SOCIETAL BENEFITS OF AGRICULTURAL BIOTECHNOLOGY Global Status and Outlook

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Submission to the Subcommittee on Horticulture, Research, Biotechnology, and Foreign Agriculture Committee on Agriculture U.S. House of Representatives

July 9, 2014

EXECUTIVE SUMMARY¹

The rise of the US biotechnology industry is largely a result of reforms in intellectual property rights that allowed for the patenting of living forms. However, global regulatory hurdles have made it difficult for society to fully reap the benefits of biotechnology. Society's innovative and entrepreneurial potentialities will be hobbled if the regulatory process for new biotechnology products takes as long as the duration of patent protection, which is at most 20 years. It has taken as long for the United States to complete the approval process for transgenic salmon. Worldwide, even more onerous and discriminatory hurdles stand in the way of societal benefits of biotechnology. Biotechnology product pipelines are being choked by discriminatory regulations, labeling threats, and a rising tide of product disparagement and misinformation.

This submission argues that although many transgenic crops are still in their early states of adoption and even more are still being tested and developed, emerging trends show significant societal benefits through positive economic impact (especially by raising farm incomes), fostering food security, and promoting environment sustainability. The crops show the potential to increase agricultural production on existing arable land; reduce losses related to pests, disease, and drought; increase access to food through higher farm incomes; raise nutrition levels; and promote sustainable agriculture. The pipeline of crops with potential benefits include a wide range of applications such as enhanced photosynthesis, stress tolerance, aluminum tolerance, salinity tolerance, pest and disease resistance, nitrogen use efficiency, phosphate use efficiency, and nitrogen fixation. However, restrictive regulations are undermining the ability of society to reap these benefits.

The largest benefits of transgenic crops are economic and derive from increased income from higher yields and resistance to loss. The best example of this is in India, where transgenic cotton production per hectare is demonstrably higher than that of non-transgenic cotton. Indian smallholder farmers who planted *Bt* cotton earned 50% more from higher production due to reduced pest damage. With the extra income, farmers' food consumption levels increased. Likewise, farmers from countries as diverse as South Africa, the Philippines, and the United States who planted *Bt* maize saw significantly higher yields. In the United States, transgenic papaya helped save the industry in Hawaii, and it is predicted that agricultural biotechnology is the most promising option for combating the citrus greening that is severely impacting those industries in Florida, Texas, and California. Finally, crops are currently in the pipeline that address loss related to local pests and disease in developing countries. Examples include transgenic bananas that combat *Xanthomonas* wilt (Uganda, Kenya), pest-resistant eggplant (Bangladesh, India, Philippines), and pest-resistant cowpea (Nigeria).

Second, transgenic crops offer the ability to biofortify key crops, which is especially helpful in numerous countries where Vitamin A deficiency is a concern (e.g., Golden Bananas in Uganda and Golden Rice in the Philippines). Furthermore, other developing countries are seeking to

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^{1.} The submission uses the term "transgenic crops" to refer only to those crops that have been developed through the use of genes derived from unrelated species. All crops that are in use today have in one way or another been genetically modified through methods that do not involve the transfer of genes across species. This paper is therefore concerned only with transgenic crops and not all genetically modified (GM) crops, which include plants derived from conventional plant breeding.

promote increased agricultural production of key staple crops that offer nutritional benefits such as transgenic cassava and sorghum in Sub-Saharan Africa. Other crops in the pipeline with nutritional benefits include high-oleic oil soybean, which aims to eliminate trans fats, and the "Arctic Apple," designed to resist browning and therefore encourage healthier lunch choices among schoolchildren.

Finally, transgenic crops offer environmental benefits by requiring less spraying of pesticides, reducing the amount of arable land needed for increased agricultural production, and combating the effects of climate change through the development of drought-resistant crops such as Water Efficient Maize for Africa (WEMA). Reduced spraying of insecticides results in improved human and ecological health (NAS 2010b).

To realize the potential of transgenic crops, it is important to view them as one of the many sources of food security and to assess the benefits and risks on a case-by-case basis. Given rising agricultural challenges including the impact of climate change, it would be a mistake to adopt agricultural policies that expressly exclude transgenic crops as one of the options.

The early days of the introduction of transgenic crops were marked by divergent views over the long-term benefits and risks. It has been 18 years since the large-scale commercial release of the products and there is now sufficient evidence upon which to base historical assessments. For example, many of the policies adopted by emerging countries to regulate transgenic crops assumed that their risks were likely to be catastrophic, thereby requiring a high degree of caution. While careful monitoring of the crops continues to be warranted, the evidence so far available does not support the adoption of restrictive and costly regulatory policies.

Transgenic crops have recorded the fastest adoption rate of any crop technology in the last century. This is mainly because of the benefits that they confer to farmers, most of whom reside in developing countries. Between 1996 and 2013, transgenic crops added US\$116.9 billion to global agriculture, more than half of which accrued to farmers in developing countries. If the crops had not been introduced, the world would have needed another 123 million hectares of land to meet the same levels of production. These benefits are inconsistent with earlier concerns that transgenic crops would not benefit small-scale farmers.

Evidence from large-scale studies supports the view that the crops on the market do not carry unique risks. For example, the European Commission funded more than 50 research projects involving 400 researchers at the cost of €200 million to evaluate this issue. The studies found that "the use of biotechnology and of GE plants *per se* does not imply higher risks than classical breeding methods or production technologies" (European Commission 2010, p. 16). The journal *Critical Reviews of Biotechnology* recently published a comprehensive literature review covering the last 10 years of transgenic crop safety and effects on biodiversity and human health. It concluded that "the scientific research conducted thus far has not detected any significant hazard directly connected with the use of GM crops" (Nicolia et al. 2013, p. 2).

