to dinner tables. (The San Diego biotech firm that invented this product claims that, if the corn were commercialized, it would prohibit plantings near other corn fields. That assurance is similar to the one given by the inventors of Starlink corn, who sought a split registration by assuring the U.S. government that they would require farmers to keep the animal and human crops segregated.) Even tighter control and caution will be needed in approving genetically modified animals, not least because animals are typically more mobile than plants, and errors can thus propagate more quickly. Innovators were lucky that the controversy over Starlink subsided after only a few months; unless the new products offer exceptional benefits, the public will tolerate few additional failures and opponents of the technology will ensure that every hiccup is widely known.

In developing countries that have become centers of food innovation, similar issues will arise, but with one big difference: their regulatory systems, with few exceptions, are not far advanced. After the United States, China is probably the second most active hub of innovation in crop engineering, yet, despite recent improvements, the Chinese system for overseeing field trials and approving novel crops is lax and opaque. This state of affairs poses dangers to all nations because some of the risks from improperly regulated biotechnology, such as gene flow, affect the entire world's heritage of biological diversity. The bigger danger, however, may be to public confidence. The entire industry of genetic engineering relies on the reputations that form around the technology. Real and prominent failures due to poor regulation will be extremely harmful—much more so than the unmerited claims that have animated the opposition so far, such as food allergies and threats to butterflies. A failure anywhere in the world harms the industry everywhere. As Joel I. Cohen of the International Service for National Agricultural Research has argued, enhancing the use of biotechnology for the poor is a matter of investment not only in the research itself but also in the "biosafety" mechanisms needed to assure that research and commercial production do not go awry. Ironically, the most important investment in carrying the technology forward may be in building serious mechanisms for regulation. Industrialized countries, such as the United States, that have a strong interest in the advancement of crop engineering should invest heavily not only in proper regulation at home but also in improving the regulatory systems in developing countries. Rob Paarlberg of Wellesley College has shown that in some developing countries regulators have been reluctant to approve GM crops—not because they have built good regulatory systems based on objective analysis of risks, which is essential, but rather because anti-GM pressure groups have sought to halt the technology altogether.

So far, industrialized countries have made only modest investments in improving biosafety for crop engineering in developing countries. The existing programs have focused on crafting model legislation and bureaucratic procedures. But detailed com-

parisons of biosafety rules show that most developing countries—including all that are centers of significant innovation in crop engineering—now have pretty sophisticated rules on the books. The weak link is in implementing meaningful biosafety rules and greater investment is needed in that area.

A Humanitarian Face for Biotechnology

The innovations of crop engineering that are delivering commercial value today—and promise even greater benefits with the next generation of products—can also help the world's poorest societies meet basic human needs. Greater quantities of more nutritious food can sate hunger. Applied properly, technologies that help make agriculture more efficient can also catalyze economic development because agriculture is the single largest occupation of the rural poor; lightening its load can lessen the toll on agricultural workers and free time for higher-value occupations.

Aiding the world's poor through better food and farming is not a new mission, but genetic engineering could make it more effective. Whereas traditional breeding requires a dozen years to develop a new crop variety, more precise genetic engineering has cut that time in half for some improvements. A shorter innovation cycle saves money and also makes it easier to develop crops in response to particular diseases and challenges. The greater precision and flexibility of genetic engineering also shifts the frontier of possible solutions to farming's most persistent challenges. Creating crops that grow in salty soils, for example, has proved extremely difficult through traditional breeding. The genetic codes that confer salt tolerance are complex, which makes them hard to transfer with traditional methods that cross large numbers of genes, both wanted and unwanted. Some crops lack wild relatives with a natural salt tolerance, which would be the raw material for traditional breeding without engineering it would be impossible to beat the salt in those cases.

