The Importance of Agricultural Biotechnology in the Response to the Effects of Climate Change

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The scope and pace of technological advances in agricultural biotechnology are without precedent in human history. Methods have been developed to improve the nutritional content of foods, combat pests in more sustainable and less environmentally malign ways, increase agricultural productivity throughout the world, and make commercially viable agriculture possible under ecologically stressful conditions. The initial wave of agricultural biotechnologies focused primarily on genetically engineering plants to produce exogenously derived proteins to usefully alter phenotypes. Technologies now being developed for commercialization take the more subtle approach of precisely modulating the expression of specific genes within the plant. These agricultural biotechnologies can play a significant role in the global community's need to adapt to potential impacts of climate change on current agricultural production.

This article examines that role. We start with a brief examination of the divergent regulatory approaches to biotechnology that have evolved internationally. This divergence can reasonably be described as circumscribed by the United States at one end and the European Union (EU) at the other, with primarily South American countries, Australia, and Asian countries gravitating toward either pole. We then examine novel genetic technologies that have the potential of reducing the time necessary to produce a crop able to withstand the effects of climate change. Next we examine agricultural biotechnology's significant role in ameliorating the impacts of climate change. We close with policy recommendations to ensure that agricultural biotechnology realizes its potential to serve the food supply needs of a global community in the face of the disruptions predicted to be caused by climate change.

Current regulatory schemes for the regulation of agricultural biotechnology vary widely. The differing approaches can be characterized as falling between two poles. One pole is represented by the science-based regulatory approval scheme implemented in the United States, which provides clarity, transparency, and relative predictability in regulatory decision making. The other is represented by the regulatory scheme in the EU, which is a much more time-consuming process that, as of this writing, has resulted in only one genetically engineered (GE) crop approved for cultivation in the EU, which is planted on minimal acreage in only a handful of EU member countries.

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The United States and the European Union

Federal regulation of agricultural biotechnology in the United States is based on the 1986 Coordinated Framework for the Regulation of Biotechnology. *See* Office of Science and Technology Policy, *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23,302 (June 26, 1986) (Coordinated Framework). The Coordinated Framework sets forth core principles for the regulation of biotechnology by the United States. The core principle that has guided regulation of biotechnology is stated as follows: "While the recently developed methods are an extension of traditional manipulations that can produce similar or identical products, they enable more precise genetic modifications, and therefore hold the promise for exciting innovation and new areas of commercial opportunity." *Id.* at 23,302. This statement established the foundational principle that the methods and products of biotechnology do not inherently pose any greater concerns than traditional genetic modification approaches (i.e., traditional breeding methods). Thus, safety assessments and regulatory review would continue to focus on the products of genetic modifications, not the manner in which the modifications are achieved. *Id.* at 23,311–12, 23,338; *see also* Wozniak, C., Waggoner, A., Reilly, R., *An Introduction to Agricultural Biotechnology Regulation in the U.S.*, Regulation of Agricultural Biotechnology: The United States and Canada (Chris Wozniak and Alan McHughen, eds. 2010).

The Coordinated Framework established that existing regulatory statutes are sufficient and appropriate for regulation of the products of biotechnology. 51 Fed. Reg. at 23,302–03. Federal agencies were allocated regulatory responsibilities consistent with their existing statutory authorities. The primary statutes relevant to the regulatory jurisdiction of US agencies with respect to agricultural biotechnology and GE foods are the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Plant Protection Act (PPA), and the Toxic Substances Control Act (TSCA). (In some instances, mostly relevant to the US Department of Agriculture (USDA), the National Environmental Policy Act may also be applicable, although, properly interpreted, that relevance is directly related to USDA's determinations under the PPA.) The US Environmental Protection Agency (EPA) has regulatory authority under the FFDCA, FIFRA, and TSCA; the US Food and Drug Administration (FDA) has authority under the FFDCA; and USDA has authority under the PPA. Factors determining which of these agencies will assert its regulatory authority include the stage of development of a GE organism or the products thereof, the intended uses of the organism or its products, potential hazards that such an organism or its products present, and the type of organism (i.e., whether it is an animal, plant, or microorganism). *See, e.g.*, Council on Environmental Quality and the Office of Science and Technology Policy, *Case Studies of Environmental Regulation for Biotechnology*, Jan. 2001, *available at* www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study1.pdf.