Transgenic crops have been shown to carry the same risk profile as their conventional counterparts. In the long-run, the risks of excluding transgenic crops from global agricultural options would outweigh the risks of including them. Moreover, preventing the

commercialization of transgenic crops undermines countries' abilities to leverage the power of biotechnology whose benefits extend to other fields such as health, environmental management, and informatics.

The way forward is clear. As mentioned, transgenic crops not only offer increased incomes for farmers, biofortification, and environmental benefits. But the impact of transgenic crops on the overall price of food is just as important, especially in a world where there is a need to feed a growing population of approximately 9 billion by 2050 and address a surge in consumption, including a 70% increase in the demand for food. Transgenic technology leads to more efficient production methods as well as a reduction in loss, which in turn leads to lower food prices both in the United States and abroad.

The balance of evidence suggests that transgenic crops offer no greater risks than their conventional counterparts, and their economic, nutritional, and environmental benefits are extensive. Yet whether or not the crops described above reach the farmers and consumers who need them most depends on the regulatory agencies and the lengthy and costly approval processes of each country, as well as on public resistance to transgenic crops in general.

The United States has historically played a critical role as a champion of biotechnology innovation worldwide. Its leadership is urgently needed at a time when global agricultural challenges are mounting. More specifically, there is a need to bring the regulatory processes governing the approval of agricultural biotechnology in line with the state of scientific knowledge pertaining to the crops and scientific advances. There is no alternative to the evidence-based regulatory processes that have enabled the United States to emerge as the world's biotechnology innovation powerhouse. To cede this responsibility to opponents of innovation will undermine U.S. competitiveness, erode its scientific leadership, and put the global community at risk from the rising economic and ecological challenges. It will deprive global citizens of important societal benefits of agricultural biotechnology. Put more directly, a national whose regulatory processes take as long as the duration of a patent cannot continue to be a champion of innovation. This has to change and there is no better time than the present.

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INTRODUCTION

The rise of the U.S. biotechnology industry is largely a result of reforms in intellectual property rights that allowed for patenting of living forms. However, regulatory hurdles around the world have made it difficult for society to fully reap the benefits of biotechnology. Society's innovative and entrepreneurial potentialities will be hobbled if the regulatory process for new biotechnology products takes as long as the duration of patent protection, which is at most 20 years. It has taken as long for the United States to complete the approval process for transgenic salmon. Worldwide, even more onerous and discriminatory hurdles stand in the way of societal benefits of biotechnology. Biotechnology product pipelines are being choked by discriminatory regulations, labeling threats, and a rising ride of product slander and misinformation.

There is a need to feed a growing population of about 9 billion by 2050 and address a surge in consumption, including a 70% increase in the demand for food. Climate change and rising food prices will negatively impact African countries the most. The challenge of feeding a growing population will include increasing production on existing arable land. One of the ways to combat climate change and higher food prices is to expand the agricultural innovation toolkit, which includes transgenic crops. The aim of this submission is to review the societal impacts of transgenic crops, which range from increased food security to economic, nutritional, and environmental benefits. In addition to these, both farmers and consumers benefit: the former from increased income and the latter from lower prices stemming from more efficient production, improved nutrition and environmental protection. Furthermore, small farmers in developing countries are shown to benefit just as much as their counterparts in industrialized countries. Finally, "adopters report improvements in health, education, debt repayment, maternal care services and food security" (Carpenter 2013, p. 249).

This submission argues that although many transgenic crops are still in their early states of adoption and even more are still being tested and developed, emerging trends show significant societal benefits through positive economic impact (especially by raising farm incomes), fostering food security, and promoting environmental sustainability. The pipeline of crops with potential benefits include a wide range of applications such as enhanced photosynthesis, stress tolerance, aluminum tolerance, salinity tolerance, pest and disease resistance, nitrogen use efficiency, phosphate use efficiency, and nitrogen fixation (UK Council for Science and Technology 2013).

The submission is divided into three sections. The first section outlines trends in food security and biotechnology. This is followed by a section that examines some of the examples of the role of transgenic crops in the wider economy, especially in raising farm incomes. The final section reviews some of the major regulatory challenges associated with the adoption of transgenic crops and animals, as well as outlining a way forward.

There are many claims that biotechnology cannot contribute to solving food insecurity or benefit smallholder farmers. Critics argue that biotechnology is a red herring—that food insecurity is

simply the result of poor infrastructure, distribution, and income level. Transgenic crops are also criticized for being part of the agro-industrial complex. Critics link transgenic crops with increased pesticide use, monoculture, and industrialized farming at the expense of smallholder farmers. They argue that large agricultural corporations perpetuate food insecurity by selling expensive, unnecessary technology to poor farmers; preventing farmers from saving seeds; destroying plant diversity; and displacing millions of farmers. Critics claim that transgenic crops were developed with industrialized countries in mind; that they would hardly be adopted or accepted in developing countries; and that the technology continues to ignore the plight of smallholders.

These claims are driven by a wide range of concerns that tend to assert what has not been denied and deny what has not been asserted. In fact, transgenic crops demonstrate numerous societal benefits. But realizing the potential needs to be viewed in a wider food security context.

1. GLOBAL SOCIETAL CHALLENGES

Agricultural and the wider economy: There is a need to feed a growing population of approximately 9 billion by 2050; address a surge in consumption and changing diets, including a 70% increase in the demand for food; and compensate for increasing biofuels production. Meanwhile, around 870 million people are undernourished (Searchinger et al. 2013, p. 1). This will require a doubling of current levels of food production. A recent study analyzed the current production and yield rates for four key crops (maize, rice, soybean, and wheat) and determined that annual yields are increasing at an average rate of 1.2%, or half the 2.4% rate that would double production and close the gap. At current rates, global production of each crop will only increase by approximately 67%, 42%, 38%, and 55%, respectively—well below what is needed to meet the expected demand (Ray et al. 2013). This is especially problematic in many developing countries where one or more of these crops are responsible for the majority of caloric consumption.