Although genetic engineering offers great potential for aiding agricultural development, these technologies will not automatically diffuse into service for the world's poorest. Most investment in innovation in crop engineering occurs in commercial markets and is driven by investors who seek profits. But as with most high-

technology novelties, only a small fraction of the commercial investment is channeled into technologies and techniques that are of generic value. The biggest costs come in applying generic technologies—such as herbicide resistance or Bt-production genes to particular varieties of crops and in clearing regulatory and marketing hurdles in order to carry those products to market. Even the simplest gene innovations are not fruits, ready and ripe, waiting to be picked and eaten. Applying gene engineering to serve the world's poorest requires, first and foremost, a hard-nosed strategy for marshaling investment. Even if commercial firms donate their generic technologies, someone must pay the cost of turning that intellectual property into useful final products. Most of the public debate about biotechnology for the world's poorest has focused on intellectual property—a topic to which we will turn in a moment—but the central problem is investment. Solve that problem and most of the others will disappear.

From the 1950s through the 1980s, world investment in public agricultural research and development rose steadily. But as Philip Pardey and Nienke Beintema of the International Food Policy Research Institute demonstrate in their recent, comprehensive survey of agricultural innovation, the 1990s brought stagnation in publicly funded research. This pattern is evident not only in the advanced industrialized countries—where private firms have taken up the slack—but also in public funding for research that aims to develop products for the world's poorest farmers and consumers. In the last fifteen years, the total budget for the CGIAR system has barely changed in real terms.

Thus, just at the time when the biotechnology revolution is offering the potential for a new pulse of success in rural agricultural development, key funders have halted the momentum of investment. And the United States has led the exodus. After peaking in the mid-1980s, the U.S. Agency for International Development's funding for public agricultural research in developing countries has declined in real terms by a factor of five. Most of the key funders of international agricultural research that remain, such as Germany, are the nations that are least enthusiastic about the widespread application of genetic engineering.

Making the case for public funding of development programs has been difficult, especially in the United States. The common charges leveled against such programs are that they do not work and that they are less efficient than private-sector solutions. Neither argument is valid in this case. It is true that much of the broadbased development assistance delivered in the last five decades has not been as effective in promoting economic growth as it should have been. As World Bank economist William Easterly has documented in a widely read recent history of development theory, fads, misguided theories, and Cold War politics have channeled billions into countries where conditions were not ripe for economic development. But the charge of waste does not apply so fully to public agricultural research, which has delivered real benefits—measured as higher-yielding crops, fewer hungry people, and higher incomes. Indeed, attempts to measure the social return from investments in public agricultural research suggest it is one of the best public investments available.

Nor will private market solutions solve the agricultural development problem. Two billion people dispersed over extremely large areas with very low purchasing power and few of the modern legal institutions necessary for encouraging private investment do not provide propitious conditions for a purely private-sector solution.

Rather, the trick to solving these development problems is to find solutions that lift standards of living while not perpetuating dependence on public aid—i.e., public investment programs that do not extinguish the private sector. The long history of programs sponsored by international and national agricultural research centers demonstrates a solution: invent better crops and agricultural systems but work through local markets to diffuse the innovations to farmers, thus allowing farmers and consumers to benefit from the new techniques while not undercutting basic market forces that determine supply, demand, and allocation of resources.

The case for increased U.S. investment in this area is particularly strong for three reasons. First, development groups as well as governments in other nations are rightly putting pressure on the United States to deliver a greater commitment to economic development for the world's poorest. Reversing the severe cuts in U.S.

support for agricultural development offers the greatest potential, with minimum expenditure, to lift incomes in the world's poorest regions. Second, the revolution in genetic engineering offers the opportunity to increase greatly the efficiency of agricultural research, making it possible to do more with less. Already a small fraction of the research activity within the CGIAR network applies the tools of modern biotechnology—not only genetic engineering but also techniques such as genomic mapping that make it possible to use traditional breeding methods to deliver greater benefits. But it is hard to redirect research budgets when the pie is not growing, especially when key funders are unenthusiastic about the innovation. The United States, with substantial incremental funding, could chart a path toward much greater use of the technology. Third, the United States has a special stake in the success of genetic engineering technology because much of the commercial research and value-added in this field occurs within the U.S. economy; even firms with headquarters overseas base a significant part of their research activities in the United States.