Thus, for example, a transgenic plant engineered with or through the use of genetic material from an organism determined by USDA to be a "plant pest" to express a pesticidal protein specifically targeting an organism determined by EPA to be a "pest" would be subject to regulation by USDA and EPA. USDA would utilize its PPA authority to determine whether the GE plant itself constitutes a plant pest. If USDA determines that it is not a plant pest, it "deregulates" the GE plant under its PPA authority. Before the plant can be sold or distributed in commerce, however, EPA must assess the pesticidal substance under its FIFRA authority to determine whether sale or distribution of the plant containing such substance could result in "unreasonable adverse effects to the environment." (EPA refers to such pesticidal substances that are intended to be produced and used in living plants as "plant incorporated protectants" or PIPs. 40 C.F.R. §§ 152.3, 174.3. The definition of PIPs includes the plant-produced pesticidal substance, the genetic material necessary for its production, and any inert materials contained in the plant or its produce.) Under FIFRA, EPA does not regulate the GE plant, per se. EPA does, however, assess the PIP in the context of it being an inherent part of the plant genome. Thus, for example, in its environmental assessment, EPA may assess the likelihood of gene transfer of the transgene. (Note, as used here, the term "transgene" refers to a gene derived from a species that is not sexually compatible with the recipient. In this respect, the converse term is "cisgene.") Under its FFDCA authority, EPA must also determine if the PIP presents food safety concerns. In contrast, a transgenic plant engineered with or through the use of genetic material from an organism determined by USDA to be a "plant pest" to express a pesticidal protein that renders the recipient plant resistant to a particular herbicide would be subject to regulation by USDA under the PPA but not by EPA, because EPA does not currently regulate GE herbicide resistant traits as pesticidal effects. In each case, if the engineered plant was a food plant, FDA would consider food safety aspects of the engineered plant under the FFDCA. *See, e.g.*, Table 1.1, Wozniak, Waggoner, and Reilly.

Irrespective of the jurisdictional scope of these agencies, the salient point remains that, under the Coordinated Framework, regulatory agencies in the United States apply the same statutory standards and concomitant regulatory procedures to products of agricultural biotechnology as to products that are genetically modified utilizing traditional methods of plant breeding.

In contrast to the US regulatory system, agricultural biotechnology in the EU is subject to a regulatory regime that is designed to apply specifically to GE food and feed. The EU has been described as having "possibly the most stringent GMO regulations in the world" (where "GMO" is intended to refer to GE food and feed). Davison, J., 178 Plant Science 94–98 (Feb. 2010). Approval of GE crops in the EU is governed by Regulation (EC) 1829/2003 on genetically modified food and feed and the Directive for the deliberate release of GMOs into the environment (Directive 2001/18/EC).

Regulation 1829/2003 establishes the regulatory framework for authorization of GE crops and sets forth the procedures by which authorization may be sought. Because authorization requires both risk assessment by the European Food Safety Authority (EFSA) and approval by the European Commission (Commission), the process can take much longer than in the United States. An example of this is the long-delayed approval of Maize 1507, an insect-resistant variety of corn that was first submitted for approval in July 2001. The applicant, Pioneer Hi-Bred International, Inc., has endured a labyrinthine regulatory process that has yet to result in an authorization for placing Maize 1507 on the market for cultivation in the EU. (For a full account of the lengthy regulatory treatment of Maize 1507, see *Pioneer Hi-Bred International, Inc. v. European Commission* (*Pioneer*), Case T-164/10 (General Court (Seventh Chamber) 26 Sept. 2013), *available at* http://curia.europa.eu/juris/document/document_print.jsf?doclang=EN&text=&pageIndex=0&part=1&mode=lst&docid=142241&occ=first&dir=&cid=127901.)

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In *Pioneer*, the General Court found that the Commission had not "put forward any valid justification for having failed to submit to the Council the proposal for a decision on the placing on the market of maize 1507," despite numerous requests to EFSA to review the application and EFSA's repeated conclusions that, after rigorous scientific examination, there was no evidence that placing Maize 1507 on the market in the EU was likely to have adverse effects on human or animal health or the environment. The Court held that the Commission had "failed to fulfill its obligation to submit, without delay, that proposal to the Council in accordance with Article 5(4) of Decision 1999/468." *Pioneer*, ¶ 58. Thus, the Commission was determined to have failed to properly act on the application as of March 1, 2010. *Id.* ¶ 80.