Transgenic crops can benefit smallholder farmers in several major ways. First, they help farmers avoid both production and income loss due to pests, disease, and environmental factors such as drought or flooding. This results in greater productivity. Insect-resistant (IR) traits are found to have the greatest impact in warm, tropical places where pests are more prevalent and where insecticides and inputs are not widely used—namely in emerging countries.

Essentially, food security is about expanding ecologically sustainable agricultural practices as well as increasing access to nutritious food. The rest of this submission seeks to address how biotechnology can play a role in increasing agricultural productivity, income levels, nutrition, and stability and resilience of the food system to various shocks, thereby helping to increase food security at the global level but especially in emerging countries.

Boosting agricultural production contributes directly to poverty alleviation by raising farm incomes, providing jobs, and reducing the cost of food. Agriculture is responsible for the

majority of employment in many parts of the world. In fact, a World Bank report (2008) has shown that the growth of the agricultural sector is more effective at reducing poverty than is growth in any other sector. In Sub-Saharan Africa for example, agriculture "contributes to 34% of GDP and 64% of employment" across the continent (Juma 2011a, p.7). Because agriculture will continue to be an important source of employment in the future as well, increasing agricultural production will result in increased farm income and consumption.

Furthermore, in areas where farmers face a variety of problems and farm extension services are limited, biotechnology can be successful at filling the void, as it can make farming less complex, which suggests that "farmers with less human capital may benefit the most" (Sexton and Zilberman 2010, p.13).

Food security and nutrition: Advancements in science have demonstrated the important role that niche crops can play in improving human health. Achieving food security depends not only on increasing production but also on improving nutrition. Increasing the production of niche crops—also known as ancient grains, orphan crops, lost crops, famine crops, local crops, neglected crops, or wild foods—is one way to achieve this. Technological advancements in agricultural biotechnology and advances in fields such as plant genomics allow for the enhancement of existing crops and the ability to breed new ones that meet higher nutritional standards. Furthermore, many communities rely on niche crops, so increasing their production would also improve nutrition in food-insecure areas (Juma 2014).

Sustainability and resilience: It is well established that the effects of climate change—from weather-related phenomena to rising food prices—will drastically affect agricultural productivity worldwide and developing countries the most. Measures will need to be taken to adapt crops to changing weather patterns. Changes in humidity are already affecting the world's primary cocoagrowing regions, while drought has affected maize crops in both the United States and sub-Saharan Africa. In Southeast Asia, rice yields are affected by drought, salinity, and rising sea levels (Redfern et al. 2012).

Another dimension to the need for increased food production is related to agriculture's historically large environmental footprint—the industry "accounted for approximately 24 percent of global greenhouse gas emissions in 2010" (Searchinger et al. 2013, p.2). It is also responsible for around 70% of global freshwater use, as well as contamination of water supplies and coastal areas from farm runoff. One of the biggest challenges of feeding a growing population is increasing production on existing arable land. Agricultural biotechnology not only has the potential to adapt crops to climate change, but it can also contribute to increasing yields on existing land and reducing emissions by encouraging fewer applications of pesticides and herbicides.

2. SOCIETAL BENEFITS OF AGRICULTURAL BIOTECHNOLOGY

2.1 Agriculture and the wider economy

Technology played an important role in generating significant increases in agricultural productivity during Green Revolution. The combination of new, high-yielding crop varieties, agro-chemicals, and better irrigation techniques helped "raise food production to levels that no one would have dared predict....farmers in the developing and developed countries nearly doubled their per-hectare output of cereal production, increasing yields during this time by 3.16% annually" (Huang et al. 2002, p.678). This led to a significant decline in poverty and hunger throughout much of Asia, because food levels rose, prices fell, as well as food trade and consumption increased.

However, the favorable conditions that led to the success of the Green Revolution have changed. Staple crops will be most affected by the "exhaustion of some past sources of growth [making] future yield expansion as great a challenge as in the past" (Ibid., p.678). Overuse of fertilizers and chemical pesticides has led to pest and weed resistance. It has also contributed to environmental degradation. Moreover, availability of arable land is declining, water resources are scarce and climate change is causing significant changes in weather patterns, making it necessary to find alternatives to current production methods.

Transgenic crops offer one alternative to addressing these challenges, as they are specifically designed to increase production while decreasing the use of pesticides and herbicides. A key point is that transgenic crops were not developed to increase yield directly but instead "to overcome barriers to efficient yield, that is, to control diseases, or yield-robbing weeds or insect pests" (McHughen 2013, p.7). Increased production is necessary to feed a growing population and meet an ever-increasing demand for food. The genetically modified soybean enabled double-cropping in Argentina, which specifically helped to meet the huge increase in soy demand—driven primarily by an increased desire for meat in Asia—with only a limited effect on prices (Zilberman et al. 2010).

Although studies that examine production increases of transgenic crops have produced varying estimates, recent cotton studies in India and China confirmed earlier results: transgenic cotton production per hectare are demonstrably higher than those of non-transgenic cotton, especially in India. Other benefits include decreased pesticide use especially in China, and health benefits in both countries (Pray et al. 2011). Cotton was the most-adopted genetically engineered crop globally and saw the highest production increase, and the global price effects of planting *Bt* cotton are estimated at 10% (Zilberman et al. 2010).