The controversy over genetically engineered foods has made it critical to demonstrate benefits to consumers—including in the developing world—as part of a strategy of assuring continued public support. We doubt that public opposition to engineered foods will halt the technology, but it has slowed investment and erased several billion dollars from the market value of U.S. corporations, notably Monsanto. With such sums at stake, Washington can surely justify leading an international coalition that would increase the level of investment in public agricultural research on the scale of \$100 million dollars per year over the next three to five years, with a substantial fraction of that increment given to the use of genetic engineering technologies. For comparison's sake, total revenue for the CGIAR in 2000 was \$342 million. That same year, U.S. spending on all foreign aid added up to about \$9.6 billion. The biotechnology increment that we propose, which would help chart a new direction for more efficient development assistance, thus amounts to a mere 1 percent increase.

At an international summit in Monterrey, Mexico, in March 2002, President Bush pledged substantial additional amounts of development assistance, and the Bush administration is giving par[36]

ticular attention to the role of agriculture in the development process. Hopefully, these are harbingers of a more constructive U.S. role in the future. More money for agricultural research alone will not unlock the potential of transgenic technologies in the developing world. Another barrier, generally less important, relates to intellectual property. Solving intellectual-property problems will require striking a balance between the interests of innovators—who want strong protection of intellectual property—and the public interest in applying intellectual innovations to the world's development problems. Again, a scheme must be devised that eases access to modern innovations while not perpetuating dependencies or undermining fundamental market concepts. Until the biotechnology revolution, private control of intellectual property posed no significant barrier to agricultural innovation because traditional breeding worked mainly with seed stocks that were held in public gene banks and available to all—public researchers as well as private seed companies. Intellectual property, where it was claimed at all, was protected through systems of plant breeder's rights. Much of the private innovation was focused on hybrid crops that had their own built-in mechanism for intellectual-property protection: hybrids lose their vigor after a generation, so commercial farmers must purchase new seed from the seed companies. That situation has changed as the intellectual enclosure movement has reached agriculture; particularly since the 1980s, patent rights have been granted for life forms, including novel seeds. And the biotechnology revolution has come in lockstep with pharmaceutical biotechnology, with both operating according to similar economic principles: huge up-front costs in development and regulatory approval have led firms to demand exclusive patent rights, rather than less strict plant breeder's rights, for their genetic innovations. But as ownership of crop innovations has conferred greater rights of exclusion, managers of research programs for public benefit have rightly feared that they will be shut out.

Clearing intellectual-property hurdles requires solving two problems. One is the growing fraction of the intellectual property in crop engineering that is falling into private hands, with no efficient mechanism in place to grant others the rights to use that

property or to compensate the owners. That tide is unlikely to turn. Some researchers in public institutions have pledged to make results of their work freely available, following the example set by the holders of patent rights on key inventions from the early 1970s, whose opening of their work to the public helped to create the recombinant DNA revolution. It is a good sign that the CGIAR institutions have recently reaffirmed their pledge to allow open access to their patentable innovations. Nonetheless, this race to invent everything in public is unwinnable: the sheer level of inventive activity related to crop biotechnology in the private sector is much higher than in public-sector institutions, and privatesector inventors are unlikely to offer unfettered free access to all. Moreover, a growing fraction of public research is also becoming tied to privately owned patent rights. Notably, the Bayh-Dole Act of 1980 has encouraged most U.S. universities to claim intellectual-property rights on their innovations with the hope of reaping blockbuster licensing revenues. Few universities ever even recoup the cost of operating their patent and technology transfer offices—Columbia, Stanford, Rockefeller University, and a few others are the exceptions—but in the meantime, this mass enclosure of results from research that is often, at least in part, funded by public revenues is tying up ideas that would otherwise be freely available.

