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Agricultural Biotechnology—An Opportunity to Feed a World of Ten Billion

Nina V. Fedoroff* & Drew L. Kershen**

Abstract

The latest United Nations population projections predict that the human population will expand from roughly 7.5 billion to between 8.3 and 10.9 billion by mid-century. This presents an acute need to increase agricultural productivity quickly and to do so without unduly damaging the many other kinds of organisms that share our planet. The advances of genetic engineering and genetic modification hold the promise of making it possible for us to grow more food on the same amount of land using less water, energy, and chemicals: critically important objectives if we are to live sustainably within planetary constraints. At the same time, these advances have evoked an almost unprecedented level of societal controversy quite specifically in the realm of food production, resulting in the proliferation of regulatory and legal issues that threaten to block their use in achieving a more sustainable existence for humanity on planet Earth. If modern science is to contribute to the agricultural productivity increases required in coming decades as the climate warms and the human population continues to grow, it is imperative to get beyond the cultural and political biases against molecular crop modification, acknowledge the safety record of GM crops, and ease the regulatory barriers to their development and deployment.

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I. INTRODUCTION

Today, we have enough food to meet the needs of the world's population. The food price spike of 2008 and the persistence of high food prices since 2011 have had little effect on the affluent citizens of the developed world who spend a small fraction of their income on food. However, food prices had, and continue to have, a profound effect on the world's poorest people, who must often spend more than half of their income on food. In 2008, there were food riots in more than 30 countries and today's continuing unrest in the Middle East is driven, in part, by the high price of food. Hunger is the result of poverty, the lack of economic access to food. Spiraling food prices drive the world's poorest into chronic hunger. Ending world hunger necessitates reducing poverty by investing in people: education, health care, and economic development.

But does today's sufficient food mean we need not worry about the global food supply? The latest United Nations population projections predict that the human population will expand from roughly 7.5 billion to between 8.3 and 10.9 billion by mid-century.[1] Yet we are already approaching—even exceeding—the planet's ability to provide food, feed, and, increasingly, biofuel using today's agriculture. Moreover, the rapid expansion of agriculture to feed today's population has had a devastating impact on biodiversity and is undermining our ability to sustain current levels of food production. Thus, there is an acute need to increase agricultural productivity quickly and to do so with less deleterious impact on the many other kinds of organisms that share our planet.

All of human civilization is built on our ability to genetically modify organisms, including plants, animals, and microorganisms, to better suit our food needs. Oddly, it is only our contemporary methods of bending organisms' genetic constitution to suit these needs that are today recognized as genetic modification, known in common parlance by

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[1] U.N. DEP'T OF ECON. & SOC. AFFAIRS, POPULATION DIV., NO. ESA/P/WP.228, WORLD POPULATION PROSPECTS: THE 2012 REVISION, HIGHLIGHTS AND ADVANCE TABLES 2, (2013), *available at* http://esa.un.org/unpd/wpp/Documentation/pdf/WPP2012_HIGHLIGHTS.pdf.

the abbreviations "GM" (genetically modified), "GMO" (genetically modified organism) or "GE" (genetically engineered). The growth of genetic knowledge during the early 20th century enabled the introduction of chemical and radiation mutagenesis into breeding practice, markedly expanding the natural genetic variation hitherto available for the modification of agricultural organisms. The molecular genetic revolution of the late 20th century powered the development of genetic modification methods capable of adding and modifying genes with precision and specificity. These advances hold the promise of making it possible for us to grow more food on the same amount of land using less water, energy, and chemicals: critically important objectives if we are to live sustainably within planetary constraints. Paradoxically, these advances have evoked an almost unprecedented level of societal controversy quite specifically in the realm of food production, resulting in the proliferation of regulatory and legal issues that threaten to block their use in achieving a more sustainable existence for humanity on planet Earth.

II. MORE WITH LESS—HOW DID WE GET HERE?

Why do we need to do more with less? We will need more food, feed, and fiber because there will be more people in the coming decades and they will be richer. Among the things that people demand as they become more affluent is more meat in their diet. Because much of our grain goes to feed animals, more meat requires more grain. But increasing the supply by expanding the land under cultivation cannot be sustained. All the best land is already under cultivation and preserving what remains of our planet's rich biological heritage by leaving the remainder unplowed is a growing priority. As well, the negative impact of climate change on agriculture is increasingly apparent and is predicted to worsen.[2] While more agriculturally suitable land may become available at greater distances from the equator as the climate warms, there is no guarantee that the productivity of these lands will compensate for productivity losses in the more populous equatorial regions.