This case provides a stark illustration of the difficulties faced by technology developers to obtain approval to market GE crops for cultivation in the EU. Less than two months after the General Court's September 26, 2013, ruling in favor of Pioneer Hi-Bred in the Maize 1507 case, the Commission referred the approval request to the EU Council of Ministers, noting that, under the applicable procedures, if the Council is unable to "muster a qualified majority, either for or against the authorisation, then the Commission is obliged by law to grant the authorisation." European Commission Press Release, *GMO: Commission Asks Council to Agree on Its Proposal to Grant Member States More Subsidiarity on Cultivation*, *available at* http://europa.eu/rapid/press-releaseIIP-13-1038_en.htm. At the same time that the Commission requested that the Council act on the Maize 1507 authorization request, it also requested action on a 2010 proposal to amend Directive

2001/18/EC to allow Member States to lawfully restrict or prohibit cultivation of GE organisms based on considerations other than valid scientific assessments of health and the environment. *Id.* The Commission noted that, since the amendment to Directive 2001/18/EC was proposed in 2010, the Council had failed to adopt the proposed revision of Directive 2001/18/EC "due to the blocking position of a minority of Member States." *Id.* The European Union Council of Ministers was unable to reach a qualified majority either for or against the authorization for cultivation of Maize 1507 in the EU. Therefore, "it is up to the Commission to authorise the maize 1507." Council of the EU, Press Release 3292nd Council meeting (11 Feb. 2014), *available at* www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/genaff/140991.pdf. On March 3, 2014, the Council of Ministers agreed to reopen consideration of the draft regulation that would amend Directive 2001/18/EEC to permit Member States to restrict or prohibit cultivation of GE organisms on grounds other than health or environmental safety. *See* www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/141298.pdf.

The difficulty of obtaining approval in the EU for the placing of GE crops on the market for cultivation has impacted decision making by developers of GE crops. In January 2014, EuropaBio reported that nine cultivation dossiers supporting approval of GE crops have been withdrawn from consideration for approval in the EU. *See* www.europabio.org/sites/default/files/position/v3_jan_2014_gm_authorisations_update.pdf ("The continued complete dysfunctionality of the approval process for cultivation in the EU has been illustrated by the withdrawal of 9 cultivation applications."). Currently, there is only one GE crop that is cultivated commercially in the EU—MON 810 maize. The producer of MON 810 maize, Monsanto, has decided to withdraw all of its other pending applications for approval for cultivation for new GE crops in the EU. Reuters, *Monsanto to Withdraw EU Approval Requests for New GMO Crops* (July 17, 2013). These decisions by various technology producers to withdraw from consideration pending applications for cultivation clearly reflect frustration over the substantial difficulties faced in attempting to gain approval for cultivation of new GE varieties in the EU. For example, eight EU Member States have prohibited the cultivation of the authorized variety, MON 810 maize, within their territories, through so-called "safeguard measures." Each one of the safeguard measures submitted to EFSA for review has been determined to be scientifically unfounded.

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Ironically, although there is only one GE crop cultivated in EU, the EU imports large amounts of GE maize for animal feed (more than 30 million metric tons in 2012), and there are currently forty-nine GE foods authorized for food and feed use in the EU. *See* http://ec.europa.eu/food/dyna/gm_register/index_en.cfm. Moreover, the EU has acknowledged that GE foods present no unique risks to human health. G. Marchant, *Counterpoint: The Case Against Mandatory Labeling of GE Food*, 28:2 Nat. Res. & Envt. 11, 12 (2013) (quoting European Commission, *A Decade of EU-Funded GMO Research* (2001–2010)). *See also Statement Complementing the EFSA Opinion on Application EFSA GMO UK 2007 41 (Cotton MON 88913 for Food and Feed Uses, Import and Processing) Taking into Consideration Updated Bioinformatic Analyses*, EFSA Journal 2014; 12(3):3591 (13 Mar. 2014), *available at* www.efsa.europa.eu/en/efsajournal/doc/3591.pdf. (Therefore, the EFSA GMO Panel considers that cotton MON 88913, as assessed in the scientific opinion on application EFSA-GMO-UK-2007-41 (EFSA GMO Panel, 2013) and in the supplementary bioinformatic dataset, is as safe and nutritious as its conventional counterpart and commercial cotton varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses.)