The other problem that must be solved is the fact that modern plant varieties combine dozens or hundreds of innovations; it is practically impossible to quantify ownership for plants with such complicated heritage. Modern wheat varieties, for example, represent the accretion of dozens of crop breeding results dating back to the late nineteenth century. Future innovations from gene engineering will overlay still more complexity because crops bred with output traits will, in most cases, require multiple genes and processes that combine many distinct pieces of intellectual property. The innovators of "golden rice" discovered this fact when they explored how they might deliver their vitamin-enriched product to real people in developing countries, finding that dozens of intellectual-property protections can potentially lock up even relatively simple crop innovations.

No easy fixes to this problem exist, but initiatives started today could evolve over time into a durable solution. One initiative would involve finding mechanisms to reduce the transaction costs for gaining access to the dozens of intellectual-property snippets that innovators weave into new, useful products. Programs to build capacity in intellectual-property law and clearinghouses can help both innovators in public research institutions as well as private firms in developing countries navigate intellectualproperty law more easily. So far, most international assistance to developing countries on crop engineering is focused on the technology itself and on mechanisms for using that technology safely; very little attention has been given to the legal infrastructure for its use. The new Management of Intellectual Property in Health Research and Development program established by the Rockefeller Foundation and other donors to ease access to intellectual property for modern drugs may offer a model. In addition to helping developing countries build the capacity to navigate the web of intellectual-property law, there is also a need to experiment with various types of patent pools that offer a single point of negotiation for innovators. It is impractical to expect that all patents that might relate to innovations in crop engineering would be included in such pools, because the holders of such intellectual property will want to negotiate their own compensation mechanisms rather than operate through a pool. But the CGIAR could take the lead in nominating especially critical innovations and using them to start the pool.

The second critical need extends the first—it must not only be easier to gain access to intellectual property, but governments must also experiment with mechanisms to allow concessional, time-limited, or some other form of conditional access to critical intellectual property. This is a highly controversial topic, and it may prove impossible to develop a general mechanism for allowing low-cost access to intellectual property. The purpose would not be to offer free blanket access, which is clearly unsustainable, but to grant temporary property rights for products that are intended only for poor farmers. It will be difficult to make clear distinctions between commercial products, which would not merit preferential access,

and those that deserve such concessions. But the difficulty of that task should not deter the effort. As John Barton of Stanford Law School and Peter Berger from the law firm Preston, Gates, and Ellis have shown in a 2001 report in *Issues in Science and Technology*, there are many policy tools available for addressing problems caused by overly restrictive intellectual property rights.

Drug companies, stung by criticism of the cost of their products in developing countries, are already exploring ways to offer their products at cost to the most needy while still charging a premium in other segments that have a higher ability to pay. Experience—good and bad—with drug pricing can help guide the creation of more humane (and politically sustainable) mechanisms for sharing the benefits of crop innovation. The major crop engineering firms already grant access to large amounts of intellectual property to developing countries for use in products that are intended to benefit poor farmers. Monsanto and Syngenta are making their draft sequences of the rice genomes freely available to researchers: unable to stop the widespread illegal copying of its Bt cottonseed in China, Monsanto simply tolerates the practice—an imperfect market in China is better than none at all. Along with other companies, Monsanto has also donated intellectual property used in the "golden rice" innovation. Moreover, Monsanto's chief executive officer, Hendrik Verfaillie, announced in November 2000 a new pledge that expanded the firm's commitment to supplying technologies for global public benefits. Such firms as Monsanto would benefit by institutionalizing a mechanism that could deliver technology for widespread use to benefit the poor while still protecting the companies' right to sell at a profit in markets where farmers and consumers can afford the innovation. These firms have already arrived at the conclusion that, in the real world, they will not be able to charge the same high price for access to their intellectual property in all markets; they should help codify that acknowledgment in a way that channels the concessions to those who need them most.