In today's highly productive developed-world agriculture, fertilizers and other chemicals are applied and used inefficiently, themselves becoming pollutants in our air, land, and water. As well, some of the chemicals used in both conventional and organic agriculture to control pests and diseases are toxic to people and to wildlife. Transitioning to more sustainable agricultural practices while doubling the food and feed

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[2] *See* John R. Porter et al., *Food Security and Food Production Systems*, *in* CLIMATE CHANGE 2014: IMPACTS, ADAPTATION, AND VULNERABILITY, at 21–24 (2014), *available at* http://ipcc-wg2.gov/AR5/images/uploads/WGIIAR5-Chap7_FGDall.pdf.

supply, even as we must increasingly cope with the negative effects on agricultural productivity of a warming climate, is among the greatest challenges of the 21st century.[3]

Concern about access to sufficient food, today called "food security," is as old as mankind. Thomas Malthus' famous Essay on Population, published in 1798, crystallized the problem of balancing food and human population for the modern era.[4] Malthus pessimistically believed that humanity was doomed to food insecurity because our numbers increased exponentially, while our ability to produce food could only increase linearly.

Curiously, Malthus penned his essay at about the time that science began to play a major role in boosting agricultural productivity. Late 18th century milestones were Joseph Priestley's discovery that plants emit oxygen[5] and Nicholas-Théodore de Saussure's definition of the chemical composition of plants.[6] Malthus could not have envisioned the extraordinary increases in productivity that the integration of science and technology into agricultural practice would stimulate over the ensuing two centuries.

Both organic and mineral fertilization of plants has been practiced since ancient times. Farmers knew that certain chemicals and biological materials, ranging from fish and oyster shells to manure and bones, stimulated plant growth.[7] Although it was known by mid-century that biological sources of nitrogen could be replaced by chemical sources, supplying nitrogen in the forms that plants use remained a major limitation until the development of the Haber-Bosch process for fixing atmospheric nitrogen early in the 20th century.[8] Today, agriculture in the developed world relies primarily on chemical fertilizers.

A. Crop Domestication

Humans practiced genetic modification long before chemistry entered agriculture, transforming inedible wild plants into crop plants. Although, today, the term "GM" is used to refer only to plants modified

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[3] Drew L. Kershen, *The Contested Vision for Agriculture's Future: Sustainable Intensive Agriculture and Agroecology*, 46 CREIGHTON L. REV. 591, 593–94 (2013).

[4] THOMAS R. MALTHUS, AN ESSAY ON THE PRINCIPLE OF POPULATION (London, J. Johnson 1798).

[5] JOSEPH PRIESTLEY, EXPERIMENTS AND OBSERVATIONS ON DIFFERENT KINDS OF AIRS (London, W. Bower & J. Nichols 1774).

[6] NICHOLAS-THEODORE DE SAUSSURE, RECHERCHES CHIMIQUES SUR LA VEGETATION (Paris, Nyon 1804).

[7] FIRMAN E. BEAR, THEORY AND PRACTICE IN THE USE OF FERTILIZERS (2d ed. 1938).

[8] Darrell A. Russel & Gerald G. Williams, *History of Chemical Fertilizer Development*, 41 SOIL SCI. SOC'Y AM. J. 260, 260–65 (1977).

using modern molecular techniques (some of which are known as "recombinant DNA" techniques), people have profoundly changed wild plants to make them suitable as crop plants over many thousands of years. All of the useful, heritable traits nurtured by people constitute "crop domestication" and all are the result of genetic modifications. Each crop has its own interesting history, but one of the most fundamental traits distinguishing wild from domesticated plants is the retention of mature seeds on the plant. Plants have many mechanisms for dispersing their seeds, but it is much easier for people to harvest seeds that remain attached to the plant. Hence, one of the earliest steps in crop domestication was the identification of mutations (genetic changes) that prevent seed dispersal.[9]

Corn, also known as maize, remains one of our most spectacular feats of genetic modification. Its huge ears, packed with starch and oil, provide one of humanity's most important sources of food and feed. Corn bears little resemblance to its closest wild relative, teosinte. Indeed, when teosinte was first discovered in 1896, it was assigned to a different species. By the 1920s, it was known that teosinte and corn readily produce fertile hybrids, but controversies about their relationship and about the origin of corn continued throughout most of the 20th century.

The key genetic changes that transformed teosinte into corn appear to have happened in the Balsas River Valley in Mexico some 9000 years ago.[10] The genetic mutations that converted teosinte, a grass with hard, inedible seeds, into modern corn altered just a handful of genes that control plant architecture and the identity of reproductive organs. Remarkably, once these mutations had been brought together in an early corn plant, they stayed together and spread very rapidly, moving from Mexico into the American Southwest by 3000 years ago.[11]

Among the many other traits altered during domestication of plants are the size and shape of leaves, tubers, berries, fruits, and grains, as well as their abundance, toxicity, and nutritional value. The changes are often in genes coding for proteins that regulate the expression of many other genes.[12] Differences in nutrient composition among varieties of the same crop are caused by mutations in genes coding for proteins in certain

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[9] NINA W. FEDOROFF & NANCY M. BROWN, MENDEL IN THE KITCHEN: A SCIENTIST'S VIEW OF GENETICALLY MODIFIED FOODS (2004).