India had one of the lowest rates of cotton production in 2001–02 (at 308kg/ha). Aggregate levels of cotton increased substantially after the introduction of *Bt* cotton post-2002, reaching 560kg/ha (Pray et al. 2011, p.98). *Bt* cotton was adopted at a rate of 90%, leading to "a 24% increase in cotton yield per acre through reduced pest damage and a 50% gain in cotton profit among smallholders. These benefits are stable; there are even indications that they have increased over time" (Kathage and Qaim 2012). With the extra income, farmers' consumption levels increased 18% from 2006 to 2008 (Juma, Conceição, and Levine 2014; Kathage and Qaim 2012).

In China, where surveys were conducted from 1999 to 2007, mean production of *Bt* cotton was higher than conventional cotton. One concern is that *Bt* cotton production levels will decline over time due to the development of bollworm resistance or as a result of being "backcrossed into more varieties by public- and private-sector plant breeders" (Pray et al. 2011, p. 93). Yet evidence does not support these concerns as "aggregate cotton yields continue to rise in China suggesting that *Bt* cotton also continues to do well" (Ibid.).

A global impact study confirms the significant income gains among farmers in India and China who adopted transgenic IR cotton, transgenic *Bt* soybeans in South America (including Argentina, Bolivia, Brazil, Paraguay, and Uruguay), and a variety of transgenic crops in the United States. South Africa, the Philippines, Mexico, and Colombia are also seeing the income benefits of adopting transgenic crops. These gains stem from greater productivity and efficiency. The largest income gains derive from the maize sector. In fact, "\$6.7 billion additional income generated by GM insect resistant (GM IR) maize in 2012 has been equivalent to adding 6.6% to the value of the crop in the GM crop growing countries, or adding the equivalent of 3% to the \$226 billion value of the global maize crop in 2012. Cumulatively since 1996, GM IR technology has added \$32.3 billion to the income of global maize farmers" (Brookes and Barfoot 2014, p.9).

In Africa, where smallholder farmers use significantly fewer inputs than in developed countries, IR crops could have the greatest impact on production. By adapting the technology to local conditions, developing countries could also address the issue of yield drag, which occurs because companies typically modify generic seeds that are unspecific to a particular region. African countries could increase the production potential of transgenic crops by applying the technology to high-quality, local crop varieties.

Higher production is not the only positive impact of transgenic crops. They also help reduce loss due to pests, weeds, and diseases. The potential of this technology lies in how it is adapted to meet specific, local needs in developing countries, which can range from combating diseases to improving indigenous crops.

Researchers in Uganda, for example, are using biotechnology to reverse the trend of *Xanthomonas* wilt, a bacterial disease that causes discoloration and early ripening of bananas and costs the Great Lakes region approximately \$500 million annually. There is currently no treatment for the disease, and given its status as a staple crop in this region, solving this problem would directly increase food security and income (Juma, Conceição, and Levine 2014; Juma 2011b). The most efficient method of containing the disease is by growing transgenic bananas instead of relying on more labor-intensive methods of removing and destroying affected bananas. By transferring two genes from green peppers, scientists were able to grow highly resistant bananas. Results from field trials in Uganda and Kenya are extremely promising, but the regulatory regimes do not yet allow for commercialization.

In Nigeria the insect *Maruca vitrata* destroys nearly US\$300 million worth of blackeyed peas—a major staple crop—and forces farmers to import pesticides worth US\$500 million annually. To solve the problem, scientists at the Institute for Agricultural Research at Nigeria's Ahmadu Bello University have developed a pest-resistant, transgenic blackeyed pea variety using insecticide genes from the *Bacillus thuringiensis* bacterium. The crop is also undergoing field trials in Burkina Faso and Ghana.

In Southeast Asian countries such as Bangladesh, India, and the Philippines, *Bt* brinjal is the region's first transgenic food crop and offers economic, nutritional, and environmental benefits. Researchers and scientists at the Bangladesh Agricultural Research Institute (BARI) developed *Bt* brinjal to resist the 'fruit and shoot borer' (FSB), with support from USAID and Cornell University. The result was significantly fewer pesticide sprays during the growing period and fewer dips in pesticide just before harvest. The transgenic eggplant has obvious farmer health and environmental benefits from reduced pesticide use. The crop was commercialized in Bangladesh, but its future remains in jeopardy as the government and opponents of transgenic crops seek to push or stall further crop sales. Furthermore, the Filipino government prohibited field trials of *Bt* brinjal, citing health and environmental concerns. As a result, commercialization of the crop remains stalled in India and the Philippines, and its future remains uncertain in Bangladesh (Hammadi 2014).

Key industries in industrialized countries are also affected by loss from disease and pests. The most dramatic example is that of transgenic papaya, which helped save the industry in Hawaii. In the early 1990s, the papaya ringspot virus (PRSV) was transmitted rapidly by aphids and nearly decimated Hawaii's papaya industry, which saw yields plummet from 53 million pounds in 1992 to 26 million pounds in 1998. After the introduction of the "Rainbow" papaya in 1998, yields rose to 46 million pounds by 2001. At the time, farmers, producers, and consumers alike embraced it. Today it accounts for 77% of the papaya grown in Hawaii (Gonsalves 2007). Other examples of transgenic food crops ready for commercialization in the U.S. include Bt sweet corn, virus-resistant summer squash, and pox-resistant plums. Finally, agricultural biotechnology offers a similar promise for combating the citrus greening disease (Huanglongbing) that is severely affecting those industries in Florida, Texas, and California. Citrus greening is caused by the bacterium Candidatus Liberibacter asiaticus (CLas), spread by the Asian citrus psyllid (ASP). Florida's citrus industry brings in an estimated \$9.3 billion annually. Farmers stand to lose income, and a dramatic reduction in output would lead to higher prices of citrus fruits and juices for consumers throughout the United States. Currently, increased use of insecticides and removal of infected fruit trees are the only known solutions. According to a recent report by the U.S. National Academy of Sciences, genetic engineering represents the best alternative to these costly and less-effective solutions (NAS 2010a, p.2).

