

BIOTECHNOLOGY IN AGRICULTURE

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■ **Abstract** The consequences of the invention of DNA-based molecular techniques and their application to agriculture have been pervasive. This review examines the key consequences for farmers and the public. These include widespread commercial applications of agricultural biotechnology in a limited number of countries, a large private-sector investment in biotechnology research, significant economic contributions to farmers, continuing controversy over its environmental impacts, a proliferation of regulations (both national and international as a consequence of the technology and property rights), a wide range of changing public reaction, and relatively little contribution of the technology to increasing food production, nutrition, or farm incomes in less-developed countries.

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INTRODUCTION

The consequences of the invention of DNA-based molecular techniques and their application to agriculture have been pervasive, both within the agriculture sector and outside it. Increased food production and profits were probably the primary hoped-for results by scientists who pioneered agricultural biotechnology while widespread public skepticism and even vociferous opposition probably were not anticipated. This review summarizes the commercial applications of agricultural biotechnology, the state of research, and the economic and environmental impacts of applications to date; identifies the main regulatory consequences; reviews the public reactions; and, in a final section, considers the implications for agriculture and food security in less-developed countries.

The term “biotechnology” has been used to refer to many biological processes that produce useful products, including some quite ancient ones such as fermentation in beer, wine and cheese (1, 2). But most frequently today the term is used to refer to knowledge about the natural processes of DNA replication, breakage, ligation, and repair that has made possible a deeper understanding of the mechanics of cell biology and the hereditary process (3). In this review, “biotechnology” refers to DNA-based molecular techniques used to modify the genetic composition of agriculturally useful plants and animals. Earlier methods of modifying the genetic composition of plants and animals, still widely used alone and in conjunction with DNA-based methods, which many agriculturalists call crop improvement or animal improvement, are referred to here as “conventional” plant or animal breeding. Organisms whose genetic composition has been modified by moving DNA from one organism to another using DNA-based techniques, i.e., not breeding, are referred to in this review as transgenic, genetically engineered, or rDNA (recombinant DNA). These terms are preferred to genetically modified organisms (GMOs) because the genetic composition of virtually all agricultural crops and animals have been modified by human actors over the past 200 or so years (4).

Biotechnology has led to a number of powerful tools in addition to genetic engineering that are useful for changing the genetic composition of plants and animals, including those identified below and explained in accessible language elsewhere (5). The techniques can be applied to plants, animals, and microorganisms of any kind, but this review will say nothing more about microorganisms and have the briefest references to animals. The major and most controversial social and regula-

tory consequences of agricultural biotechnology derive from the ideas associated with genetic engineering and food made from transgenic crops, whereas varieties produced without genetic engineering are ignored. In any case they are more difficult to identify, few and little data about them exist (6). This review focuses largely on transgenics.

APPLICATIONS OF AGRICULTURAL BIOTECHNOLOGY

The primary tools used in agricultural biotechnology are defined below using layman's definitions to serve the purposes of the review (1, 2).

- *Genetic engineering* inserts fragments of DNA into chromosomes of cells and then uses tissue culture to regenerate the cells into a whole organism with a different genetic composition from the original cells. This is also known as rDNA technology; it produces transgenic organisms.
- *Tissue culture* manipulates cells, anthers, pollen grains, or other tissues; so they live for extended periods under laboratory conditions or become whole, living, growing organisms; genetically engineered cells may be converted into genetically engineered organisms through tissue culture.
- *Embryo rescue* places embryos containing transferred genes into tissue culture to complete their development into whole organisms. Embryo rescue is often used to facilitate "wide crossing" by producing whole plants from embryos that are the result of crossing two plants that would not normally produce offspring.
- *Somatic hybridization* removes the cell walls of cells from different organisms and induces the direct mixing of DNA from the treated cells, which are then regenerated into whole organisms through tissue culture.
- *Marker-aided genetic analysis* studies DNA sequences to identify genes, QTLs (quantitative trait loci), and other molecular markers and to associate them with organismal functions, i.e., gene identification.
- *Marker-aided selection* is the identification and inheritance tracing of previously identified DNA fragments through a series of generations.
- *Genomics* analyzes whole genomes of species together with other biological data about the species to understand what DNA confers what traits in the organisms. Similarly, proteomics analyses the proteins in a tissue to identify the gene expression in that tissue to understand the specific function of proteins encoded by particular genes. Both, along with metabolomics (metabolites) and phenomics (phenotypes), are subcategories of bioinformatics.

Commercialization of Transgenic Crops

Private companies have produced and sold virtually all transgenic seed currently in use, although agriculture is a small part of the biotechnology industry—barely

20% of U.S. firms are in the field (7). In 2005, genetically engineered varieties of maize (corn), cotton, canola, and soybean were widely planted in North America and Asia while there was minimal use of such varieties in Europe and Africa.¹ Most transgenics have been engineered to confer a single plant trait (8–12), but multiple trait varieties comprised 20% of the total transgenic crops in 2005 (13). The global area of transgenic crops first exceeded 1 million hectares in 1996; over the next four years the area increased to over 40 million hectares, reaching 90 million hectares by 2005 (13). Over half of the global soybean crop was planted to transgenic herbicide-resistant soybeans in 2004, almost 30% of the cotton was planted to insect-resistant varieties engineered to include a gene from *Bacillus thuringiensis* (Bt), and 20% of the world's canola and almost 15% of the maize are transgenic for one or both of the same traits (13). Transgenic rice was grown commercially for the first time in 2005, in Iran, and is being widely field tested in China. Although not directly contributing to food consumption, transgenic cotton adds to income and hence food security and has rapidly spread in the United States, China, India, and elsewhere, covering over 5 million hectares. Only a handful of other transgenics, including papaya and squash, are commercially grown (14).

Approximately 60% of the total transgenic crop area was in the United States, about 20% in Argentina; Canada, Brazil, and China each had about 6%, whereas the rest of the world had less than 2% of the total area in 2005 (13). In Europe, Germany, Portugal, France, and the Czech Republic had small areas, but only Spain planted more than 50,000 hectares. Transgenic soybean, cotton, and maize adoption rates have been extremely rapid by historic standards, similar to those of the green revolution in Asia (15) and of hybrid corn in the United States (16).