Outside the United States and the EU: Asia and South America

After the United States, the areas with the most hectares of GE crops under cultivation are Asia and South America. Approval and acceptance of GE crops in Asia is mixed. While GE cotton is planted on fairly substantial hectarage, approval and adoption of GE feed and food crops have occurred much more slowly. In India, GE cotton, the first varieties of which were approved in 2002, is cultivated in substantial quantity. In 2013, India planted 11 million hectares of insect-resistant, GE *Bacillus thuringiensis* (*B.t.*) cotton, accounting for 95 percent of cropland planted to cotton in India. James, Clive, *Global Status of Commercialized Biotech/GM Crops: 2013*, International Service for the Acquisition of Agri-biotech Applications Brief No. 46 at 61 (ISAAA 2013). Notwithstanding the success of *B.t.* cotton, there is a significant backlog of regulatory approvals for GE food crops, including brinjal, maize, and rice, and for new cotton varieties. Recently, however, the Indian Agricultural Minister indicated that the Indian government will renew consideration of field trials of GE crops and is committed to the use of biotechnology and other new technologies for agriculture development. *See* http://economictimes.indiatimes.com/news/economy/agriculture/govt-moves-closer-to-allow-field-trials-for-gm-crops-in-india/articleshow/31088625.cms?prtpage=1. In addition, the Department of Biotechnology published for public comment its draft National Biotechnology Development Strategy—2014 (Biotech Strategy II). In addressing the issue of regulation, Biotech Strategy II states: "[it is] important to build a world class regulatory system that is science based, transparent, efficient and dedicated to the safety of consumers and environment." *See* http://dbtindia.nic.in/docs/NBDS_2014.pdf. Biotech Strategy II proposes the establishment of an independent Biotechnology Regulatory Authority to serve as the sole point of entry for safety assessment of GE products and processes.

In China, where the regulatory scheme for GE crops can be described as evolving, *B.t.* cotton received regulatory approval in 1996, has been grown commercially since 1997, and, according to ISAAA 2013, in 2013 was grown on 4.2 million hectares. In addition to *B.t.* cotton, *B.t.* poplar trees and virus-resistant peppers, tomatoes, and papaya were grown commercially in China in 2013. *Id.* at 104. In 2009, the

Ministry of Agriculture granted biosafety certificates for two *B.t.* rice varieties, and a maize variety GE to produce phytase, which enables more efficient uptake of phosphorus and other nutrients from animal feed. To be approved for cultivation, however, the Ministry of Agriculture must also grant certificates permitting cultivation, which it has not done. Thus, it is unclear when the *B.t.* rice and *B.t.* maize varieties will be approved for cultivation in China.

GE maize was first approved in the Philippines in 2003 and in 2013 was estimated to be planted on 800,000 hectares. ISAAA 2013 at 145. As of 2013, there are eight GE maize varieties approved in the Philippines, and it is estimated that approximately 90 percent of the GE maize cultivated in the Philippines are varieties with stacked insect-resistant and herbicide-resistant traits. *Id.* at 147. GE crops currently under development and at the preapproval stage in the Philippines are Golden Rice and *B.t.* brinjal.

In contrast to the somewhat mixed picture in Asia, South America has proven to be much more fertile territory for adoption and cultivation of GE crops. Ten countries in South America grew GE crops in 2013, with Brazil, Argentina, Paraguay, Uruguay, and Bolivia having one million or more hectares of GE crops. ISAAA 2013 at 14. The regulatory systems in these countries have facilitated the adoption of agricultural biotechnologies. Brazil and Argentina rank second and third worldwide in area of cropland planted to GE varieties (trailing only the United States). In 2011, Brazil accounted for 19 percent of worldwide cropland planted to GE crops, and, in 2013 Brazil is estimated to have planted approximately 40 million hectares of GE soybean, corn, and cotton. ISAAA 2013 at 37. Argentina adopted GE crops very early; by 2002, 90 percent of Argentinean soybeans and 50 percent of its corn were genetically engineered. In 2013, Argentina is estimated to have planted approximately 24.4 million hectares of GE crops. ISAAA 2013 at 53. While the hectares planted in Paraguay and Uruguay are much less extensive, 3.6 million and 1.5 million, respectively, they are still significant.