It is also important to note what is not in the pipeline, namely smaller crops that are a staple in certain regions of the world but are unlikely to be developed in the foreseeable future because of prohibitive regulatory costs and risks. Regardless, promising transgenic vegetable crops such as insect-resistant bananas, blackeyed pea, eggplant, papaya, sweet corn, summer squash, plums,

citrus fruits, and wheat must clear significant resistance and regulatory hurdles before their societal benefits can be realized.

As demonstrated, these techniques have the potential to address a wide range of agricultural, health, and environmental issues in emerging countries, resulting in societal benefits such as increased productivity and therefore contributing to increased food security.

Increasing production, reducing loss, and encouraging higher agricultural productivity among smallholder farmers has a significant effect on income and poverty. For one thing, growth in the agricultural sector is more effective at reducing poverty and increasing access to food than growth in any other sector. Since smallholder farmers comprise the majority of the workforce in sub-Saharan Africa, boosting their income levels through agricultural productivity would go a long way toward increasing food security.

The evidence from several long-term studies suggests that biotechnology is successful at helping smallholder farmers increase their income through costs savings. The last section showed how transgenic crops improve production and reduce loss. This translates into higher incomes at the farm level. A recent study explains how planting transgenic crops results in cost-savings up front, specifically with IR crops, which "require little capital and can substitute for chemical applications altogether" (Zilberman et al. 2010, p.5). Not only were farmers able to reduce pesticide use, but they were also able to limit the related health risks.

Similarly, both IR and herbicide-tolerant (HT) crops can reduce input expenses associated with pesticide use, such as machinery costs, fuel costs, and water use. Although seed prices for transgenic cotton were higher than for conventional seeds in India, these costs were "offset by reductions in expenditures on pesticides and labor, due in large part to reductions in number of required sprays" (Pray et al. 2011, p.94). Overall production costs decreased, and net revenue increased. In fact, revenue from *Bt* cotton exceeded that of conventional cotton in every household surveyed in China (Ibid). Results of *Bt* cotton studies in India also indicated that cost savings related to pesticide use, as well as higher production, offset the higher seed costs.²

When faced with fewer costs upfront, a reduction in crop loss, and more time available to pursue other income-generating activities, farmers have more income at their disposal, which also leads to greater consumption. So far, Bt cotton—which is the most widely adopted transgenic crop worldwide—has had the most significant impact on income. Approximately 15 million smallholder farmers in Burkina Faso, China, India, Pakistan, and a few other developing countries are growing Bt cotton. Several studies in India demonstrate the positive effects of Bt cotton on income, nutrition, and food security among poor farmers. Specifically, "Bt cotton adoption has raised consumption expenditures, a common measure of household living standard, by 18% during the 2006-2008 period" (Kathage and Qaim 2012). In Burkina Faso, which grew 125,000 hectares of Bt cotton in 2009, rural households saw production increases of

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² Different studies used different methods for calculating income gain from Bt cotton, but all indicated significantly higher profit margins for Bt cotton farmers (Pray et al. 2011, pp. 99–100).

approximately 18.2% over those that grew conventional cotton; earning \$39 per ha in profit. Although the seeds were more expensive, farmers saved money on inputs and labor (Vitale 2010). The reduced insecticide spraying also contributed to human and environmental health.

Although *Bt* cotton does not directly contribute to better nutrition, it does indirectly contribute to food security by increasing household income levels and improving access to more nutritious food. This in turn increases the "purchasing power of farmers (and thus their exchange entitlements) and their access to food" (Juma, Conceição, and Levine 2014). A recent study analyzes the impact of *Bt* cotton on caloric consumption and nutrition at the household level in four cotton-producing Indian states from 2003–09. The authors find that households growing *Bt* cotton leads them to consume significantly more calories—specifically, "each ha of Bt cotton has increased total calorie consumption by 74 kcal per AE [adult equivalent] and day" (Qaim and Kouser 2013, p.6).

Furthermore, a smaller proportion of households are food insecure (7.93% of adopting Bt cotton households vs. 19.94% of non-adopting households) (Ibid., table 2). The results also show that Bt adoption has led to consumption of more nutritious foods such as fruits, vegetables, and animal products. The authors estimate that if the households that do not currently grow Bt cotton switched, "the proportion of food insecure households would drop by 15–20%" (Ibid., p.6).

These findings indicate that increased income among smallholder farmer households that grow *Bt* cotton lead to greater food security and consumption of more nutritious food. But the results also demonstrate that farmers are the main beneficiaries of *Bt* cotton, rather than seed companies or biotechnology companies. This reinforces how plant biotechnology can be one important tool in addressing food insecurity.

Finally, farmers have seen their insurance costs decline as production risks stabilize. As a result, they will also gain access to better risk-management products. Given the increased production and income associated with *Bt* cotton, it can be extrapolated that further development of IR crops could "serve as an engine of rural economic growth that can contribute to the alleviation of poverty for the world's small and resource-poor farmers" (James 2013).

2.2 Food safety and nutrition

The safety of transgenic foods has been a hotly debated issue. It gained international prominence following the publication of a paper that claimed that transgenic maize containing *Bt* genes caused cancer in rats (Séralini et al. 2012). The paper was used as a basis for regulatory action against transgenic foods in a number of countries. Upon closer scrutiny, however, several regulatory bodies including the European Food Safety Agency condemned the study as being methodologically defective (Arjó et al. 2013). The paper was later retracted by the journal that published it.