Animal Applications

Animal biotechnology has proceeded in two directions: the production of animals for meat or milk and the creation of animals that produce biomedically useful proteins in their blood or milk. The latter is a highly specialized application directed at human health and is limited to a few companies (17). Farmers and researchers have long used animal breeding to improve animals for food, but to date, genetic engineering has not been commercially used in animal breeding. Techniques like artificial insemination long predate the discovery of DNA, and even the seemingly more exotic technology, embryo transfer, was developed a century ago (18).

Transgenic research on farm animals is not widely conducted, and progress is relatively slow (17, 19) for several reasons. Farm animals have much longer reproductive cycles than plants; so seeing the result of any breeding innovation takes much longer. Techniques for superovulation, ovum recovery, in vitro fertilization, nuclear transfer, cloning, and embryo transfer have low rates of success; therefore,

¹In contrast to most other international agricultural data, for which the UN Food and Agriculture Organization (FAO) is the accepted source, international data on commercialization of transgenic crops are provided by an independent observer who annually collates information from many sources (13).

applying genetic engineering to animals is inefficient (19a). Animals are costly; so the low rates of success mean the economics mitigate against commercialization. Social concerns include “the inadvertent release of dangerous microorganisms, the safety of products derived from biotechnology, the impact of genetically engineered animals on the environment, . . . animal welfare concerns, and our societal and institutional capacity to manage and regulate the technology and its products” (20). So, although animal agriculture is a dynamic and important sector of agriculture, this review says little more about it.

Specialty Applications

Herbicide tolerance and Bt genes both make a direct difference in farming, but newer types of transgenic crops are foreseen with human health or environmental applications. Companies are developing transgenic varieties without the anti-nutritive or allergenic factors that some foods, such as peanuts, soy, and wheat, naturally contain as well as other kinds of plants designed to improve health. Specific targets include plants designed to contain increased amounts of nutritionally desirable components (including lysine, methionine, zinc, iron, and vitamin A) or reduced amounts of undesirables, for example, trans fats. Other applications are aimed at plants that remove heavy metals from contaminated soils and plants with enhanced levels of sugars to serve as higher-productivity feedstock for ethanol (21). Anticipated value-enhanced crops include soybean and canola with modified oil composition and corn with white, waxy, hard food grade endosperm, high oil, or high amylose. One of the most revolutionary applications is creating plants that produce edible vaccines or compounds that can combat various maladies (22, 23). Of these, only a few have been commercialized, and none of these products has yet achieved “significant commercial acreage” (24).

RESEARCH AND EMERGING APPLICATIONS

In the mid-1990s about \$33 billion a year was spent worldwide on all agricultural research, split about equally between the industrialized and developing countries (25). Public agencies spent two thirds of the total, and private companies spent the remainder. About \$2.5 billion a year was spent on agricultural biotechnology research globally, with nearly 90% directed at agriculture in the industrialized north; private companies made well over half of the agricultural biotechnology research investment (26, 27).

Between 1976 and 2000, U.S. commercial firms obtained about 4500 plant biotechnology patents; foreign commercial firms, about 3000; and U.S. university and nonprofits, about 2500. About 1500 new patents were being issued annually around 2000 (28), and there has been continued exponential growth in U.S., European, and Japanese patents since then (29, 30). Private-sector research organizations obtained about three quarters of U.S. patents and an even higher proportion

in Europe and Japan (30). The innovations have generated a large number of transgenic varieties, and there have been over 10,000 transgenic crop field trials in the United States through 2003 (24). By contrast, developing countries have evidenced much lower levels of biotechnology research and development (R&D) with but 200 transgenic variety field trials undertaken and recorded in the FAO database from 1976 through 2003 (31).

Nutrition

Biotechnology has the potential to address nutritional needs in the developing world, but the path is not straightforward. Increased and more stable yields provide greater quantities of food, and resistance to pests may prevent the formation of toxins that are generated when grain is damaged by insects, a problem of huge, if poorly documented, dimensions (32). The density of micronutrients, such as vitamin A and the minerals iron and zinc, can be increased through genetic approaches (33).

“Golden rice,” one of the highest profile applications of genetic engineering, attracts kudos from supporters (34–36) and brick bats from critics (37, 38). Called golden because it contains beta carotene, which imparts a light yellow color to the grain, the beta carotene is converted to Vitamin A after ingestion, providing this essential nutrient to the person ingesting it. The opportunity for such a product to alleviate effects of Vitamin A deficiency of an estimated 400 million people (39) was one of the reasons it was identified as a high priority at an early stage of the Rockefeller Foundation’s international program in rice biotechnology (40, 41). Its development was funded through that program (35, 36, 41) with no financial backing from the private sector, a fact that has not stopped companies from using it as a “poster child” in their promotional efforts.

Like many early innovations, golden rice was publicized before a practical version was available. Generated in public-sector research laboratories, it was produced with the help of patented tools used under research licenses. Commercialization will require negotiation of numerous licenses (42) and use in conjunction with other dietary sources of Vitamin A or will have to be re-designed to contain a higher beta carotene content to meet nutritional needs (33, 39). Syngenta Corporation, which owns some of the intellectual property, has donated it to be used in poor countries and has been instrumental in forming, along with the Rockefeller Foundation, a humanitarian board to guide the development of practical golden rice products for poor developing countries (43).

Drought

Tough plant breeding problems are sometimes mentioned as a justification for biotechnology, and none is more frequently cited than drought. There has been significant recent progress in the scientific understanding of the processes underlying plant responses to drought from the molecular through the whole-plant level (44, 45). Widely recognized as an important constraint to agriculture in most situations, drought resistance has long been a top-rated objective of conventional breeding

(46, 47) as well as applied agricultural biotechnology programs (40). Commercial companies are as anxious as the public sector to develop more drought-tolerant cultivars and recognize that the “potential benefits of combining genomic tools with traditional breeding have been a source of widespread interest and resulted in numerous efforts to achieve the desired synergy” (48). But progress has been slow (49).