[10] Viviane Jaenicke-Després et al., *Early Allelic Selection in Maize as Revealed by Ancient DNA*, 302 SCIENCE 1206, 1206–08 (2003).

[11] Nina V. Fedoroff, *Prehistoric GM Corn*, 302 SCIENCE 1158, 1158–59 (2003).

[12] John F. Doebley et al., *The Molecular Genetics of Crop Domestication*, 127 CELL 1309, 1313–15 (2006).

biosynthetic pathways. Thus, for example, sweet corn has mutations that prevent the conversion of sugar to starch.

B. Modern Crop Improvement

Two revolutions of the 20th century, one genetic and one molecular, both benefitted crops. Austrian monk Gregor Mendel's pioneering observations on inheritance were published in 1865, but did not get wide attention until a half-century later.[13] A simple demonstration project to illustrate Mendelian inheritance led to the discovery of hybrid vigor, a phenomenon whose incorporation into crop breeding resulted in a dramatic expansion of the corn ear and, thereby, crop yield.[14]

However, when corn hybrids were first introduced in the United States during the 1930s, they faced resistance and criticism similar to that leveled at contemporary GM crops. The hybrids were complex to produce and agriculture experiment stations were not interested. Eventually a company was formed to produce hybrid seed. But farmers accustomed to planting seed from last year's crop saw no reason to buy it. It was only when farmers realized the yield benefits and the drought-resistance of hybrid corn during the 1934-1936 dust-bowl years that farmers began rapidly to adopt hybrid corn.[15]

Techniques for accelerating mutation rates with radiation and chemicals and through tissue culture were developed and widely applied in the genetic improvement of crops during the 20th century.[16] Such techniques introduce mutations rather indiscriminately and require the growth of large numbers of seeds, cuttings, or regenerants to detect desirable changes. Nonetheless, all of these approaches have proved valuable in crop improvement and by the end of the 20th century, more than 2300 different crop varieties, ranging from wheat to grapefruit, had been developed using radiation and chemical mutagenesis.[17]

C. Mechanization of Agriculture

A major development with impact Malthus could not have envisioned is the mechanization of agriculture. Human and animal labor provided the motive force for agriculture throughout most of its history

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[13] *See* ELOF A. CARLSON, THE GENE: A CRITICAL HISTORY (1966).

[14] James F. Crow, *90 Years Ago: The Beginning of Hybrid Maize*, 148 GENETICS 923, 923-27 (1998).

[15] A. RICHARD CRABB, THE HYBRID-CORN MAKERS: PROPHETS OF PLENTY (1947).

[16] *See generally* M. Maluszynski et al., *Application of* In Vivo *and* In Vitro *Mutation Techniques for Crop Improvement*, 85 EUPHYTICA 303 (1995).

[17] INST. MED. & NAT'L RESEARCH COUNCIL NAT'L ACADS., SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS (2004), *available at* http://www.nap.edu/openbook.php?record_id=10977.

and continues to do so in many less-developed countries. The invention of the internal combustion engine at the turn of the 20th century led to the development of small, maneuverable tractors. The mechanization of plowing, seed planting, cultivation, fertilizer and pesticide distribution, and harvesting accelerated in the United States, Europe, and Asia following World War II.[18] Agricultural mechanization drove major demographic changes virtually everywhere. In the United States, 22 percent of the workforce was employed in agriculture in 1900.[19] By 1945, the figure had declined to 16 percent and by the end of the century the portion of the population employed in agriculture had fallen to 1.9 percent. At the same time, the average size of farms increased and farms increasingly specialized in fewer crops.[20]

D. *The Green Revolution*

Malthus penned his essay when the human population of the world stood at less than a billion. The population tripled over the next century and a half. As the second half of the 20th century began, there were neo-Malthusian predictions of mass famines in developing countries that had not yet experienced science- and technology-based advances in agriculture. Perhaps the best known of the mid-century catastrophists was Paul Ehrlich, author of The Population Bomb.[21]

The extraordinary work of just a handful of scientists (and their teams), principally plant breeders Borlaug, Swaminathan, and Khush, averted predicted Asian famines.[22] The Green Revolution was based on the development of dwarf rice and wheat varieties that responded to fertilizer application without falling over, called "lodging." Subsequent breeding for increased yield continued to improve the productivity of these crops by as much as one percent per year. Perhaps most remarkably, the Green Revolution and other technological advances reduced the fraction of the world's hungry from half to less than a sixth, even as the population doubled from three to six billion.

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[18] Hans Binswanger, *Agricultural Mechanization: A Comparative Historical Perspective*, 1 WORLD BANK RES. OBSERVER 27, 27-56 (1986).

[19] CAROLYN DIMITRI ET AL., ECON. RESEARCH SERV., U.S. DEP'T AGRIC., EIB NO. 3, THE 20TH CENTURY TRANSFORMATION OF U.S. AGRICULTURE AND FARM Policy 2 (2005).

[20] *Id.*

[21] PAUL R. EHRLICH, THE POPULATION BOMB (1968).