It is important to apply a case-by-case approach and focus on those foods that are on the market. Detailed reviews of the evidence so far available have come to the conclusion that the transgenic

foods currently on the market carry the same risk profile as their conventional counterparts (Ricroch, Bergé and Kuntz 2011). A comprehensive review of safety studies published over the last decade has examined the available evidence on the "safety of the inserted transgenic DNA and the transcribed RNA, safety of the protein(s) encoded by the transgene(s) and safety of the intended and unintended change of crop composition" (Nicolia, Manzo, Veronesi and Rosellini 2013, p. 81). While acknowledging the need for further research, the review confirmed the general understanding that transgenic foods on the market today did not carry unique risks.

Interest in transgenic crops also includes their potential contribution to nutritional enhancement in staple crops, specifically targeting low-income families. There are several bio-fortified crops that are currently available or being tested in developing countries. These include "Golden Rice," which contains more beta carotene or Vitamin A, under evaluation in the Philippines and Bangladesh; and the "Golden Banana," bio-fortified with Vitamin A and iron and developed by Ugandan researchers (Wamboga 2011). Nearly 15 million people either rely on bananas for their income or consumption, making it one of the most important crops in Uganda. It is estimated that the per capita consumption of bananas in Uganda is 0.7 kg per day. Scientists applied the pro-Vitamin A genes used in Golden Rice to a popular local crop to help solve a regional health issue. Addressing vitamin deficiencies would lead to lower healthcare costs and higher economic performance.

In the UK, researchers at the John Innes Centre created a bio-fortified "purple tomato" by expressing genes from the snapdragon in the transgenic tomato. The dark color derives from the same antioxidant that is found in blueberries and cranberries—anthocyanin—and offers similar health benefits at a lower cost to consumers. By increasing the antioxidant levels in a common food such as the tomato, researchers hope to stimulate greater consumption of antioxidants. The purple tomato contains the "highest levels of anthocyanins yet reported in tomato fruit," and an early study of cancer-prone rats suggests that the tomato's high levels of anthocyanins increased the lifespan of these rats when eaten regularly. The purple tomato also has a longer shelf life than a nontransgenic tomato (Butelli et al. 2008; Shukman 2014).

Other examples include the "Arctic apple" and J.R. Simplot's "Innate" potato, under development in Canada and the United States respectively. Both crops are designed to resist browning, making the apple an especially appealing choice for healthier school lunches. Browning is one of the most significant sources of food quality loss worldwide. The techniques applied by such companies to address the challenge have the potential to be extended to fruits and vegetables in other regions of the world experiencing similar challenges. This would extend the shelf life of fruits and vegetables, thereby addressing the larger post-harvest loss problem.

Nutritional enhancements through genetic modification are still in their infancy. Examples such as Golden Rice and purple tomatoes are important because they represent proof of concept. When confirmed, they will open a wide range of opportunities for related modifications in other crops as well as the use of new techniques to improve human nutrition.

2.3 Sustainability and resilience

It is well established that climate change will adversely affect agricultural productivity primarily in developing countries. Many regions are expected to suffer production loss due to "drought, flood, storms, rising sea levels, and warmer temperatures" (Goering 2012). In the past, these events were rare, and it was possible for farmers and regions to recover during the next growing season. Now it is imperative to determine ways of increasing the resilience and stability of food systems so that productivity is less affected by drought, flood, or both in the same season. Challenges include increasing productivity on existing land to conserve biodiversity and protect vulnerable land, as well as reducing agriculture's traditionally large environmental footprint.

Transgenic crops, for example, are one of the better land-saving technologies available, as they are designed to increase production on existing plots, avoiding slash and burn agriculture often practiced in developing countries. Indeed, "if the 377 million tons of additional food, feed and fiber produced by biotech crops during the period 1996 to 2012 had been grown conventionally, it is estimated that an additional 123 million hectares...of conventional crops would have been required to produce the same tonnage" (James 2014a).

Transgenic crops have succeeded in reducing the environmental impact of agriculture by reducing pesticide use (by an estimated 8.5% in 2011 alone); and reducing fossil fuels and CO₂ emissions through less ploughing and less chemical spraying (saving approximately 1.9 billion kg of CO₂—the equivalent of removing 0.8 million cars from the road). The adoption of HT crops allows farmer to use a single broad-spectrum herbicide.

Limiting the practice of tilling, which is the use of mechanization for planting, weed control, and harvesting, is an important trend in sustainable agriculture. It refers to "direct planting into previous crop stubble without further soil disturbance" (Dill et al. 2008, p.329). Farmers who practice conservation tillage aim to leave 30% residue on the surface of the soil, which can help reduce soil erosion by 70%.

Finally, several biotechnology tools, including tissue culture, diagnostics, genomics, and marker-assisted selection can be used collectively to isolate new traits such as drought or flood tolerance that can help mitigate the effects of climate change.

In 2012, drought wreaked havoc on maize production in the United States, highlighting what farmers in Africa already know: drought is, "by far, the single most important constraint to increased productivity for crops worldwide." The development of drought-tolerant crops is arguably the most important transgenic trait that will occur in the next decade of commercialization (Edmeades 2013). The gene in question was isolated from a common soil bacterium known as *Bacillus subtilis*. It helps the plant cope better with stress caused by water shortages, allowing the plant to focus on filling the grains. In 2013, some 2,000 American farmers started to grow drought-tolerant maize. Indonesia has approved field trials of drought-tolerant sugarcane. Field trials of drought-tolerant maize, wheat, rice and sugarcane are in field trials in Argentina, Brazil, India, Egypt, South Africa, Kenya and Uganda (Marshall 2014). It is

hoped that the first drought-tolerant maize will be commercially available in sub-Saharan Africa by 2017.