Two broad approaches are used. One attempts to optimize phenotypic traits, including deep roots, vigorous root systems, stomata control, osmoregulation, and leaf epicuticular wax (50), the other, to optimize response to drought by manipulating production rates of plant growth enzymes. Some argue that limited progress has been made by the first approach because “internal consistency in the correlations between presence of traits and the intervening processes are rarely proven beyond doubt. Therefore, in spite of several advantages offered by the analytical approach, impact will be limited until the physiological and biochemical components of critical traits are understood. However, the time is ripe to test the usefulness of simpler traits such as specific metabolite or stress-induced protein accumulation by such techniques as genetic transformation” (51). Efforts have been made to identify molecular markers associated with drought tolerance (52), and hundreds of genes induced by drought have been identified. An emerging lesson from such efforts is that plant responses to stresses, e.g., drought, may involve hundreds of genes, making a determination of what each does extremely complex. This complexity means that the function of many of the genes is still unknown (44).

Genomics-Assisted Breeding

Although transgenic varieties have captured much attention and are the base for current commercial applications of biotechnology, many scientists believe that greater progress can be made in changing crop performance through applications of genomics tools (53–55) that do not involve genetic engineering. There is tremendous genetic variation and, hence, potential within crops that is not obvious by looking at plants (i.e., observing phenotype) but that can be utilized through non-transgenic breeding methods by looking for genes. “For example, if one line of rice is high yielding and another low yielding, one might assume that the high yielding type possesses most if not all of the genes for high yield and that the low yielding parent has little or nothing to offer in this regard. However, when populations derived from such crosses are examined with molecular markers and the loci controlling yield are identified, a much different picture emerges. While the high-yielding line does contain a great number of positive alleles at the loci associated with yield, there are almost always some loci for which the inferior parent contributes a superior allele” (56).

Molecular markers can be used to determine whether a desired gene is present in an individual plant, and genomics has led to the development of an array of molecular markers. The types include restriction fragment length polymorphisms, random amplification of polymorphic DNAs, cleaved amplified polymorphic sequences,

simple sequence repeats, amplified fragment length polymorphisms, and single nucleotide polymorphisms, all of which can all be used to mark the location of genes of potential interest. These kinds of “advances in genomics can contribute to crop improvement in two general ways. First, a better understanding of the biological mechanisms can lead to new or improved screening methods for selecting superior genotypes more efficiently. Second, new knowledge can improve the decision-making process for more efficient breeding strategies” (57).

The rapidly growing power of informatics resources can be used to interpret the genomic data in order to understand the evolution of crops and lead to “improvement of a wide range of crop plants that sustain much of the world’s population” (58). Indeed, some believe that “there is every reason to believe that the synergy of empirical breeding, marker-assisted selection and genomics will truly ‘produce a greater effect than the sum of the various individual’ actions” (59).

Unanticipated Research Opportunities

In addition to the applications mentioned above, biotechnology has created entirely unexpected opportunities for agriculturally related research in the detection of GMOs (19a); in handling, analyzing, and interpreting the massive amounts of data generated by automated laboratory processes (61); and in understanding the likely consequences for nontarget organisms (62). Other opportunities seem to follow commercial developments in more predictable ways as scientists seek practical approaches to homologous replication, gene deletion, and gene silencing. All these research activities are in laboratories in 2005 and have demonstrated their potential but are not yet in routine commercial applications (13, 63).

Remaining Challenges

Essentially two transgenic traits are being used in commercial varieties in spite of the huge investments made in agricultural biotechnology. Practical results from those investments will require identification of many more genes and understanding what controls their expression (49). Genomics and its sister tools are powerful, but two major gaps remain. “The first gap lies in understanding the desired phenotypic trait of crops in the field and enhancing that knowledge through genomics. The second gap concerns mechanisms for applying genomic information to obtain improved crop phenotypes. A further challenge is to effectively combine different genomic approaches, integrating information to maximize crop improvement efforts” (48). The opportunities for increasing the rate of genetic improvement depend on four issues: “(1) the complexity of the target genotype-environment system; (2) the genetic resources available to the breeding programs; (3) clarity of the breeding objectives, capacity of the adopted breeding strategy to achieve the necessary genetic modifications and selection strategy; and (4) the physical and human resource capability to implement, evaluate and manage the necessary breeding strategies” (64).

CONSEQUENCES FOR PRODUCTION AND ENVIRONMENT

The rapid, widespread adoption of genetically engineered seeds indicates that many farmers have found them attractive. Because they are widely grown and have new biological characteristics, they are likely to have somewhat different effects on the environment than previously grown varieties. The questions of their impact on farm production and profit as well as their impact on the environment have motivated much research.

Production and Income

Farm-level impact is assessed from data on changes in area planted, yield, production value, inputs, and input costs (including seeds), using transgenic varieties compared to nontransgenic varieties of the same crop. The validity of results depends on how closely the comparison represents what would have been the case in the absence of the transgenic seeds, but estimating such counterfactual information is challenging (65). Estimates may be generated from experiment station trials, by comparing transgenic and nontransgenic varieties on farms that produce both, by comparing yields of all transgenic and nontransgenic fields of all farmers, or by comparing the yields of farmers who only planted transgenic with those who only plant nontransgenic varieties; each approach has its limitations and would generate four different estimates, although most reports rely on a single comparison (66, 67).

Government crop reports show continued widespread adoption of transgenic crops in most U.S. states, suggesting farmers continue to find them attractive (68), and the application of estimates of yield, cost, and prices to such data generates estimates of their impact on farming (14). A meta-analysis of 71 studies from 1996 through 2001 argued that the experience base with transgenic crop studies was too small to draw strong conclusions about the impact on crop yield or farm profits (67), although it was suggestive of (a) increased yield and profit with Bt corn over conventional, (b) a slight yield reduction and insufficient profit data for transgenic soybeans, (c) a wide range of yield effects between Bt and conventional cotton associated with a wide range of pest pressure, and (d) evidence of reduced insecticide sprays and increased profit with Bt cotton (67). Reduced insecticide use in crops with the Bt gene reduces costs and increases economic profit (69), and these profits have been estimated prospectively (70, 71).

Standard economic analysis recognizes that farmers benefit from the technology, the companies selling the transgenic seed also seek to retain some of the economic gains, and to the extent that new technology generates downward pressure on food prices, consumers may also benefit (72). In the case of Bt cotton in the United States, one estimate found that farmers captured 60% of the benefit and Monsanto, the technology developer, captured 20%, with the rest going to consumers (73). An estimate of the benefits of Bt maize in Spain found that farmers captured two thirds of the benefit, the seed developer, the remainder (74).