So far, lack of access to intellectual property has not been an impassable obstacle in applying gene engineering for the world's poor. In part this is because the industry, reeling from public opposition to its technology, has been prone to give away its

intellectual property for highly visible public research programs; it is also a byproduct of the fact that few innovations in crop engineering have been applied in developing countries, and none of the crops developed in public agricultural research centers has been planted widely. The technology is still in its infancy and the most promising products remain in the early research and development process. Challenges from possible patent infringements are still more hypothetical bogeymen than real threats. For products that benefit the poorest farmers, the holders of intellectual property such as multinational corporations and U.S. universities that have claimed property rights under the Bayh-Dole Act—should learn a cautionary lesson from the drug companies that encountered a public relations nightmare when they attempted to enforce their intellectual-property rights on AIDS drugs in South Africa. The current state of affairs, based on donations and tolerance of patent infringement, will work temporarily but it is not a durable model for fostering innovation; it offers breathing room for the development of permanent solutions, but the absence of pressure also raises the danger that no effort will be made to find solutions to this complex problem.

A Great Transformation

Some of the most difficult policy issues in managing transgenic food technologies arise in the international institutions that oversee trade—particularly the WTO. The WTO is both cause and emblem of a great transformation in world trade law. Traditionally, trading rules acted at national boundaries, dealing with tariffs and quotas that governments could directly control. Also, traditional trade law made a clear distinction between products and production methods. Governments could regulate trade in products so long as they did not discriminate and did not exceed agreed limits on tariffs and quotas. Trade rules that targeted production methods, however, were off-limits. Both traditions are now waning, which is carrying the WTO into uncharted seas that are both difficult to navigate and extremely dangerous for the organization.

The WTO's reach now extends far beyond national borders to include "internal" policies, such as food-safety standards, that affect the products that countries allow to be imported. In creating such rules, the WTO's architects attempted to strike a careful balance between the need to avoid discriminatory or protectionist policies and the prerogative, correctly reserved to individual nations, to set and implement their own internal food-safety regulations. Similar issues arise with "technical" rules such as labeling, which can impose additional costs and stigmas on products that are thus singled out. Moreover, although the WTO's architects apparently did not contemplate the possibility of nations' using trade restrictions as levers on other countries' production methods, recent legal disputes within the organization have introduced that possibility. In particular, in the fall of 2001, the WTO's Appellate Body upheld U.S. bans on importing shrimp caught in a manner that killed sea turtles. At least in some cases, it would seem, the WTO will allow countries to use trade barriers to enforce ideas about unacceptable production methods.

Trade disputes over genetically modified foods put these issues into sharp relief. GM crop producers claim that their products are the same as conventionally bred crops because both types of crop are equally safe to humans. By that logic, modified crops should not face special labeling requirements or government import bans. Opponents, especially in Europe, argue that the crops are different for three reasons: first, they might be dangerous for humans to eat; second, engineered genes may "flow" into wild relatives and also contaminate organic non-GM crops; and third, growing modified crops on extremely large scales might cause long-term damage to the environment. This conflict is reflected in the current standoff between the United States, the world's largest exporter of genetically modified foods, and the European Union. The EU, which had previously approved more than a dozen varieties of genetically modified crops, has halted approvals of new GM technologies for nearly four years and will soon require any product containing even the smallest quantity of the engineered genes to bear a consumer information label.

Counter-intuitively, the best remedies to the EU-U.S. impasse lie almost entirely outside the field of trade law. If nations were to make a concerted effort to clarify the trade law they would probably fail. Current efforts focus on the Codex Alimentarius Commission, a joint body of the Food and Agriculture Organization and the World Health Organization that adopts food-safety standards to be used in WTO disputes. For more than four years, the commission has attempted to clarify concepts such as the "precautionary principle," which is used in Europe especially to justify strict food-safety rules. More recently, the commission has launched a process to set detailed standards for genetically modified crops. Despite public annoucements of progress, these efforts have achieved little and are doomed to fail in yielding useful guidelines. Views across the Atlantic diverge too widely to find a meaningful compromise, especially one that would be codified into standards that could have binding application in trade disputes.

