1 Governing Risk in GM Agriculture

An Introduction

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Biotechnology and the Transformation of Agriculture

Biotechnology is generating the knowledge and skills for modifying all forms of life – plant, animal, human, and microbial. It is enabling researchers to map the genetic composition of organisms and identify the functions of their genes, and to determine the roles that selected genes play in creating proteins that, in turn, establish the physical and biological traits of the organisms. With this knowledge, researchers are then able to conceptualize modified versions of selected organisms that would be endowed with new traits, such as various species of plants, and undertake a process that subsequently involves splicing new genetic material into the genomes of the plants to modify their genetic composition and proteins. If successful, the redesigned plants will have the new intended characteristics. Thus, the scientific approach to agriculture pioneered by Mendel and others in the nineteenth century is dramatically amplified by biotechnology.

Over the past decade, commercial interests have promoted genetic modification (GM) of basic commodity food crops such as corn, soy, and rice, and important nonfood crops such as cotton, to endow these species with traits that will enhance agricultural productivity. Notable achievements include modified versions of selected crops with superior ability to withstand the chemical herbicides used in agriculture to eradicate weeds and to withstand various insect pests, crop diseases, frost, and drought. In

addition, crops have been modified to improve their commercial quality and nutritional value to make them more desirable to the manufacturers of processed foods and attractive to consumers.

These remarkable achievements far surpass what can be done by the traditional agricultural practice of modifying crops through cross-breeding, a trial-and-error process carried out over generations of experimentation that can be successful only within a very narrow range of related species. In contrast, the biotechnological approach enables the splicing of genes from totally unrelated species for the rapid production of modified crops with traits that could not be imparted by natural processes or by the artisans of cross-breeding. Well-known examples involve the splicing of selected genes from fish into tomatoes to create tomato crops that withstand frost and the splicing of bacteria genes into corn and cotton to create versions of these crops that repel and destroy insect pests.

The ability to incorporate genetic material from unrelated species into traditional crops makes GM agriculture a disturbing development to persons whose values and beliefs hew to a religion or tradition that rejects the unnatural, and to others who have cultural or economic commitments to conventional agriculture. It is also worrisome to many others because the long-term consequences of growing and consuming GM crops are uncertain and could be harmful to ecosystems and their biodiversity, lead to inadvertent modification of wild plants and conventional crops, and cause harm to the health of the people and animals that consume genetically modified (GM) crops and derivative food products. For these and other reasons, GM agriculture has fueled a global public discourse, and the process of developing policies and regulations for governing GM agriculture has been contentious and has sparked intense conflicts in many countries.

Another cause of widespread concern is the prospect of biocolonialism. A small group of very large multinational corporations (MNCs) based in the United States and European chemical industry sectors have led this new agricultural enterprise and could eventually gain control of

global food systems. These MNCs have been acquiring biotech research firms and seed marketing companies, doing the research and producing the test results needed for official approval of their GM crops, patenting their innovations, and suing customers for patent infringement if they attempt to save the seeds of GM crops for subsequent use. They also aggressively market their GM crop seed to farmers in developed and developing nations. As a result, acreage dedicated to growing GM versions of corn and soy now far exceeds that used for growing conventional corn and soy in the United States, Brazil, Canada, and several other major agricultural nations. A similar trend is anticipated for GM versions of rice, alfalfa, potatoes, and other major crops that are essential to the food and feed systems of many nations.

MNC activities also encompass a broader range of plants, animals, and bacteria to create GM versions of these organisms that will serve as sources of nonfood products for industrial and consumer use, such as vaccines, drugs, fuels, pesticides, fertilizers, plastics, building materials, and organic agents for treating and destroying industrial wastes. Growing, harvesting, distributing, and using these nonfood GM crops and organisms in a manner that ensures their total containment so they do not mix with or contaminate conventional food crops, or GM food crops, and wild plants, is considered essential for safeguarding human and animal health, wildlife, and ecosystems. This presents a major challenge for risk governance because of the technical and managerial difficulties and costs involved in ensuring complete containment of the nonfood crops by physical or biological means.