[22] *See, e.g.*, Gurdev S. Khush, *Green Revolution: The Way Forward*, 2 NATURE REVS. GENET. 815 (2001).

E. *Genetic Modification of Crops*

The molecular genetic revolution that began in the 1960s led to the development of new methods of crop improvement. The basic methodology lies in the construction of tiny hybrid chromosomes, called "recombinant DNA (R-DNA)" because they consist of a piece of bacterial or viral DNA combined with a piece of DNA from a different kind of organism, plant or animal. The ability to amplify such artificial chromosomes in turn made it possible to develop the DNA sequencing techniques that underlie today's genomic revolution.

As well, techniques were developed to introduce genes into plants using either the soil bacterium *Agrobacterium tumefaciens*, which naturally transfers a segment of DNA into a plant cell, or mechanical penetration of plant cells using tiny DNA-coated particles.[23] This combination of methods and knowledge made it possible to transfer a well-understood segment of genetic material from either the same or a related plant or from a completely unrelated organism into virtually any crop plant, creating what is known as a "transgenic" plant. Because genes work the same way in all organisms, it therefore became possible to introduce a desirable trait, such as disease- or pest-resistance, without the extensive genetic disturbance attending what we now consider to be the "conventional" crop improvement techniques of breeding and mutagenesis.

Several crop modifications achieved using these methods are now in widespread use. Perhaps the best known of these are crop plants containing a gene from the soil bacterium, *Bacillus thuringiensis*, long used as a biological pesticide because it produces a protein that is toxic to the larvae of certain kinds of insects, but not to animals or humans.[24] The toxin gene is often called the "Bt gene," but is actually a family of related toxin genes from a group of closely related bacteria.

Herbicide tolerance is another widely accepted crop modification.[25] Among the most common herbicides in use today is a class of compounds that interfere with the production of certain amino acids that

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[23] *See generally* Robert G. Birch, *Plant Transformation: Problems and Strategies for Practical Application*, 48 ANNU. REV. PLANT PHYSIOL. PLANT MOL. BIOL. 297 (1997).

[24] John F. Witkowski, *Corn Production*, UNIV. OF MINN. EXTENSION, http://www.extension.umn.edu/distribution/cropsystems/DC7055.html (last visited May 7, 2014).

[25] Jed Colquhoun, *How Herbicides Work in Terms that We Can All Understand*, CRANBERRY SCHOOL PROCEEDINGS (2009), http://fruit.wisc.edu/wp-content/uploads/2011/05/How-Herbicides-Work-in-Terms-That-We-can-All-Understand.pdf.

plants synthesize, but animals do not.[26] Such herbicides therefore kill plants, but do not affect animals or people. Herbicide-tolerant crops make it possible to control weeds without damaging the crop and without tilling the soil. Such crops have been derived through natural mutations, induced mutations, as well as by introduction of genes from either bacterial sources or plant sources. Today, herbicide-tolerant varieties of many crops, most importantly soybeans and canola, are widely grown.

Papaya varieties resistant to papaya ringspot virus (PRSV) are a public-sector GM achievement that saved the Hawaiian papaya industry.[27] PRSV is a devastating insect-borne viral disease that wiped out the papaya industry on Oahu in the 1950s, forcing its relocation to the Puna district of the big island. PRSV was first detected in the Puna district in 1992; by 1995, it was widespread and threatening the industry. A project initiated in 1985 introduced a gene from the PRSV into papayas based on reports that introducing a viral gene could make a plant resistant to the virus from which the gene came.[28] Transgenic seeds were released in 1998; by 2000, the papaya industry was returning to pre-1995 levels. This remarkable achievement of disease resistance enhanced a virus protection mechanism already present in the plant, much as vaccination protects people and animals from infection by pathogens.[29]

New methods are rapidly being developed that promise to further increase the specificity and precision of genetic modification. These techniques capitalize on growing knowledge of the dynamic processes underlying genome maintenance, particularly the repair of breaks in the genetic material, DNA. Known under the general rubric of "site-directed nuclease (SDN)" technology, this approach uses proteins (or protein-nucleic acid complexes) that seek out, bind to, and cut specific DNA sequences, introducing breaks in the DNA at one or a small set of sequences targeted for modification.[30] Repair of such DNA cuts by natural cellular processes results in precisely targeted genetic changes rather than the random ones introduced by older methods of mutagenesis. This method can also be used to introduce a gene at a pre-identified site

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[26] Siyuan Tan et al., *Herbicidal Inhibitors of Amino Acid Biosynthesis and Herbicide-Tolerant Crops*, 30 AMINO ACIDS 195, 195–204 (2006).

[27] Dennis Gonsalves et al., *Transgenic Virus Resistant Papaya: From Hope to Reality for Controlling Papaya Rinspot Virus in Hawaii*, APSNET FEATURES (July 2004), http://www.apsnet.org/publications/apsnetfeatures/Pages/papayaringspot.aspx.