Transgenic crops are estimated to have contributed between \$20 and \$30 billion to farmers' incomes worldwide between 1996 and 2004 as a result of yield increases and cost savings (75). This amounts to 3% to 4% of the total global value of these crops. Herbicide tolerant soybeans contributed nearly half the total, insect-resistant cotton about one quarter, and insect-resistant maize about 10%. About \$10 billion was contributed to farm income in the United States and Argentina, with the increases in China estimated at just over \$4 billion; Brazil, at \$830 million; and Canada, at \$800 million (75).

Environment

Transgenic crops may affect the environment differently from their nontransgenic counterparts in a number of ways. Considerable resources have been expended to measure and understand these effects because assessing them is neither straightforward nor cheap (76, 77).

In ecological terms, transgenic crops are new, so the possibility of their producing environmental harm is a concern. These may include possible negative effects on "friendly" insects, birds, and plant species (78–80), among which the impact of Bt on Monarch butterflies is perhaps the most well-known. In this case, normal scientific investigation of the consequences of Bt on an iconic species led to sensational and misleading reporting by the mainstream media. In retrospect, Bt likely has had little effect on the Monarch (81). Five years later, extensive testing of the effects of Bt on "nontarget plant-feeding insects and beneficial species that has accompanied the long-term and wide-scale use of Bt plants has not detected significant adverse effects" (82).

Another environmental concern is gene flow from crops to weeds and other crops (83–86), potentially making weeds more difficult to control than before the innovation (87, 88). "Gene flow can be surprisingly widespread... they have the potential to create or exacerbate weed problems... it is much easier to rule out unwanted scenarios for certain low-risk crop plants, such as soybean in the United States, than to demonstrate that higher-risk crops such as Bt sunflower pose serious environmental risks" (89). Still another is the potential for erosion of transgenic resistance, so that the transgenic crop loses its new trait, perhaps leading farmers to use more toxic alternatives (83, 90). Some look at the evidence on potential with the view that it should "be assumed that GM crops will have unintended and possibly harmful phenotypic effects, and that horizontal gene transfer of unstable vectors and transposons used in the modification process is a distinct possibility" (85). However, as in any risk assessment, one must distinguish between the probability that an event will take place (e.g., that pollen will flow from a transgenic to a nontransgenic plant) and the hazardous consequences to humans or nature of such a flow. Even where the former is almost sure to happen, the latter may be small, so quantitative information on both elements of the risk is needed (86).

As well as potential negative environmental effects, there are positive ones on people and the environment. Pesticides are an important cause of ill health among farmers and applicators, so built-in resistance may generate benefits by reducing

pesticide exposure (91–93). Reducing the pesticide load into the environment may also generate health benefits to the general public (69), and there is evidence that the use of transgenics has “reduced pesticide spraying by 172 million kg and has reduced the environmental footprint associated with pesticide use by 14%” (75). The technology has also significantly reduced the release of greenhouse gas emissions from agriculture “by over 10 billion kg, which is equivalent to removing five million cars from the roads for a year” (75).

REGULATION AND AGRICULTURAL BIOTECHNOLOGY

Before 1980, there were relatively few regulations on production or trade of crop seeds. Since then, there has been a proliferation of national regulations and international agreements that seem to have led to ever more regulations. The first transgenic organisms were unregulated laboratory creations with the first national standards outlined in 1976 by the National Institutes of Health (NIH). Those provided for regulations by committees of the institutions in which the research sponsored by NIH was done, and most researchers adhered to them (94). With the development of transgenic seeds intended for farming, a procedure to regulate their release into the environment was needed. In 1986, the U.S. government developed a coordinated framework for transgenic crops built on the existing statutory authority of the Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) (95). Other countries have taken their own approaches, and related international agreements have proliferated.

Food Safety

In the United States, the responsibility for assuring that new foods from whatever source are safe for consumption is largely the responsibility of the FDA. Its primary concerns are contamination by bacteria, mycotoxins, chemicals, and pesticides. For biotechnology-derived food, “FDA operates a voluntary premarket notification and consultation system that provides biotech companies an opportunity to demonstrate that foods produced from their biotech crops are as safe as their traditional counterparts” (96). The FDA assumes that before seeds from genetically engineered crops are grown commercially the USDA must be satisfied, that field tests show only desirable changes have been made in the crop, that “the plants look right, grow right, produce food that tastes right,” and have nutrients similar to their nontransgenic counterparts (97). This is the “substantial equivalence” approach. The FDA can ban and compel the recall of food ingredients and foods that do not meet these criteria (98).

Wide variations exist in food safety regulations across countries. European Union countries are working toward common or compatible standards with foods derived from transgenic crops subject to specific “scientific evaluation of any risks which they present for human and animal health or the environment” (99). Despite this, in Europe, there is a low level of trust in government agencies assigned the

responsibility for ensuring food safety, which some trace to lapses in those systems (100–102). Because so much food moves internationally, most countries desire compatible standards and support the Codex Alimentarius, an international agreement of over 100 nation members. Administered jointly by the FAO and World Health Organization, it promotes coordination of all food standards work by international organizations with the goal of “protecting the health of consumers and ensuring fair trade practices in food trade” (http://www.codexalimentarius.net/web/index_en.jsp).

Biosafety

In the United States, the EPA is responsible for pesticidal substances, and the USDA, for seeds, with the two agencies sharing responsibilities for the environmental safety of transgenic seeds that produce pesticidal substances, such as Bt. The Animal and Plant Health Inspection Service (APHIS) has responsibility for field testing, movement, and importation of genetically engineered organisms that are known to be, or could be, plant pests (<http://www.aphis.usda.gov/brs>). Two major steps are involved in clearing transgenic seeds for commercial use: The producing institution must first obtain a permit to conduct field trials; then after conducting those trials, the institution may petition APHIS to have the article removed from regulated status. If the petition is granted, the product may be commercialized. Once an article is removed from regulated status, subsequent varieties of the crop created through conventional breeding using the approved article can be developed without additional approvals. From 1987 through 2004, about 10,000 such field tests were conducted in the United States (24).