Novel Genetic Technologies

Current regulatory schemes for approval of GE crops typically address production of exogenous proteins by recipient plants. Novel techniques have been developed, however, that do not require the commercialized plant to contain transgenic DNA to confer desirable traits. These novel techniques have the ability to reduce the time needed to develop new crops on the order of years, which, as discussed below, has significant implications for adapting to climate change.

These novel genetic techniques include site-directed nuclease technology, oligonucleotide-directed mutagenesis, RNA interference methodologies, and cisgenetic approaches. Regulatory schemes developed to address GE crops that result from transformation of recipient plant species by exogenous genetic constructs expressing novel proteins may not be appropriate for methodologies that, rather than producing new proteins, effectuate altered phenotypes by altering or regulating the target species' existent genome and modulating normal protein production or other metabolic functions. Moreover, a threshold question is whether certain of these techniques should be subject to regulatory scrutiny at all, because equivalent modifications could be achieved through traditional mutagenesis methods and plant breeding; further, if it is determined that they should, what is the most appropriate and efficient way to go about such regulation. Consider the examples of RNA interference technology and site-directed nuclease mutagenesis. It is possible that these new approaches, as well as others, will require new regulatory thinking. These new technologies enable plant developers to strategically target specific genes. Thus, in contrast to earlier genome bombardment techniques, these methods are far less likely to have unintended effects on the plant. The greater certainty as to the actual effects of these techniques should be reflected in lower regulatory scrutiny being applied to such plants.

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RNA interference (RNAi) technology currently being developed for agricultural purposes operates by suppression of gene expression by double-stranded RNA molecules. RNAi techniques are being developed that utilize genomic constructs expressing gene silencing sequences and/or exogenously applied RNAi that works after transport into the cell nucleus. Both EPA and EFSA are taking proactive steps to address the novel issues raised by RNAi risk assessment. In January 2014, EPA convened a meeting of its FIFRA Science Advisory Panel to address issues related to problem formulation for risk assessment and regulation of RNAi constructs. *See* www.epa.gov/scipoly/sap/meetings/2014/012814meeting.html. EFSA also is taking pro-active steps to address how best to consider the novel risk-assessment issues raised by this new technology. EFSA has scheduled a meeting of leading scientists and risk-assessment experts to discuss (1) RNAi mechanisms in plants, mammals, and invertebrates; (2) current and anticipated RNAi applications in GE plants, and (3) appropriate risk-assessment approaches for such plants. *See* www.efsa.europa.eu/en/events/event/140604.htm. It is encouraging that both of these leading risk-assessment organizations see the necessity for early engagement on these critical questions in an open and transparent fashion that should engender public confidence.

Various nuclease mediated mutagenetic processes have been developed that effectuate highly specific genetic alterations. These technologies, known as site-directed nuclease mutagenesis, can be employed in different ways to effect nucleotide deletions, specific nucleotide sequence alterations (e.g., specific codon changes), or insertion of an entire gene in a precise chromosomal location. These alterations can be heritable and can be utilized to effectuate stable genomic alterations. Examples of site-directed nuclease mutagenetic techniques include meganucleases, zinc-finger nucleases, and transcription activator like effector nucleases (TALENs). *See* Podevin, N., Davies, H., Hartung, F., Nogue, F., and Casacuberta, J., *Site-Directed Nucleases: A Paradigm Shift in Predictable, Knowledge-based Plant Breeding*, 31 Trends in Biotechnology 375 (June 2013). These techniques have been demonstrated to effectively transform crop plants (e.g., meganuclease mutagenesis in maize; TALENs have been used to transform tobacco and rice, and zinc-finger nucleases have been used to transform tobacco and soybean). *Id.*

It will be interesting to see how regulatory bodies that have developed regulatory approaches based upon transgenic technologies will respond to these new technologies and whether they will be up to the task of efficiently and appropriately regulating these products, particularly considering the substantial benefits these technologies may offer in terms of ameliorating the negative impacts of climate change on food production. These more targeted and specific genetic technologies will result in crop plants that, from a risk perspective, inherently present less uncertainty than previous generations of GE crops. This decreased uncertainty as to the potential effects of the genetic alterations should be reflected in the regulatory scrutiny applied to these plants. This is particularly true in those countries, such as the United States, that have implemented a science-based risk assessment regulatory program that objectively evaluates each newly developed crop and make regulatory approval decisions based on objective assessments of the actual risk posed by the crop. Adjusting the regulatory approval process to shorten the time to approval for these products with inherently lower risk potential will enable growers and consumers in such countries to benefit sooner from these improved crop varieties.