[28] Patricia Powell Abel et al., *Delay of Disease Development in Transgenic Plants that Express the Tobacco Mosaic Virus Coat Protein Gene*, 232 SCIENCE 738, 738–43 (1986).

[29] Paula Tennant et al., *Papaya Ringspot Virus Resistance of Transgenic Rainbow and SunUp is Affected by Gene Dosage, Plant Development, and Coat Protein Homology*, 107 EURO. J. PLANT PATHOLOGY 645, 645–53 (2001).

[30] Nancy Podevin et al., *Site-Directed Nucleases: A Paradigm Shift in Predictable, Knowledge-Based Plant Breeding*, 31 TRENDS BIOTECH 275, 375–83 (2013).

in the genome or to modify a resident gene precisely, something that could not be done with pinpoint specificity and precision by R-DNA methods. As well, such genetic changes can often be made without creating a transgenic plant. The changes are the same at the molecular level as those that occur in nature or can be induced by older mutagenic techniques. What is new is that the genetic changes introduced by SDN techniques are not random, but confined precisely to the gene or genes selected by the plant breeder.

III. ADOPTION OF GM CROPS

Although the use of molecular modification techniques in crop improvement engendered controversy from the beginning, GM crops have experienced unprecedented adoption rates since their commercial introduction in 1996. In 2013, GM crops were grown in 27 countries on 175.2 million hectares. More importantly, more than 90 percent of the 18 million farmers growing biotech crops today are smallholder, resource poor farmers. The simple reasons that farmers migrate to GM crops are that their yields increase and their costs decrease.[31] The vast majority of GM hectarage is devoted to the growing of GM corn, soybeans, cotton, and canola with either Bt toxin-based pest resistance or herbicide tolerance traits. The reasons for the narrow GM crop and trait base to date lie in a combination of the economic, regulatory, and legal issues discussed below; here we address GM crop efficacy and safety concerns.

While some resistance to the Bt toxin has developed, it has not been as rapid as initially feared and second-generation, two-Bt gene strategies to decrease the probability of resistance are already being implemented.[32] Predicted deleterious effects on non-target organisms, such as monarch butterflies and soil microorganisms, have either not been detected at all or are insignificant.[33] The development of herbicide tolerance in previously susceptible weeds, while not unique to GM crops, is becoming an increasing problem because of the widespread use of glyphosate with glyphosate-tolerant GM crops.[34] Unfortunately, the pace of herbicide discovery has slowed markedly since the 1980s and the

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[31] CLIVE JAMES, ISAAA BRIEF NO. 46, GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2013 (2013), *available at* http://www.isaaa.org/resources/publications/briefs/46/default.asp.

[32] *See* Peggy G. Lemaux, *Genetically Engineered Plants and Foods: A Scientist's Analysis of the Issues (Part II)*, 60 ANN. REV. PLANT BIOLOGY. 511, 515–16 (2009).

[33] Mark K. Sears et al., *Impact of Bt Corn Pollen on Monarch Butterfly Populations: A Risk Assessment*, 98 PROC. NAT'L ACAD. SCI. U.S. 11937, 11942 (2001).

[34] Jerry M. Green, *Current State of Herbicides in Herbicide-Resistant Crops*, 70 PEST MGMT. SCI. (forthcoming 2014), *available at* http://onlinelibrary.wiley.com/doi/10.1002/ps.3727/abstract.

development of new herbicide-tolerant traits is costly, exacerbating reliance on a single herbicide.

The overwhelming evidence is that GM foods are as safe, or safer, than non-GM foods.[35] The European Union alone has invested more than €300 million in GMO biosafety research. Quoting from its recent report:

> The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not *per se* more risky than e.g. conventional plant breeding technologies.[36]

Every credible scientific body that has examined the evidence has come to the same conclusion.[37]

Despite occasional one-of-a-kind, often sensationalized reports, the vast majority of feeding studies have identified no meaningful nutritional differences between GM and non-GM foods and feeds. Indeed, and perhaps unsurprisingly, comparative molecular analyses show that GM techniques have less impact on the genetic and molecular constitution of crop plants than conventional plant breeding techniques.[35] This is because conventional breeding mixes whole genomes comprising tens of thousands of genes that have previously existed in isolation, while GM methods generally add just a gene or two to an otherwise compatible genome. Thus, the probability of introducing unexpected genetic (or epigenetic) changes is much smaller by GM methods than by conventional breeding methods.

Crops modified by GM techniques are also less likely to have unexpected genetic effects than crops modified by the more conventional techniques of chemical and radiation mutagenesis methods simply because of the greater precision and predictability of molecular modification. Taken together with the closer scrutiny paid during product development to the potential for toxicity and allergenicity of novel proteins expressed by GM methods, GM crops are arguably the safest new crops ever introduced into the human and animal food chains.

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35. *See, e.g.*, Peggy G. Lemaux, *Genetically Engineered Plants and Foods: A Scientist's Analysis of the Issues (Part I)*, 59 ANN. REV. PLANT BIOLOGY 771 (2008); Agnès E. Ricroch, *Assessment of GE Food Safety Using '-omics' Techniques and Long-Term Animal Feeding Studies*, 30 NEW BIOTECH. 349 (2013).