In March 2008, a public-private partnership called 'Water Efficient Maize for Africa' (WEMA) was formed between Monsanto, which developed the drought-resistant technology; the African Agricultural Technology Foundation, which directs the partnership; the International Maize and Wheat Improvement Center; and five national agricultural research systems in East and Southern Africa (including Kenya, Mozambique, South Africa, Tanzania, and Uganda). WEMA is working to make the drought-resistant technology available to smallholder farmers through local and regional seed companies. The crop is being developed using conventional breeding, marker-assisted selection, and genetic modification to find the optimal crop for local conditions. Confined field trials thus far show 20–30% higher production than conventional hybrids. Sites were selected specifically for their dry conditions. The five national research systems are coordinating the field trials. WEMA hopes to offer at least five "farmer-preferred" IR maize hybrids with and without the drought-tolerant gene by 2017, pending field trials and regulatory approval. It is undergoing field trials in Kenya, South Africa, and Uganda, but the regulatory regimes in Mozambique and Tanzania so far prohibit field trials.

The 2008 food crisis demonstrated the effect of an increase in demand and a tightening of supply on the price of rice. After severe flooding in 2007 and 2008 decimated rice production in Southeast Asia, twelve countries including India and China responded by initiating export restrictions. Riots broke out in Haiti, Bangladesh, and Egypt. Although the food crisis affected all grains, a shortage of rice would prove disastrous. According to the International Rice Research Institute (IRRI), in 2005, rice comprised 20% of global calories consumed; in Asia, 30%. In addition, "two-thirds of the world's poor...subsist primarily on rice." With consumption and prices rising, production declining, and climate change effects expected to grow (e.g., Asia currently loses approximately \$1 billion from flooding), IRRI estimates that "by 2015 the world must grow 50 million tons more rice per year than the 631.5 million tons grown in 2005. This will require boosting global average yields by more than 1.2% per year, or about 12% over the decade" (Normile 2008).

Furthermore, 25% of the global rice supply comes from flood-prone regions. One solution has been to isolate the gene present in a variety of Indian rice that allows plants to survive after up to three weeks underwater. In collaboration with IRRI, researchers at the University of California at Davis used marker-assisted selection to breed this gene into locally important varieties. The result is a variety of rice that can tolerate flooding but which also retains the capability to produce high production. IRRI partnered with PhilRice, a nonprofit organization in the Philippines, to distribute the rice free of charge to seed growers and certain farmers who can disseminate further to other farmers. In 2011, over 1 million farmers in the Philippines, Bangladesh, and India planted the rice (Clayton 2009; Ronald n.d.) So far, it has led to production increases of 1–3 tons after 10–15 days of flooding. Other varieties are also being studied, including drought tolerance, heat and cold tolerance, and salt tolerance. In Africa, IRRI is partnering with the Africa Rice Center (AfriRice) to develop rice that can tolerate poor soils.

Two other crops in the pipeline are being developed to resist cold temperatures (eucalyptus) and drought (sugarcane). These examples prove that agricultural biotechnology has the potential to increase the resilience of crops to climate change.

3. REGULATORY IMPLICATIONS AND OUTLOOK

The claim that transgenic crops have no societal benefits is clearly false. As population growth, climate change, and rising food prices become more important, it is imperative to consider all options for increasing agricultural productivity. Transgenic crops offer one option in the agricultural innovation toolbox, and must be considered as such. To be sure, transgenic crops are not without criticism. However, biotechnology is an important tool that society can use to address food security. Risks should be taken into account and the technology strengthened, but to deny farmers the right to grow transgenic crops would be irresponsible.

Combating these production, economic, nutritional, and environmental challenges necessitates the expansion of the agricultural innovation toolkit, which includes agricultural biotechnology. It is important to note, however, that agricultural biotechnology is one option among many for increasing food security. To truly have an impact, it must be viewed in a context of system-wide improvements in agriculture (Juma and Gordon 2014).

Agricultural biotechnology, which was commercialized on a large scale in 1996, refers to the application of scientific information and methods such as genetic modification of crops or animals to select certain traits that are more productive or desirable. Plant breeders have long sought to improve crops through traditional methods such as cross-breeding and hybridization, a time-consuming process that results in the presence of undesirable traits mixed in with desirable ones. Genetic modification is a significantly faster, more precise technology that is designed to achieve similar results as conventional plant breeding techniques by allowing the transfer of one specific gene to another plant.

The major types of transgenic crops commercially available are herbicide-tolerant crops that are resistant to broad-spectrum herbicides such as glyphosate and gluphosinates; insect-resistant crops that include genes from a specific bacterium, *Bacillus thuringiensis* (*Bt*), which is poisonous to certain insects and not humans; and crops with a combination of both (stacked trait). HT and IR traits help make weed and pest control more efficient, as crops need fewer applications of herbicides and/or eliminate the need for pesticides. HT crops are the most common, comprising more than half of the 175 million hectares of transgenic crops grown globally in 2013, followed by stacked-trait crops at 27%, and IR crops at around 16% (James 2014a; James 2014b).

Both first- and second-generation transgenic crops are produced commercially; most consist of animal feed, fiber, and biofuels. First-generation crops typically have a single trait introduced. Newcomers, such as Burkina Faso, benefit most from adopting second-generation transgenic

seeds, which contain two or more genes to resist specific pests or weeds. Monsanto's GenuityTM Bollgard II ® cotton, for example, "work[s] against leaf-eating species such as armyworms, budworms, bollworms, and loopers...[and] cotton leaf perforators and saltmarsh caterpillars" (Juma 2011a, p.37). Second-generation cotton is a superior technology because it takes longer for pests to develop resistance. First-generation transgenic technology is still beneficial but will break down sooner in terms of pest resistance. Researchers and scientists have come a long way since developing these early-generation crops. Today there are also multi-HT crops such as corn, cotton, and soybeans that provide farmers with even more options for combating weeds. It is important to note, however, that most transgenic crops grown today are either cash crops or are used in animal feed, cooking oils, and biofuels (Rotman 2013). Opposition to transgenic food crops has been so strong that investment in their development has been limited. There are, however, transgenic crops in the pipeline have the potential to offer significant societal benefits if they can overcome regulatory hurdles and reach the market. These crops will be discussed in the following sections.