The EPA's role is focused on plants, like Bt cotton, that have been genetically engineered to produce a pesticide under the same laws it uses to regulate conventional pesticides. EPA is charged to ensure that a transgenic plant does not pose an unreasonable chance of harm to human health or the environment (96). Pesticides, whether from plants or chemical factories, that pass the EPA's evaluation are granted “registration” and may be sold under established conditions (95). For transgenic events unrelated to pesticides, for example, drought resistance, EPA has no authority.

At the 1992 Earth Summit in Rio de Janeiro, world leaders agreed on the Convention on Biological Diversity as a comprehensive strategy for “sustainable development.” Signed but not ratified by the United States, it “established three main goals: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources” (103). As part of the goal of equitable sharing of the benefits of biodiversity, the Convention included a provision that vested germ plasm ownership rights in the nations where it originated. Parties to the Convention on Biological Diversity adopted a supplementary agreement known as the Cartagena Protocol on Biosafety on 29 January 2000. It establishes procedures for advance notification of international shipments of transgenic organisms to enable countries to make

informed decisions before such organisms come into their territory and provides information to assist countries in the implementation of the Protocol (104).

International Crop Genetics Undertaking

The first comprehensive international agreement dealing with plant genetic resources for food and agriculture was the International Undertaking on Plant Genetic Resources, adopted by the FAO conference in 1983. Monitored by the Commission on Genetic Resources for Food and Agriculture within the FAO, the Undertaking seeks to ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated, and made available for plant breeding and scientific purposes and “to promote international harmony in matters regarding access to plant genetic resources for food and agriculture” (105). The international agricultural research centers of the Consultative Group on International Agricultural Research pledged adherence to the principles of the Undertaking and continue to emphasize the concept that crop germ plasm is the common heritage of all humanity (106).

The Cartagena Protocol led, for several reasons, to great consternation in agricultural circles when it was introduced just a few years after the Undertaking was adopted: It contradicted the “common heritage” concept of the Undertaking (106, 107), and for another, it is almost impossible to define the origin of crop germ plasm as it has been moving with migrating human beings since the beginning of agriculture, accelerating with each technological innovation in transportation (108–110). Given the practical difficulty in identifying the national origin of germ plasm, the provisions on national origin and benefits’ sharing will be difficult to define and enforce. The inherent conflicts between the Undertaking and Cartagena led to seven years of negotiations to formulate a new treaty on crop genetic resources, which came into force in June of 2004 after it was ratified by FAO member states (<http://www.fao.org/ag/cgrfa/itpgr.htm>).

Intellectual Property

Some countries have long recognized intellectual property in crop varieties, and in 1961, the International Union for the Protection of New Varieties of Plants (UPOV, from the French) initiated international efforts at harmonizing plant variety protection property rights. In 1970, the United States passed a Plant Variety Protection Act, administered by the USDA (http://www.ams.usda.gov/science/PVPO/PV_Pindex.htm). After the 1980 U.S. Supreme Court decision on *Diamond v. Chakrabarty* declared that any living organism that is the product of human intervention, specifically including plants, could be patentable in the United States under the administrative authority of the Patent Office, the number and types of intellectual property protection for plants have accelerated (111, 112). In recent years, some disquiet over the potential imbalance between the rights of those developing intellectual property and the public interest has gained strength (113), and some continue to oppose the entire idea of property rights in plants (114).

Intellectual property law is national, so innovators must file for protection in each national jurisdiction in which they wish to claim property rights. The role of the World Intellectual Property Organization is to “promote the protection of intellectual property throughout the world through cooperation among States” (<http://www.wipo.int/about-wipo/en/dgo/pub487.htm>).

The World Trade Organization is the ongoing global forum for international negotiations on international trade, and its provision for trade-related intellectual property rights (TRIPS) has made it the de facto international forum for negotiations on intellectual property. TRIPS is almost as contentious in the agricultural community as in the health community. Designed to prevent others than a patent owner from importing patented goods, it has been vigorously applied to protect designer jeans, popular music, movies, and pharmaceuticals. TRIPS requires every member nation to have an enforceable system of intellectual property protection, including protection for plant varieties. The requirement may be met by allowing plant patents or UPOV-type plant variety rights, or through a country-specific sui generis system (111). Because the United States favors patents, whereas most European countries favor UPOV, developing countries are subject to pressure from the two major international economic blocs (45).

PUBLIC REACTIONS TO TRANSGENIC FOODS

In the United States, there is relatively high acceptance of foods from transgenic crops, although some Americans remain opposed to them, while in Europe, opposition is strong (115, 116). Facts about the scientific and economic questions can be established, but views based in beliefs and nonquantifiable values seem unlikely to change with further scientific information. Advocacy groups opposing transgenics may be reflecting these ethical positions as much as determining them, although some opposition does not marshal a consistent, measured, rational argument that is the mark of an ethical position but rather appeals through emotive terms like “frankenfood” and “terminator” (117–119).

The Safety of Transgenic Food

The greatest food safety threat resulting from genetic engineering is likely from DNA that generates unknown toxins or allergens, and consequently, transgenic foods are screened for all known allergens and toxins using highly accurate analytical methods (120). That procedure seems to have been effective in the United States, where genetically engineered foods have been consumed since 1996, and “no adverse health effects attributed to genetic engineering have been documented in the human population” (121).

Still, foods are composed of huge numbers of chemical substances, and even though the known problems can be prevented, there is limited ability to predict all possible “health effects that result from the consumption of food” (121). Given the

impossibility of proving a negative, scientists will not categorically say transgenic seeds could never cause any particular problem, but the consensus of scientific views, forming the basis for food safety regulation in the United States, is that “the process involving rDNA technology is not inherently hazardous” (121). Those introducing transgenic seeds must provide assurances that hazardous substances are not present and that they have substantially the same nutrition as nontransgenic—the “substantial equivalence” approach (122).