36. EUROPEAN COMM'N, FOOD, AGRIC. & FISHERIES & BIOTECH., A DECADE OF EU-FUNDED GMO RESEARCH 16 (2010), *available at* http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf.

37. David Tribe, *600+ Published Safety Assessments (Version 2)*, GMOPUNDIT, http://gmopundit.blogspot.com/p/450-published-safety-assessments.html (last visited May 8, 2014).

Indeed, to date, the only unexpected effects of GM crops have been beneficial. Many grains and nuts, including corn, are commonly contaminated by mycotoxins, which are toxic and carcinogenic compounds made by fungi that follow boring insects into the plants. Bt corn, however, shows as much as a 90 percent reduction in mycotoxin levels because the fungi that follow the boring insects into the plants cannot get into the Bt plants.[38] There is also evidence that planting Bt crops reduces insect pressure in non-GM crops growing nearby. The widespread adoption of Bt corn in the U.S. midwest has resulted in an area-wide suppression of the European corn borer.[39]

IV. FUTURE CHALLENGES IN AGRICULTURE

Since Malthus' time, the human population has expanded more than six fold. Through science and technology, agriculture in developed nations has become far less labor-intensive and has kept pace with population growth worldwide. Today, fewer than 1 in 50 citizens of developed countries grow crops or raise animals for food. But after a half-century's progress in decreasing the fraction of humanity experiencing chronic hunger, the food price and financial crises commencing in 2008 have begun to swell the ranks of the hungry once more.[40] Population experts anticipate the addition of another two to four billion people to the planet's population within the next three to four decades,[41] but the amount of arable land has not changed appreciably in more than half a century.[42] Moreover, arable land continues to be lost to urbanization, salinization, and desertification.

Supplies of fresh water for agriculture are under pressure, as well. Today, about one-third of the global population lives in arid and semi-arid areas, which cover roughly 40 percent of the land area. Climate scientists predict that in coming decades, average temperatures will increase and dryland area will expand. Inhabitants of arid and semi-arid regions of all continents are extracting ground water faster than aquifers

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[38] Gary P. Munkvold, *Cultural and Genetic Approaches to Managing Mycotoxins in Maize*, ANN. REV. 41 PHYTOPATHOLOGY 99, 108–10 (2003).

[39] William D. Hutchison et al., *Areawide Suppression of European Corn Borer with Bt Maize Reaps Savings to Non-Bt Maize Growers*, 330 SCIENCE 222 (2010).

[40] Briefing Paper of Food & Agric. Org. of the U.N., Hunger on the Rise: Soaring Prices Add 75 Million People to Global Hunger Rolls 1 (Sept. 17, 2008).

[41] Joel E. Cohen, *Human Population: The Next Half Century*, 302 SCIENCE 1172, 1172 (2003),

[42] FARMLAND INVESTMENT REPORT, THE LAND COMMODITIES GLOBAL AGRICULTURE & FARMLAND INVESTMENT REPORT 2009 12 (2009), *available at* http://www.farmlandinvestmentreport.com/Farmland_Investment_Report.pdf.

can recharge and often from fossil aquifers that do not recharge.[43] Yet the major crops that now feed the world—corn, wheat, rice, soy—require a substantial amount of water. It takes 500 to 4000 liters of water to produce a kilogram of wheat[44] and the amount of water required to produce a kilogram of animal protein is 2 to 10 times greater.

Increasing average temperatures and decreasing fresh water availability in coming decades present critical challenges to agricultural researchers to increase crop performance under suboptimal conditions. Rapid advances in our knowledge of plant stress responses and improving molecular knowledge and tools for plant breeding have already resulted in the introduction of new drought-tolerant crop varieties, both GM and non-GM.[45] New varieties of drought-tolerant maize produced using modern breeding approaches that employ molecular markers, but do not generate transgenic plants, have been released in the North American market by Syngenta and DuPont Pioneer, while Monsanto and BASF have jointly developed MON87460 (aka Genuity DroughtGard Hybrids), a drought-tolerant maize variety expressing a cold-shock protein from the bacterium *Bacillus subtilis*, introducing it in the United States in 2013.[46]

However, it should be noted that suboptimal "stress" conditions necessarily move plants from their peak ability to use sunlight to convert carbon dioxide, water, and other simple compounds into the carbohydrates and proteins that feed people (and all other animals). Stress-tolerant varieties do not generally outperform less stress-tolerant varieties by much or at all under optimal conditions but simply survive better under suboptimal conditions, losing less of their yield potential.