Climate Change

As demonstrated by the preceding overview of international regulation of agricultural biotechnology, approval and adoption of these technologies spans a spectrum from almost nonregulated status to total rejection. At the same time, human civilization faces unprecedented environmental challenges, perhaps the most significant of which is climate change. We next examine how agricultural biotechnology has the capacity to substantially ameliorate the risk posed by climate change.

According to the United Nations (UN) World Meteorological Organization, the year 2013 will go down as the sixth-warmest year in history. *See* Feb. 5, 2014, Press Release, "WMO: 2013 Among Top Ten Warmest on Record, *available at* www.wmo.int/pages/mediacentre/press_releases/pr_983_en.html. Independent of these meteorological pronouncements, the effects of agricultural practices on the state of the climate are separately being tracked with the aid of emissions inventory data collected on a worldwide basis. The results of national-level greenhouse gas (GHG) inventories are reported through the United Nations Framework Convention on Climate Change (UNFCCC), and they provide an excellent vantage point from which to evaluate the relationship between climate change, agriculture, and agricultural biotechnology. After the energy sector, agriculture, deforestation, and other land use changes have been the second-largest contributors to GHG emissions. Emission of GHGs in this sector increased by 20 percent from 1970 to 2010 and contributed 20–25 percent of global emissions in 2010. *See* Climate Change 2014: Mitigation of Climate Change, IPCC Working Group III Contribution to the IPCC 5th Assessment Report, Sec. 5.3.5.4, p. 43 (accepted by the 39th Session of the IPCC on 12 Apr. 2014 in Berlin, Germany). Agricultural practices figure into GHG emissions from wastewater discharges, energy, and transportation as well.

As for the agriculture sector, there are further indications that GHG emission contributions will continue on an upward trajectory. The United Nations Food and Agriculture Organization has concluded that GHG emissions from agriculture, forestry, and fisheries have "nearly doubled over the past fifty years and could increase an additional 30 percent by 2050." *See* Agriculture, Forestry and Other Land Use Emissions by Sources and Removals by Sinks, 1990–2011 Analysis, FAO Statistics Division, Working Paper Series, ESS/14-02, Mar. 2014 (FAO Report).

Admittedly, these estimates do not take into account the carbon dioxide (CO2) savings that agriculture ecosystems remove from the atmosphere. At 76 percent of total GHG emissions in 2010, CO2 remains the major target for achieving reductions in emissions. While measuring the amount of CO2 removal is subject to large uncertainty, recent estimates indicate that ecosystems on land remove about twice as much CO2 as is lost by deforestation on a global scale.

Agriculture affects our climate. The inevitable corollary is that changes in the climate on the order of what could occur by 2050 will affect and change agriculture as we know it today. According to the USDA, exposure to temperatures that are 1° to 4° C above optimal reduces vegetable yield, and temperatures more than 5° to 7° C above optimal can cause severe or total production loss. *See* Climate Change and Agriculture in the United States: Effects and Adaptation, Tech. Bulletin 1935, Feb. 2013. Average surface temperatures globally have increased by about 0.8° C since 1900, and additional temperature shifts of between 2.6° to 4.8° C could occur if GHG emissions continue without abatement by 2050. *See* Climate Change Evidence & Causes, An Overview from The Royal Society and the National Academy of Sciences, Feb. 2014, *available at* http://dels.nas.edu/resources/static-assets/exec-office-other/climate-change-full.pdf (NAS 2014 Report on Climate Change). The predicted increase in average temperature will shift precipitation and crop production to higher latitude, temperate regions where the growing seasons will become longer than they are right now. Where heat already limits production in subtropical and tropical areas, these lower latitude regions of the world (think of the state of Florida in the United States and parts of Asia) may experience long spells of drought as average rainfalls decrease by approximately 20 percent. In a recently published study, the International Food Policy Research Institute used agricultural crop production modeling combined with economic modeling to assess the potential impacts of climate change on global agricultural productivity for maize, rice, and wheat. The results showed decreased yields by 2050, when compared to 2010 yields, ranging from 2.6 to 16.5 percent for maize; 14.9 to 24.8 percent for rice; and 7.9 to 10.8 percent for wheat. *See* M.W. Rosegrant, J. Koo, N. Cenacchi,, C. Ringler, R. Robertson, M. Fisher, C. Cox, K. Garrett, N. Perez, and P. Sabbagh, *Food Security in a World of Natural Resource Scarcity* at 57, International Food Policy Research Institute (Mar. 2014).