A better approach would begin by recognizing the enormous achievements so far: despite their completely contradictory policies on genetically modified foods, the EU and the United States have not filed a single formal trade conflict. Instead, they have found ways to accommodate each other's interests. U.S. corn growers, for example, are preparing a program to deliver segregated corn to the European market so that, in effect, U.S. exports will be unaffected by the European wariness about genetically modified corn. Soybeans, of equal importance for U.S. exporters, have not thus far flared into a trade conflict; most soybeans exported to Europe go to animal feed and much of the soybean oil produced in Europe is re-exported. The only way to sustain this delicate dance is to keep dancing. The needed actions and measures are too complicated to write into a formal trade agreement. Moreover, neither side would be willing to acknowledge formally this sensitive and, until now, tacit game.

Launching a formal trade dispute would push the sides into opposing corners. The United States opened such a conflict in 1995 by claiming (correctly) that Europe's ban on importing beef produced with hormones was not based on science. Washington won and confirmed important principles about the types of trade measures

that are acceptable in the WTO, but the victory may prove in the long run to have been Pyrrhic. Belying the relatively small amounts of trade at stake, American and EU trade negotiators have clashed repeatedly over hormones ever since. The United States has retaliated against European products without ever inducing Europe to adopt a plan to comply with the terms of the original settlement. In matters involving food safety, which often arouse strong public passions, a clear decision from the WTO does not guarantee compliance. Rather, it can often redouble public convictions that international institutions are stealing their sovereignty. Victories in WTO battles can lose the war. With bigger matters at stake, such as the success of the new trade round launched in Doha, care is needed to skirt such land mines.

There are worrying signs, however, that Europe does not understand its dance card. The latest round of rules working their way through the EU legislative process might ultimately include the requirement that meat produced with genetically modified feed, such as from U.S. soybeans, carry a label despite the fact that no trace of the genetically modified protein found in GM soybeans appears in the final meat and despite the absence of any evidence that the protein (if present at all) might be dangerous. Rather than attacking the entire EU rule-making process frontally, Washington should focus pressure on this particularly egregious provision, with the goal of pressuring Brussels to implement it in a way that would let the dance continue. Firms that stand to lose if the EU imposes discriminatory meat- or feed-labeling rules can also help bring the EU back to a more justifiable position by working inside the EU's own institutions—for example, by challenging the rules in the European Court of Justice.

The other part of the response to these trade threats involves addressing one by one each genuine concern about genetically modified foods. We have cited the three that are used most frequently: danger to human consumers, gene flow, and environmental harm from large-scale long-term commercial planting. Governments could address worries that GM foods are unsafe with trade measures, such as import bans or labeling requirements. This concern, however, is the weakest of the three. In Europe especially, public fears are so strong that there must be labeling provisions.

The European public is fretting about GM foods because they are worried about general food and health safety—a basic function of modern government that European institutions so far have failed to supply. Reforming the food safety system in Europe, not launding trade disputes, is essential to restoring public confidence. In turn, greater confidence will help open markets for novel foods—especially the next generation of food products that offers apparent benefits to consumers.