Whether our current highly productive food and feed crops can be modified and adapted to be substantially more productive at the higher temperatures expected or at more northern latitudes with shorter growing seasons is not known yet. It is therefore imperative to increase research not just on the salt, drought, and temperature tolerance of existing crop plants but also to invest in research on plants that are not now used in

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[43] THE AGRICULTURAL GROUNDWATER REVOLUTION: COMPREHENSIVE ASSESSMENT OF WATER MANAGEMENT IN AGRICULTURE (Mark Giordano & Karen G. Vilholth eds., 2007).

[44] INT'L WATER MGMT. INST., WATER POLICY BRIEFING NO. 25, DOES FOOD TRADE SAVE WATER?: THE POTENTIAL ROLE OF FOOD TRADE IN WATER SCARCITY MITIGATION 3 (2007), *available at* http://www.iwmi.cgiar.org/Publications/Water_Policy_Briefs/PDF/WPB25.pdf.

[45] Gregory Graff et al., *The Research, Development, Commercialization, and Adoption of Drought and Stress-Tolerant Crops*, *in* CROP IMPROVEMENT UNDER ADVERSE CONDITIONS 1, 16–18 (Narendra Tuteja & Sarvajeet S. Gill eds., 2013).

[46] *Genuity DroughtGard Hybrids*, MONSANTO, http://www.monsanto.com/products/pages/droughtgard-hybrids.aspx (last visited May 8, 2014).

agriculture, but that are capable of growing at higher temperatures and using saline water for irrigation. Indeed, the array of molecular tools and knowledge available today make it possible to design a wholly new kind of agriculture for a more arid, hotter world.

V. IMPEDIMENTS TO THE DEVELOPMENT OF GM CROPS

Productivity gains based on earlier scientific advances can still increase food production in many countries, particularly in Africa. But such productivity gains appear to have peaked in most developed countries and recent productivity gains have been achieved largely through adoption of GM crops. Yet even though the knowledge and GM technology are available to address these challenges, there are political, cultural, and economic barriers to their widespread use in crop improvement. Although scientific communities worldwide acknowledge that GM crops are safe, the political systems of Japan and most European and African countries remain opposed to growing GM crops. Many countries lack GM regulatory systems or have regulations that prohibit growing and even, in some countries, importing GM food and feed.

Even in countries such as the United States that have a GM regulatory framework,[47] the process is complex, slow, and inordinately expensive. U.S. developers must often obtain the approval of three different agencies, the Environmental Protection Agency, the U.S. Department of Agriculture, and the Food and Drug Administration, to introduce a new GM crop into the food supply.[48] Complying with the regulatory requirements can cost as much at $35 million for just one modification of an existing crop.[49] The effort, time, and cost for regulatory approval have largely eliminated the participation of public sector researchers in using GM technology for crop improvement and commercialization.

In Europe, the regulatory framework is practically nonfunctional; only one GM crop is currently being grown and only two others have gained approval since 1990 when the EU first adopted a regulatory

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[47] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (announced June 26, 1986).

[48] Neil A. Belson, *U.S. Regulation of Agricultural Biotechnology: An Overview*, 3 AGBIOFORUM 268, 268 (2000), *available at* http://agbioforum.org/v3n4/v3n4a15-belson.pdf.

[49] *Fact Sheet: Getting a Biotech Crop to Market*, CROPLIFE INT'L 1 (Nov. 2011), http://www.croplifeasia.org/wp-content/uploads/2013/02/Fact-Sheet-Getting-a-Biotech-Crop-to-Market.pdf (based on a 2011 Phillips McDougall study titled, "The cost and time involved in the discovery, development and authorization of a new plant biotechnology derived trait").

system.[50] As a consequence, plant breeders and seed companies have abandoned European agriculture, putting it at risk of becoming "museum" agriculture.[51]

There are also regulatory obstacles at the international level. Countries do not give legal recognition to the approvals of other countries. As a result, GM crops must undergo repetitive regulatory approvals entailing additional human effort, time, and cost in each country. Moreover, countries do not act in a coordinated fashion, which means that trade and food aid between countries is disrupted as a GM crop grown under approval in one country awaits approval in another country.[52]

Developing countries have uniquely felt the impact of the regulatory antagonism to agricultural biotechnology. European influence has been especially corrosive on African governments, causing African leaders to be excessively precautionary or outright prohibitive about importing or growing GM crops.[53] With these imported antagonisms to agricultural biotechnology, Africa is at significant risk of failing to encourage and create the innovative agriculture essential to feeding its growing population.[54]

Furthermore, what developing countries need is not just more food but also more nutritious food. Agricultural biotechnology is being used to create biofortified crops that address micronutrient deficiencies, such as Vitamin A and iron. Golden Rice is the best example. Yet, despite the fact that Golden Rice is a public good from public breeders and is a viable source of the Vitamin A precursor beta-carotene,[55] Golden Rice remains unavailable to farmers because of regulatory and legal barriers.[56] Millions suffer and die while Golden Rice remains in test plots rather

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[50] Drew Kershen, *European Decisions About the "Whack-a-Mole" Game*, 5 GM CROPS & FOOD 1, 1 (2014).