The Risk Discourse

Perhaps no other technology has prompted a public discourse about its uncertainties and risks as extensively and intensely as the discourse fueled by GM agriculture. This may be due to the intersection of several factors, such as the aggressive promotional activities and ambitions of powerful corporate proponents, public mistrust of risk regulators and

risk analysts, the high value assigned to conventional agriculture by defenders of national culture and national autonomy, the extremely precautionary mindset of consumers in Europe and Japan after "mad cow disease" and other food safety incidents, exploitation of public concerns about food safety by the media, the persistence of interest groups dedicated to opposing corporate-driven technologies and "Frankenfoods" in particular, and the democratization of risk regulation, which makes it more transparent and attentive to public opinion.

According to the corporate proponents of GM agriculture, it is inevitable that their increasing capability to design and produce new crops containing genetic material from diverse life forms will progressively transform agriculture, the livestock and fish farming sectors of the food system, forestry, and the downstream industries that use plants and animals as raw materials for making a universe of processed foods, medications, building materials, and many other products. GM proponents' optimistic view, presented with supportive scientific studies and test data, holds that the risks posed by GM crops are minimal; that managing any residual risks will be economically and technically feasible (e.g., by maintaining buffer zones around GM crop planting areas); and that GM crops and foods will provide health, environmental, and economic benefits for developed nations.

Proponents promise even greater benefits and humanitarian outcomes for less developed and poor countries, namely the ability to ensure reliable and sufficient food supplies to meet the needs of their growing populations by planting high-yield GM crops designed to withstand drought, pests, and other naturally occurring agricultural adversities. They also promise that consuming GM rice and other GM crops with nutritional enhancements will overcome dietary deficiencies in certain cultures and thereby eliminate the chronic illnesses caused by the traditional reliance on a single conventional crop. Proponents further claim that more efficient production of GM crops will enable such countries to sell surpluses in the lucrative international markets created by free-trade treaties. Finally, they point out that growing hardy varieties of GM crops

that are intrinsically pest-resistant, instead of conventional crops that require the broad-scale application of toxic chemical pesticides and other agrochemicals, can provide a cascade of health and environmental benefits, such as avoid exposing farmers and their families to toxic chemicals, prevent toxic contamination of public water supplies and fishing areas, and make agricultural activities more environmentally sustainable.

Opponents contest these claims and present many arguments for resisting GM agriculture, including that growing and consuming a food crop containing genes from unrelated species violates nature, confounds adherence to dietary regimes ordained by religion or by personal choice, and could pose new risks to human and animal health over the long term. They warn that the new genetic content of GM crops will be released and flow into, pollinate, or otherwise cause contamination of related wild plants and conventional crops; eliminate insect and plant species; destabilize ecosystems and food systems; and cause loss of biodiversity and other irreversible ecological harms. Some of these risk claims have been evaluated by industry and government and found to be plausible, such as that pest-killing GM crops will eradicate certain insect species that are necessary for the survival of birds and other wildlife, and that the few insects of such species that survive because of their superior resistance will have progeny that are similarly resistant, thereby accelerating the evolution of super-resistant insects. Studies prompted by these and other concerns have, in some instances, led to more stringent requirements on the siting and configuration of GM crop-growing.

Opponents have also sought to refute claims that GM agriculture will benefit poor countries, arguing that it will instead cause social dislocation in agrarian regions by displacing small-scale subsistence farming with large-scale agribusiness owned and controlled by large companies remotely based in developed nations, and that consumers of the new foods will be exposed to allergenic risks and dietary disorders. Finally, there are deep fears in the poorer nations that they will be used as subjects of experimentation with new GM crops by the multinational firms

that dominate GM agriculture. Although opponents lack conclusive factual support for most of these contentions, several incidents indicate that some of their arguments have merit, and that has kept many others from accepting industry claims.