Addressing the other two worries—gene flow and environmental risk—will require very different policies. Trade restrictions provide little leverage over these two problems because neither concern is intrinsic to the traded products. These issues should be handled outside of trade institutions, and both offer ways for the United States and Europe to cooperate more constructively. One area is in building capacity in developing countries to conduct and regulate crop engineering safely. European nations will be opposed to funding crop engineering activities, but they could find common cause with the United States in building up biosafety capacities in developing countries, which in turn will help reduce the potential for gene flow. The other area of useful joint work is in monitoring large-scale planting of GM crops. To date, much of the concern about such planting has focused on the Monarch butterfly and the dangers from Bt corn pollen. Yet the primary threat to the Monarch butterfly appears to have been the expansion of eco-tourism into its traditional winter nesting habitat in Mexico rather than the widespread planting of genetically engineered corn. Nonetheless, care must be taken to anticipate and avoid damage to nontarget species when biotechnologies are used, just as is true in the use of any pesticide. It is hard to have such effect on large-scale planting and monitoring activities through trade measures such as Europe's de facto ban on registering new GM foods. Cooperative programs on the ground, with the results openly published in scientific literature, undoubtedly represent a more sound approach.

Reprise

As long as the greatest benefits of gene engineering have yet to be realized, advocates of genetic engineering should strive to

keep the current, symbol-laden controversies from boiling over while encouraging firms and societies to invest in the generation of products that might deliver the most tangible benefits to consumers. Already farmers around the world have seen substantial gains from gene engineering innovations. Field trials have demonstrated the advantages of crops engineered for resistance to disease, drought, and salt or designed to deliver higher-quality nutrition. In late 2001, for example, Kenyan farmers harvested their first trial crop of sweet potatoes engineered for resistance to an aphid-borne disease that in the past has killed up to 80 percent of the sweet potato crop. In the words of Gordon Conway, president of the Rockefeller Foundation, a "doubly green" revolution is nearly upon us.

We have argued that sustaining investment in crop engineering will require a complex array of policies. Three, in particular, stand out. First, countries must invest in traditional crop breeding and farmer extension programs in major developing countries that have languished in the past decade. The conventional argument—that investing in agriculture will help poor farmers and societies—seems to be losing force. Despite strong evidence that investing in agriculture yields substantial social returns on agricultural investments, external funding for public international agricultural research, such as at the CGIAR centers, has leveled off. The opportunities from genomics and transgenics, however, could generate a new wave of funding, both by making crop research more efficient and by offering tangible and widely recognized global benefits.

The effort to apply biotechnology in developing countries should include not only investment in the techniques of crop engineering but also serious programs to improve regulatory capacity. The dangers of poor regulation are large, not only in terms of risks to the environment but also in public confidence. In 2001, for example, the discovery of transgenic corn in Mexico raised fears (so far unfounded) that wild corn relatives and germplasm in major corn breeding programs could be contaminated. All major centers of transgenic crop research and planting already have good biosafety rules in place, partially as a result of the adoption of the 1992 Convention on Biological Diversity. Implementation

of these regulations, however, especially in major developing countries, remains spotty.

Second, the patchwork of regulatory and legal intellectual-property protections has impeded the timely application of crop engineering, especially in programs designed to help poor farmers in the developing world. Some innovations from gene engineering in advanced industrialized countries have spun off into low-income societies. But the present method of delivering technology, in which companies use philanthropy to deflect harsh public criticism, is unsustainable. An explicit mechanism for reducing transaction costs and facilitating access is needed.

Third, countries and international organizations must take great care in managing trade disputes. New international trade rules, such as those that restrict national food-safety laws, have extended the influence of international trade law to include areas traditionally reserved to sovereign national policy. The EU and United States, bruised from past disputes, appear to have recognized the futility of fighting over popular food-safety rules. Both should be eager to avoid an open conflict over engineered foods. However, we argue that they are not working hard enough; a formal dispute now looms larger than ever before.

Skeptics of active policy strategies such as the one that we outline here see open markets as the best and most appropriate adjudicator and are wary of any effort by policymakers to intervene in the direction of technological change. Perhaps they are right. The spectacular fallout from Starlink and the looming trade dispute between the United States and Europe suggest, however, just how strongly passions over perceived food-safety issues can flare. These public, caustic conflicts have already destroyed much of the market value of the major biotechnology firms and have also impeded the flow of biotechnology to the countries and peoples that need it most. A conscious and deliberate strategy, rather than wistful hope for light at the end of the tunnel, is needed to carry this innovation toward its ultimate and promising future.