Developing countries have seen clearly the potential of transgenic crops to increase agricultural productivity, income, and food security. Since their commercial introduction in 1996, transgenic crops have been one of the "fastest adopted crop technologies in recent history" (James 2014a). In 2013, "a record 175.2 million hectares of biotech crops were grown globally...at an annual growth rate of 3%" (James 2014a). This is a 100-fold increase from 1996, when 1.7 million hectares were planted. Of the 28 countries that plant transgenic crops, 20 are developing countries. Finally, 90% of those who grew biotech crops—that is, more than 16 million—were resource-poor smallholder farmers in developing countries (Ibid.). The impact of transgenic crops at the farm level has been significant. In 2011 alone, net economic benefits were \$19.8 billion, and cumulative economic benefits amounted to \$98.6 billion since 1996. The key point is that the "majority of these gains (51.2%) went to farmers in developing countries" (Brookes and Barfoot 2013, p.74).

Yet countries worldwide could benefit even more from adapting biotechnology to address local problems. The technology used to delay the ripening of tomatoes, for example, could be applied to tropical fruits, which ripen too quickly and end up going to waste due to lack of proper storage or transportation infrastructure. Another problem that is prevalent in tropical countries is soil acidity. "Acidic soils comprise about 3.95 billion ha...about 68% of tropical America, 38% of tropical Asia, and 27% of tropical Africa. In spite of its global importance...problems that affect acid soils are investigated by only a handful of scientists in developed countries" (Herrera-Estrella 2000, p.924). This problem is not limited to soil acidity. In fact, there is much scope for developing countries, especially in Africa, to invest in their own science and technology research institutes, which would allow local scientists to come up with solutions specific to local contexts. This is also relevant for the United States, which is spending millions of dollars combating citrus greening in Florida, Texas, and California, where the simplest and most cost-effective solution would be to employ agricultural biotechnology.

Despite the obvious benefits, however, transgenic crops and animals for human consumption face some the most stringent regulatory processes throughout the world. As an example, a

Massachusetts-based firm, AquaBounty Technologies, developed a transgenic salmon that could mature in half the time while retaining material equivalence with its natural counterparts. In 1995, the firm applied to the US Food and Drug Administration (FDA) for approval of AquAdvantage salmon. By the end of 2013, the fish had passed all the human health, environmental safety assessments required by FDA but still has not been granted approval. Transgenic crops face identical regulatory hurdles.

Society must overcome strong regulatory barriers to adoption of transgenic crops. One of the biggest barriers to adoption is the controversy over the safety of transgenic crops, both in terms of human consumption and their effect on the environment. However, recent studies tend to support the safety of transgenic crops. For example, the European Commission funded more than 50 research projects involving 400 researchers at the cost of €200 million to evaluate this issue and found that "the use of biotechnology and of GE plants *per se* does not imply higher risks than classical breeding methods or production technologies" (European Commission 2010, p. 16). A literature review covering the last 10 years of transgenic crop safety and effects on biodiversity and human health concludes that "the scientific research conducted thus far has not detected any significant hazard directly connected with the use of GM crops" (Nicolia et al. 2013, p. 2).

Despite the growing body of scientific evidence, many countries around the world still follow a strict interpretation of the European regulatory model, which uses the precautionary principle to evaluate transgenic crops (as opposed to the United States, which evaluates the crop itself). Given the differences between U.S. and European regulatory systems, there is a lack of harmonization that hinders the adoption process. A final barrier to adoption is that farmers in emerging countries have little political power and cannot make the case for adoption, despite comprising such a large percentage of the population. This is not always the case, however. South Africa, for example, has produced transgenic crops for the past 18 years and has a particularly effective biosafety regulatory framework and R&D investment. South Africa also trained farmers and scientists and embarked on a substantive public awareness campaign. In addition, farmers groups (including both large-scale and smallholder farmers) were supportive of the adoption of transgenic crops (Adenle et al. 2013).

Similar forward-looking strategies need to be adopted in emerging countries. The focus should first be on developing strategies, policies, and laws aimed at promoting biotechnology. Biosafety should be part of a broader biotechnology development strategy, not the other way around. Such an approach should seek to create a coordinated biotechnology research strategy that involves government, national research institutes, universities, the private sector and relevant civil society organizations. A broad consultative process should be launched that seeks to enable emerging countries to leapfrog in biotechnology in the same way they did in mobile technology. Failure to do so would be to mortgage emerging economies to the forces of technological stagnation, agricultural decline, and economic decay.

CONCLUSION

The future of the role of transgenic crops in addressing global challenges will be influenced greatly by advances in science and technology. New developments in genomics, molecular biology, and other allied fields will expand technological options in ways that will address some of the current uncertainties. The growth in technological abundance will also play an important role in democratizing biotechnology and bringing more players into the field. This will go a long way in helping to spread the societal benefits of biotechnology.

However, advances in biotechnology research can only be translated into societal benefits with the help of enabling policy environments. More important, regulatory processes need to be brought in line with the state of knowledge on the benefits and risks of biotechnology. The United States has historically played a critical role in the creation of the biotechnology industry by crafting founding legislation. The time has come for the United States to renew its leadership role by ensuring that regulatory processes help to spread further the benefits of biotechnology.

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Acknowledgements

This submission is based on Juma, Calestous and Gordon, Katherine (Forthcoming), Transgenic Crops and Food Security, in Ricroch, A, Chopra, S. and Fleischer, S. eds. *Plant Biotechnology—Experience and Future Prospects*. Dordrecht, The Netherlands: Springer. Additional information was derived from the author forthcoming book, *Innovation and Its Enemies: Resistance to New Technology*.