Public discourse on the uncertainties, benefits, and risks of GM agriculture has been robust, but its influence on the development of regulatory programs and other aspects of risk governance has varied. This is made clear in several chapters that follow. In the United States and other major commodity crop growing countries such as Argentina, Australia, and Canada, the discourse has been overwhelmed by well-established commercial and governmental interests in exports, with the result that residual issues are channeled into formal regulatory proceedings wherein industry views and scientific studies dominate decision making. In large rapidly developing nations such as India and China, the risk discourse continues but has been subsumed to official policies designed to meet the urgent food needs of their rapidly growing populations. As a result, early doubts and exclusionary policies have been replaced by policies that accept GM agriculture as a societal necessity. Brazil and Spain have similarly changed course and come to accept GM agriculture because of the opportunities it provides for boosting their exports under global free-trade regimes. However, the discourse remains vibrant and has brought about precautionary and exclusionary policies in Japan and the majority of the twenty-six member-states of the European Union (EU), including Austria, France, Germany, Greece, Italy, and Poland. Indeed, several have rejected EU directives that would slowly open the door to GM crops and have established GM-free zones.

New developments continuously arise that recharge the discourse and, in some instances, cause reexamination of policies. Perhaps most notable are several incidents of contamination of conventional crops by GM crops in the United States that have caused business losses as orders for the conventional crops were cancelled. Such contamination, which can arise from gene flow or the inadvertent mixing of both types of crops, presents a problem that is considered unacceptable by farmers, food

retailers, and consumers but that persists despite containment efforts of regulators and GM seed makers and their customers. Also entering the discourse is the growing preference by elite consumers for organic foods and conventional crops from local farms, a preference that is spreading to a much broader sector of consumers in highly developed nations.

Another emergent consideration is the application of nanotechnology to a growing number of consumer products despite the risks it poses to workers and others heavily exposed to nano-scale materials. It is foreseeable that nano-scale substances will be applied to conventional food products to enhance nutrition, flavor, shelf life, and other qualities, in lieu of genetic modification, and this awaits the reactions of the food industry and consumers. Another topic entering the discourse involves the growing of GM crops for producing vaccines, drugs, and other non-food items. Given the proven difficulties of segregating GM crops to prevent contamination of conventional food crops, this development poses new threats to food safety that will intensify concerns and cause more stringent regulation of GM agriculture.

The practice of genetically modifying food crops is entering its second decade, accompanied by many issues and conflicts. Is it morally wrong to mix disparate species? To what extent should cultural traditions, attitudes, and perceptions shape public policy, or should these be subordinated to expert judgments about safety and the assurances provided by companies and regulators? Is it irresponsible or dangerous to proceed given current uncertainty about health and environmental risks and the limitations of risk assessment and short-term field testing as means of reducing this uncertainty and avoiding worst-case scenarios? Will commercial experience produce learning about risks that will enable GM agriculture to be more safely managed over time by the companies, regulators, and growers involved in GM agriculture? Can the promised benefits for human well-being be achieved without destabilizing agrarian societies or bringing about biocolonialism by multinational firms? Are existing corporate practices, legal and regulatory safeguards, and international treaties sufficient to provide biosafety and protect

biodiversity or should more precautionary principles be followed? These are some of the critical issues confronting nations as this powerful technology advances.

Governing the Risks

Many countries have developed systems for governing GM agriculture and food products. Although they differ in their institutions, procedures, and criteria for decision making, each governance system is premised on the need to prevent unacceptable risks to human and animal health, natural resources, and ecosystems. Some countries also strive to contain GM agriculture so that it does not harm biodiversity, interfere with conventional agricultural activities, or impair the availability of non-GM foods to consumers. In countries with democratic and transparent processes for policy making and regulation, the types of risks being addressed and the decision criteria used to determine when a risk is unacceptable are derived from the processing of scientific and economic information and cultural and political considerations. These matters are discussed in several chapters that follow.