Europe has taken a much more cautious approach, following the “precautionary principle,” which strictly interpreted requires evidence that no harm will be done through the introduction or consumption of a new product (123). Whether this impossibly high standard is particularly championed by the European Community as a genuine effort to protect against risk or simply as a trade barrier is to be seen (124). But things seem to be gradually changing (125, 126). As part of an assessment of transgenic food safety by the European Union, a group of distinguished scientists has proposed that transgenic food safety assessment begin “with the comparison of the new GM crop with a traditional counterpart that is generally accepted as safe based on a history of human food use” (120). Such a case-focused approach would be very close to the concept of substantial equivalence used in the United States.

The Acceptability of Transgenic Foods

Biotechnology is not a leading preoccupation of U.S. consumers. Handling, contamination, nutrition, ingredients, packaging, antibiotics, and chemical residues all seem to worry people more than transgenics, at least when they are asked to name their concerns (127–132). However, this may be because 60% to 70% of people in the United States are not aware that currently available food contains ingredients from transgenic crops (115).

About 70% are generally “supportive” of food from transgenic crops (116). Industry groups report that a majority of people support current U.S. policies of not requiring approval for genetically engineered foods (132, 133). However, that is a small majority (55%), and the proportion supporting nonapproval has fallen at a steady pace from nearly 80% in the late 1990s (116, 133). A less self-interested source reports that a significant majority of U.S. consumers wants government to certify the safety of food from transgenics (115). An underlying cause of this public wariness about transgenic foods may be that neither nations nor individual consumers perceive significant benefits to themselves while fearing possible risks, however small. The ubiquitous role of food and the increasing distance between production and consumption may lead consumers to be concerned not only about cost and measurable attributes of food but also “the technology and methods used in food production and processing” (134).

Some believe that more education about transgenics will relieve consumer apprehension and that may work only for some subjects and locations (100, 135). Others stress the issue of trust, and research shows that the level of trust in regulations designed to protect against potential risk is associated with

acceptability of the risk, but it is unclear whether trust generates acceptance or whether other general evaluative judgments are more important in driving specific risk judgments (136). It seems clear that information from some sources is trusted more than from others. In the United States, evaluators, such as scientists, universities, and medical professionals, are trusted more than “watchdogs,” e.g., consumer advocacy organizations, environmental organizations, and media sources; and merchants, including grocers, grocery stores, industry, and farmers, are least trusted (137). In Europe, advocacy groups are most trusted (101, 138).

Although food is important to people, opinion polls may be of limited value for predicting behavior because the technology is relatively new, and most people have a relatively low level of knowledge about it. Some believe that even when individuals have some information and are willing to express an opinion about a specific object that they perceive as not directly relevant to them, “chances are that we will be measuring no more than ‘opinions,’ or attitudes that are not rooted in an individual’s enduring interests and values, and which are therefore extremely unstable and of little value for predicting behavior” (101).

The efforts to consider and address public concerns about crop genetic engineering and transgenic food (139–141) have not overcome all misgivings. “One almost universal feature is the public fear of possible long-term and as yet unknown risks to health and the environment that no amount of scientific assurance seems able to assuage. Despite statements to the contrary by researchers and officials, the public by and large perceives decisions to be based as much on politics as science. The public questions the role of industry in the decision making as a conflict of interest” (142).

The Power of Multinational Seed Companies

In the mid-1970s, agricultural chemical companies began acquiring seed companies, perhaps anticipating a time when biology would replace their agricultural chemicals. Sandoz, later to become a part of Syngenta, acquired Rogers seeds; Monsanto acquired Jacob Hart; and DuPont acquired Pioneer, then one of the world’s largest seed companies. Bayer, Advanta, and Limagrain also acquired companies, and by 2005, these six owned almost half the commercial seed sales capacity in the world (118, 143, 144). In addition, the six plus BASF accounted for over 80% of genetically modified crop field trials and controlled over 40% of private-sector agricultural biotechnology patents issued in the United States (145).

The concentration of crop seed production capacity in the hands of a few multinational companies has generated vocal opposition by advocacy organizations, including the Third World Network (<http://www.twinside.org.sg/>); Rural Advancement Foundation International, now renamed as the ETC Group (also known as the Action Group on Erosion, Technology and Concentration) (<http://www.etcgroup.org/>); Greenpeace (<http://www.greenpeace.org/>); and Genetic Resources Action International (GRAIN) (<http://www.grain.org/>). They seize on issues such as the possible introgression of transgenes in Mexican maize or toxic effects on Monarch

butterflies and conflate them with information about seed industry concentration, farmers' rights, and gene patenting with the terms "biopiracy, Frankenfoods, genetic pollution, and corn grenade" in a virtual war against crop genetic engineering (117). They ignore later evidence on Mexican maize and Monarch butterflies that contradicts their position (81, 146).

One fear is that the largest companies will control the supply of seeds and food and may eventually control the fundamental rights of access to food somewhat like they have controlled the price of pharmaceuticals (118). The economic theory of oligopoly provides some support for this concern, but empirical studies raise doubts (73, 147–149). Pricing analyses "suggest that despite a near monopoly, herbicide-tolerant cotton and soybeans are priced so that farmers and/or consumers get the largest portions of the benefits from innovation" (150).

Seed companies cannot extract very high excess profits (147) because of limits to market power that derive from fundamental differences in the nature of consumer demand for drugs and food and from the close substitutes that exist for transgenic seeds. People are willing to pay very dearly for a drug they think will cure them, but farmers are quite willing to substitute one crop variety for another because there are many close substitutes. In fact, even in advanced countries, farmers could produce their own seeds of most crops as they did in the past. Farmers sell into competitive markets; seed companies sell to farmers, also a competitive market (151). Analyses of the welfare effects of transgenic seeds can give estimates of the gainers and losers under reasonable assumptions (152), and such analysis shows that the gains are shared among consumers, farmers, and seed companies. Where intellectual property is strongly protected, analysis shows that increased profits to "the R&D firms comes at the expense of the rest of society; and that total welfare can sometimes be increased by reducing the level of intellectual property protection" (151).

Hybrid corn seed, the major business of private seed companies, carries natural built-in protection from duplication, and until about 1985, most new crop varieties, other than hybrid corn, were produced by plant breeders working for land grant universities, international agricultural research centers, or other public institutions (153). As a result of the dynamic interaction of patents on plants, changing technology, and market forces, private investment in plant breeding and seed production boomed. In 1994, private companies supported two thirds of the crop breeding in the United States (154) and a growing proportion throughout the world (155). Plant variety protection, as endorsed by UPOV, gives less robust protection than patenting (148), and between 1998 and 2002, over 50,000 applications for plant breeders rights were filed worldwide, 80% in industrialized countries (111).