[51] Press Release, Institut de France Académie des Sciences, Les Académies Demandent de Restaurer la Liberté de la Recherche sur les Plantes Génétiquement Modifies (Mar. 17, 2014), *available at* http://www.academie-sciences.fr/presse/communique/pgm_170314.pdf; AGRIC. BIOTECH. COUNCIL, GOING FOR GROWTH (2012), *available at* http://www.appg-agscience.org.uk/linkedfiles/Going%20for%20Growth%2026%2006%2012.pdf.

[52] Darren Abrahams, *Legal Considerations Related to the Authorisation, Import and Cultivation of GM Crops in the European Union: A Precedent for Other Regulated Industries?*, 13 BIO-SCI. L. REV. 155, 155 (2014).

[53] ROBERT PAARLBERG, STARVED FOR SCIENCE: HOW BIOTECHNOLOGY IS BEING KEPT OUT OF AFRICA 13 (2009).

[54] CALESTOUS JUMA, THE NEW HARVEST: AGRICULTURAL INNOVATION IN AFRICA (2011).

[55] *See generally* Guangwen Tang et al., *Golden Rice is an Effective Source of Vitamin A*, 89 AM. J. CLINICAL NUTRITION 1776, 1776-1783 (2009).

[56] Ingo Potrykus, *Regulation Must be Revolutionized*, 466 NATURE 561, 561 (2010).

than in farmers' fields.[57] Sadly, similar stories afflict other "golden crops" such as cassava and maize.

Regulatory barriers to the use of modern plant breeding involving biotechnology may become even broader in scope and, therefore, a significant disincentive to innovation in agricultural development. As noted earlier, newer, more precise techniques for altering plant genomes, such as SDN technology and synthetic biology, are rapidly being developed.[58] Nations are just now beginning to classify them and make decisions about whether and how to regulate them. Uncertainty about the legal status of these new techniques means that individual scientists, universities, public entities such as international agricultural research institutes, and private companies cannot accurately gauge the likely time, effort, and cost incurred during crop commercialization to comply with legal and regulatory requirements. At present, it is not known whether crops produced using these modern approaches will face the burdens and barriers currently faced by crops modified by R-DNA techniques.

What the innovation-discouraging regulatory and legal barriers to agricultural biotechnology evidence is the need for a re-examination of current attitudes towards GM crops. The UK Advisory Committee on Releases to the Environment ("ACRE") expressed a first glimmer of such a re-examination in the executive summary to a recent report:

> Our understanding of genomes does not support a process-based approach to regulation. The continuing adoption of this approach has led to, and will increasingly lead to, problems. This includes problems of consistency, i.e. regulating organisms produced by some techniques and not others irrespective of their capacity to cause environmental harm.[59]

The summary goes on to say: "Our conclusion, that the EU's regulatory approach is not fit for purpose for organisms generated by new technologies, also applies to transgenic organisms produced by 'traditional' GM technology. . . . [T]he potential for inconsistency is inherent because they may be phenotypically identical to organisms that are not regulated."[60]

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[57] ADRIAN DUBOCK, GOLDEN RICE HUMANITARIAN BD., GOLDEN RICE: A LONG-RUNNING STORY AT THE WATERSHED OF THE GM DEBATE 3, 7–10 (2013), *available at* http://www.www.goldenrice.org/PDFs/GR_A_long-running_story.pdf.

[58] *See* Elizabeth Pennisi, *The CRISPR Craze*, 341 SCIENCE 833, 833-836 (2013).

[59] U.K. ADVISORY COMM. ON RELEASES TO THE ENV'T, REPORT 2: WHY A MODERN UNDERSTANDING OF GENOMES DEMONSTRATES THE NEED FOR A NEW REGULATORY SYSTEM FOR GMOS 1 (2013), *available at* https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239852/genomes-and-gm-regulation.pdf.

[60] *Id.*

Paradoxically, ACRE's 2013 conclusions are virtually identical to those of a 1987 statement on the introduction of R-DNA organisms into the environment from the Council of the U.S. National Academy of Sciences: 1) "There is no evidence that unique hazards exist either in the use of R-DNA techniques or in the transfer of genes between unrelated organisms;" 2) "The risks associated with the introduction of R-DNA engineered organisms are the same in kind as those association with the introduction into the environment of unmodified organisms and organisms modified by other genetic techniques;" and 3) "Assessment of the risks of introducing R-DNA-engineered organisms into the environment should be based on the nature of the organism and the environment into which it will be introduced, not on the method by which it was modified."[61]

VI. CONCLUSION

If modern science is to contribute to the agricultural productivity increases required in coming decades as the climate warms and the human population continues to grow, it is imperative to get beyond the cultural and political biases against molecular crop modification, acknowledge the safety record of GM crops, and ease the regulatory barriers to their development and deployment.

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[61] ARTHUR KELMAN ET AL., COUNCIL OF THE NATURAL ACAD. OF SCIS., COMM. ON THE INTRO. OF GMOS INTO THE ENV'T, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES 22 (1987).

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