The activities subject to risk governance systems may encompass the import, distribution, field testing, sale, and planting of GM crop seed, and the import, testing, and marketing of GM crops, their derivative by-products, and GM food and feed products for consumption by humans and livestock. Thus, governing GM risk involves several important sectors of commercial activity, the agricultural, food production, and food retailing sectors, each of which has been subjected for many years to numerous requirements for conventional seeds, crop growing, and food products. Governance also involves protecting environmental quality and consumer rights.

As a result, the threshold question for many countries has been whether these previously existing frameworks and institutions are suitable for governing the risks posed by GM crops and foods, or whether new approaches and expertise are needed. In sharp contrast to the

threshold policy determination in the United States that the same regulatory requirements and procedures are sufficient and must be applied, the EU has created new requirements and an elaborate procedural framework for the GM enterprise.

A system for governing the risks may involve the application of several types of social controls, as discussed in the ensuing chapters. These may include reliance on self-regulation by corporate seed producers and the agricultural, food producing, and retailing entities and trade associations involved in the GM enterprise, and the application of information disclosure requirements to inform the marketplace and respect consumer rights. In common law countries, such as the United States and Britain, there is also reliance on the judicial system to impose liability on companies or individuals when their activities involving GM crops or foods fail to meet prevailing standards of care and cause harm to persons or property. However, in all countries, the most favored social control is some form of risk regulation by one or more public agencies that have been empowered by national legislation, a development usually accompanied by the creation of a scientific advisory apparatus.

Regulatory approaches differ, with some agencies enacting and enforcing detailed prescriptive rules and permit procedures, and others applying more flexible performance-based requirements to the entities subject to their authority. Common features include field testing and risk assessment requirements, permit procedures for agency review and approval of new GM crops before commercial planting, and additional procedures for review of food products with GM content before commercial marketing. In addition, various means of eliciting, listening to, and responding to public opinion have been implemented by progressive agencies in democratic nations, and in the EU, regulations impose special labeling requirements for marketing foods with GM content. A more detailed account is presented in subsequent chapters, including discussion of the criteria and assumptions applied in agency decision-making processes, such as use of cost-benefit analysis to determine whether a risk is reasonable, application of the "precautionary principle" when coping

with scientific uncertainty and reliance on templates for approving GM foods that are shown to be "substantially equivalent" to conventional food products.

Corporate proponents of GM crops and foods must therefore comply with numerous requirements to gain regulatory approvals. However, the requirements and their stringency differ between countries because regulatory activities, although directed by official policies, are nevertheless subject to the influence of many factors, political, economic, and cultural, as well as the ongoing risk discourse and the occurrence of harmful incidents, or the lack thereof. As a result, regulators in the United States, for example, have relaxed many requirements, deferred to corporate studies and findings, and disregarded petitions by consumer groups for the labeling of GM foods. In contrast, regulators in the EU domain are attentive to Eurobarometer and other public opinion polls in pursuing their mandates and have been extremely precautionary and stringent, indeed to some observers as being obstructionist.

Despite such differences, each governance system ultimately creates a responsibility for safety management by GM proponents in the conduct of their activities. Fulfilling this responsibility requires their compliance with risk regulations and meeting other standards of acceptable behavior. However, when such requirements are ambiguous, incomplete or otherwise inadequate, or nonexistent as in poor countries, safety management is confronted by ethical challenges. In developed nations, companies are expected to meet these challenges by developing a safety culture that promotes deep organizational commitment to identifying and minimizing risks and voluntary adoption of appropriate safety practices. As discussed in Chapter 9, GM agriculture may benefit from safety management knowledge gained in other, more mature technological sectors.

Reflections on Risk and Responsibility

For decades, progressive countries have sought to gain the benefits and minimize the risks of technological advance, and devised policies for