Comparisons of the markets for hybrid corn, soybean, and cotton seed, where genetic engineering is important and which have become increasingly concentrated, with the market for wheat seeds, where genetic engineering is not used and seeds come largely from the public sector, showed that genetically engineered cotton and corn seed "resulted in a cost-reducing effect that prevailed over the effect of enhanced market power" (24, 156). Hence, although there is public

apprehension over the economic power of the big seed companies, the available evidence suggests that the technology benefits not only the companies but farmers and consumers.

THE POTENTIAL CONTRIBUTION IN DEVELOPING COUNTRIES

Biotechnology can only contribute to developing country food security if it is used in the countries, so the “big question” is whether biotechnology will be good for food security and whether a country ought to embrace it—essentially an ethical question. Most countries have limited ability to address the scientific aspects of the question themselves, and considerable efforts are being made to influence the answers countries give to the question, not generally with the most balanced information. Although there are millions of hectares planted to transgenic crops in the developing world, they are concentrated in only a few countries; the rest continue to struggle with the big question.

The Ethical Question

Over the past decade there have been a number of high-visibility efforts to address the “big question” of whether agricultural biotechnology will be good or not for developing countries. Many of these feature impressive information about the likely positive and negative impacts of the technology (102, 140, 141, 157, 158); others hold that the real cause of world hunger is not lack of food but lack of income and that biotechnology does not increase yields, could lower nutrition, and may threaten food security because of corporate control over seeds (38, 159). Opposition to agricultural biotechnology, especially to transgenic crops, has become a topic of serious research among applied ethicists (160–162), some of whom examine intrinsic concerns like moving genes across species, becoming what one eats, or “playing God” (163–165), whereas others examine more mainstream issues, for example, distrust of multinational seed companies (166, 167).

Unfortunately, there is no single ethical analysis that will answer the “big question.” All who articulate a rational argument about the desirability of biotechnology, whether biologists, economists, environmentalists, or religious groups, are making ethical cases. Ethics “is an inquiry that proceeds through the rational and critical examination of the reasons, arguments, and theories that can be given to show that one type of behavior is morally right or that another is morally wrong” (168). Therefore, an ethical position is one that is systematically based on consistently articulated reasons to give guidance about the desirability of an activity and to facilitate choice (169).

Economic benefits and costs are one widely used basis for choice, and environmental costs and benefits are another; the two generally give different results. However, both reflect utilitarian ethics that give primacy to the expected result of an action or situation. In contrast, choices driven by the desire to “do the right

thing” are varieties of deontological ethics that give primacy to the motive for an action (170). Utilitarians base their judgments on what happens (or is expected to happen) as a result of an action, and deontologists, who hold to a view most notably expounded by Immanuel Kant, base their judgments on why an action is taken (170). Thus, the utilitarian (economic and scientific) view that seeks to compare increased positives and negatives attributed to the technology simply misses the primary criterion of deontological ethics, which is intent.

This reviewer’s conclusion is that the gulf between scientists and economists who fervently believe that the benefits of increased food production, farmer profit, or reduced pesticide from transgenic crops far outweigh any possible associated drawbacks and those who are categorically opposed to producing food from transgenic organisms is a reflection of the differences in the ethical systems of the two groups, regardless of the basis for the views held. For opponents, “many of the negative aspects of agricultural biotechnology are generated at the level of the underlying conceptual frameworks that shape the technology’s internal modes of organization, rather than the unintended effects” (160). Science, being self-limited to repeatable, measurable observations, is by its nature unable to bring the necessary viewpoints about nonmeasurable phenomena to bear. The possible harmful effect of biotechnology “to the environment or to agriculture is a matter of definition, necessarily tied to basic assumptions and value judgments regarding the nature of nature, the nature of society and man, and of the common good.” Therefore, adding criteria such as human welfare, justice, and people’s rights to yield, profit, and pesticide use, thereby expanding the utilitarian argument beyond what is possible with strict scientific measurement, however laudable for utilitarians, is unlikely to satisfy deontologists. Moreover, it burdens science with a task for which it is poorly equipped.

Who Decides?

While academics can debate, governments have to make decisions about a range of related issues: whether to allow imports of food from transgenics, whether to require labeling, how to regulate, and whether to support research on transgenics. Given the controversy, the polarized positions of North America and Europe and the possible contributions to food security, developing countries have responded in a number of different ways (171). Especially in Africa, the issues are “subject to furious scientific debate and intense public controversy” and so “formal consensus-building platforms of the kind that have been effective in other parts of the world” might be helpful (172). Although such efforts can provide the opportunity for exchange of information and opinions, in the end governments are responsible for their own decisions, and many, but not all, have been cautious about importation and commercialization of transgenic seeds.

Transgenics Now in Use

In 2005, some 7.7 million poor developing country farmers grew transgenic crops on 34 million hectares (13). Argentina had 17 million hectares of transgenic

soybeans, maize, and cotton; Brazil, about 9.4 million hectares of transgenic soybeans; China, about 3.3 million hectares of transgenic cotton; India, about 1.3 million hectares of transgenic cotton; and South Africa, about 500,000 hectares of transgenic maize, cotton, and soybeans.

Dominated by soybeans for export and cotton, benefits from these transgenic varieties come to farmers not from food consumed but from increased income. A global analysis based on adoption and yield effects of all transgenic crops grown between 1996 and 2004 (75) suggests, taking into account the number of farmers in each country, that these benefits amounted to annual income increases of about \$10 per farmer in Argentina, about \$6 per farmer in the United States, about \$0.11 per farmer in Brazil, less than \$.02 per farmer in China, and less than \$0.001 per farmer in India. The magnitude of benefits from transgenics and their direct contribution to food security will change if the transgenic rice now being tested on a broad scale on farmers' fields in China is approved, as some anticipate (173).