STUDY GROUP MEMBERS

Study Group Chair: Project Co-Directors:

DAVID L. AARON, Dorsey & Whitney DAVID G. VICTOR, Council on Foreign

Relations and Stanford University C. FORD RUNGE, University of

Minnesota

Study Group Members*

BOB ANDERSON

USDA National Organic Standards Board

WILLIS ANTHONY

Anthony Farms, Inc.

Jesse H. Ausubel

Rockefeller University

THOMAS C. BEIERLE

Resources for the Future

Andrew Cash

UBS Warburg

JUDITH CHAMBERS

Monsanto

JOEL E. COHEN

Rockefeller University

JOEL I. COHEN

International Service of National Agricultural Research

RAFFAELLA CRISTANETTI

Dupont

SAM DRYDEN

Emergent Genetics, Inc.

RUBEN ECHEVERRIA

InterAmerican Development Bank

^{*}Study group members participated in discussions but are not responsible for the content of this paper, which is the sole responsibility of the authors.

CATHY ENRIGHT

U.S. Department Agriculture

RICHARD L. FEIGEN

Myra M. Frazier

Environmental Protection Agency

FRANCIS FUKUYAMA

Paul H. Nitze School of Advanced International Studies

RICHARD L. GARWIN

Council on Foreign Relations

LAWRENCE K. GERSHWIN

National Intelligence Council

RICHARD GILMORE

GIC Group

MARIANNE GINSBURG

German Marshall Fund of the United States

REBECCA J. GOLDBURG

Environmental Defense Fund

JOHN HAAPALA

Oregon Tilth, Inc.

PHILLIP HENDERSON

German Marshall Fund of the United States

Alexia Herwig

New York University

THOMAS R. JACOB

DuPont

GREG JAFFE

Center for Science in the Public Interest

ROBBIN S. JOHNSON

Cargill, Inc.

KENNETH H. KELLER

University of Minnesota

JENNIFER KUZMA

National Academy of Sciences

HEATHER LAIR

Meridian Institute

HERBERT LEVIN

America-China Forum

MARC LEVINSON

J.P. Morgan Chase & Co.

JONATHAN MALKIN

ATP Capital LP

FELIPE MARDONES

University of Minnesota

JOHN J. MOORE JR.

Morgan Stanley & Co.

Julia A. Moore

Woodrow Wilson International Center for Scholars

PETER MORICI

Economic Strategy Institute

PAT W. NASH JR.

U.S. Naval Academy

RODNEY W. NICHOLS

New York Academy of Sciences

LARA PALEVITZ

UBS Warburg

SANDRA PANEM

Cross Atlantic Partners, Inc.

Lara Papi

Council for Biotechnology Information

SEEMIN PASHA

Council for Biotechnology Information

STEWART M. PATRICK

New York University

ROBERT PINGEON

Mestre Associates

CHANNAPATNA S. PRAKASH

Tuskegee University

DANIEL P. PUZO

Edelman Public Relations Worldwide

SUSAN SECHLER

Rockefeller Foundation

SOROUSH RICHARD SHEHABI

U.S. Department of Justice

Anne Shusterman

Emergent Genetics, Inc.

[50]

ALLISON SNOW

Ohio State University

CORRINA STEWARD

Meridian Institute

GORDON C. STEWART

Insurance Information Institute

RICHARD STEWART

New York University

AUSTIN SULLIVAN

General Mills, Inc.

DAVID H. SWANSON

Explorer Nutrition & Fiber Group

LINDA WIESSLER-HUGHES

National Intelligence Council

CATHERINE E. WOTEKI

U.S. Department of Agriculture

MICHAEL YUDELL

American Museum of Natural History

NORTON D. ZINDER

Rockefeller University