The food-insecure countries of Africa have little capacity to use biotechnology, even the tools of genomics that have the potential to lead to advances without genetic engineering. The international agricultural research centers that developed many of the crop varieties now in use also have limited capability for genetic engineering and genomics. In part, this lack of capacity arises because the suite of skills needed to develop new varieties using transgenics is so much broader than previously—not just plant breeding and seed production but negotiating intellectual property rights, preparing biosafety and food safety dossiers, and persuading ministers and nongovernmental organizations of the value of new technology. At the same time, using nontransgenic genomics-assisted plant breeding requires new skills that few African plant breeders have. Much tighter intellectual property rights are part of the challenge, resulting from an enclosing of the previous commonly held global germ plasm (174), and the new international regime for germ plasm development entails all the features discussed above and makes the challenge of variety development much greater than it was in 1970 (175).

Prospects for Biotechnology

Despite the commercialization of tissue-culture-derived rice varieties as early as 1997 (6, 176), biotechnology is making barely any difference in developing countries. What will it take to make a significant contribution? First, appropriate varieties are needed, varieties adapted to the target agroecologies that increase production and income so farmers adopt them. Varieties must conform to all applicable food, biosafety, and intellectual property regulations. Seeds of the varieties must be multiplied and sold at attractive prices. Farmers must have well-functioning markets into which they can sell additional production, and the innovation should not harm nonfarmers in those societies. But investments in these activities are small.

Although multinational companies sell transgenic seeds in developing countries, they are making little effort to produce seeds specifically for those countries.

Monsanto's Bt technology played important roles in transgenic cotton in both India (177, 178) and China (93) and in transgenic soybeans grown in Brazil and Argentina, even if unofficially at first (179). But these technologies were essentially by-products of innovations aimed at the United States. Biotechnology research directed at developing countries, which support more than 95% of the world's farmers on over 65% of the world's farmland (157), represents no more than 10% of the world's biotechnology research effort (26).

Only 14% of all transgenic crop field trials were conducted in developing countries (157). There were no trials on cassava, millet, sweet potato, sorghum, lentils, beans, and other food crops important in the developing world, and trials on wheat and rice, the most important food crops in the developing world, comprised less than 4% of field trails. There are many constraining factors (180). Researchers from 16 developing countries report having transformed 46 different crops "for a wide array of locally important traits" (181), so the limited number of field trials would seem to be at least partly a result of regulatory constraints. Intellectual property issues have been manageable for these researchers, but moving these events into field testing has been limited by the high costs of meeting biosafety requirements.

In contrast to what happened in North America, even if regulatory and intellectual property issues are resolved, it is unlikely that the private sector will drive biotechnology innovations in sub-Saharan Africa (182). Currently private-sector research comprises no more than 5% of the total (183); total foreign direct investment is inversely correlated with the strength of intellectual property protection systems (113, 184). There simply is little incentive for private seed companies to invest more: Most farmers grow seed saved from earlier plantings, intellectual property protection is weak, markets for seeds are small, and the countries are inherently high-cost places with limited profit potential for multinationals (36).

Although there may be little private profit potential, the importance of "orphan crops" in the consumption patterns and income of farmers determines the potential payoff to such investment. Analysis to permit public-sector decisions about such investments requires a comprehensive model and extensive data about each candidate as illustrated for banana biotechnology choices in Uganda (185). Global decision making will have to rely on projecting likely effects, so-called *ex ante* impact analysis (67).

Several publicly supported institutions, designed to assist developing countries overcome some of the challenges associated with accessing agricultural biotechnology, have been created. The CAMBIA (center for the application of molecular biology to international agriculture) is an Australian nonprofit organization working to assist developing country scientists to access new technologies, information, and technical training. CAMBIA hosts one of the world's largest and most comprehensive searchable patent databases, including the full text of all Patent Cooperation Treaty, European, and U.S. patents relevant to biotechnology, and provides a no-cost patent search service through the Internet (<http://www.cambiaip.org/Home/welcome.htm>). PIPRA (Public Intellectual Property Resource for Agriculture) is

designed to make agricultural technologies for subsistence crops more easily available to Africans by facilitating access to technologies created by U.S. universities (<http://www.pipra.org>). The African Agricultural Technology Foundation is designed to facilitate partnerships of public- and private-sector entities to remove barriers that have prevented smallholder farmers in sub-Saharan Africa from gaining access to existing agricultural technologies (<http://www.aatf-africa.org>). Special educational opportunities for African scientists also exist (186). Whether such efforts will be effective in bringing benefits to developing countries remains to be demonstrated.

CONCLUDING OBSERVATIONS

Over a mere 25 years, biotechnology went from a scientific curiosity to one of the most divisive issues in society. The discovery of DNA generated a continuing stream of related discoveries for describing and locating nucleotide sequences and irregularities as well as the genes they comprise. In the early 1980s, a few scientist-entrepreneurs saw a potential for applications to crop variety development and started their own biotechnology companies to exploit that potential. Financiers promoted biotechnology as a radically new technology and hyped it to investors as a road to easy wealth. Questions of intellectual property were resolved at the highest level in the United States. Large corporations came to believe that agricultural biotechnology offered potential for dramatic business growth and began acquiring biotechnology start-ups and seed companies. Some observers raised ethical issues about the transfer of genetic material across species, and social justice advocates became concerned about the concentration of seed production in the hands of a few companies; substantial opposition arose to genetically engineered crops as food sources. Corporations, scientists, and advocates favoring transgenics fought back with their own public campaigns.

International agreements proliferated, responding to calls for biodiversity preservation, biosafety, intellectual property protection, and international trade. Advocates on all sides inserted their views into treaties and other international agreements, effectively requiring a whole new level of certification for internationally traded food. Many poorer countries struggled to find people to participate in the international negotiations or relied on advice from others. In about 1996, genetically engineered crops began to be planted widely in the United States, Canada, Argentina, and China; Europe continues to resist. Developing countries are subject to pressures from the United States to adopt its permissive stance, and from the European Union to adopt its precautionary stance. Government agencies assure the public that transgenics are benign, but questions continue. As of 2006, the gap between advocates and critics remains, with each side pursuing vigorous public information campaigns. It may be, as one observer put it, that there is no certainty that our social institutions will be able “to adapt, adopt and use the technology in a way that will satisfy society and improve social welfare” (187).

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