As of 2012, almost 40 percent of the world population of 6.7 billion, equivalent to 2.5 billion people, relied on agriculture for their livelihood. As the world's population continues to climb toward nine billion by 2050, temperature shifts, altered precipitation patterns, insect and weed infestation, soil quality and erosion, water quality, species pollination, and extreme weather events will necessitate changes in cultivation practices and locations and could displace sizable portions of this demographic in search of jobs and food.

Agricultural biotechnology holds promise for mitigating the effects of climate change and corresponding shifts in population in at least three significant respects. First, plants and soils have a central role to play in carbon sequestration. Photosynthesis by terrestrial plants provides a natural "sink" for accumulating and storing carbon-containing chemical compounds for indefinite periods of time. Conversion of grassland to cropland contributes to the decomposition of soil organic matter, soil erosion, and results in a net loss of carbon from the soil. Soils contain more carbon than all terrestrial vegetation and the atmosphere combined. Swift, Roger S., *"Sequestration of Carbon by Soil,"* Soil Science 166 (11): 858–71 (Nov. 2001); Batjes, Niels H., *"Total Carbon and Nitrogen in the Soils of the World,"* European Journal of Soil Science 47 (2): 151–63 (1996). Public awareness of the significance of carbon sequestration by natural CO2 sinks has grown since passage of the Kyoto Protocol, which promotes their use as a form of carbon offset. Increasing crop yields through agricultural biotechnology lowers the amount of carbon that is released from the soil from harvest to planting. Higher yields lessen deforestation pressures and reduce soil erosion by allowing agriculture to devote more land to "no-till" farming practices, in which soil is left relatively undisturbed. Commercialized herbicide-tolerant soybean, corn, cotton, and canola are among the important biotech crops that are already contributing to the reduction of CO2 emissions due to reduction in tilling practices

Second, higher-yield and pest-resistant crop species reduce our use of carbon-intensive inputs—fuels and other chemicals such as insecticides. According to experts, GE crop adoption can reduce fuel consumption by 19 percent on average. *See* Sexton, S. and Zilberman, D. Agricultural and Resource Economics Update, V. 14 No. 2, p. 3 (Univ. of Calif. Nov/Dec. 2010). This is an area in need of attention, with emissions from electricity and fossil fuels burned to power agricultural machinery and irrigation pumps having increased by 75 percent since 1990. *See* FAO Report.

Field trials and farmer surveys indicate that overall pesticide use declines with the use of GE crops. These crops, which include important varieties of cotton and corn, produce their own pesticides and, thus, reduce carbon emissions as pesticides do not have to be manufactured, shipped, and applied. Because elevated CO2 levels will stimulate insect pressure, it will be important to be able to respond to these changing conditions through the use of pest-resistant crop varieties. Sexton and Zilberman report that carbon emissions associated with production, packaging, and transport of agrochemicals could be reduced in the United States through the use of GM cotton in an amount equivalent to removing 23,000 cars from the road.

Third, climate change, through shifts in our agricultural landscape, threatens food security on a global scale. Severe weather elsewhere affects domestic pricing and availability due to the global nature of agriculture production and demand. By mid-century, the state of California, one of the largest and most productive agricultural regions in the world, may not sustain the temperatures necessary for the growth of fruit and nut trees. *See* Climate Change and Agriculture in the United States: Effects and Adaptation, *Tech. Bull.* 1935, p. 3, USDA, Feb. 2013. The global interdependence of agriculture creates a transcending need to be ready to adapt *wherever* shifts in climate conditions take place in important agricultural regions. The traditional cultivation of new crops to meet new conditions commonly requires fifteen to thirty years to develop. That puts us right on the brink of severe predicted climate change. Assuming regulatory accommodation, the novel breeding techniques discussed above that reduce the time to develop new crops on the order of years may be essential to adapt crops to these changing environmental conditions.

Through the Water Efficient Maize for Africa (WEMA) project, for example, drought-tolerant corn varieties developed through marker-assisted breeding could be available to farmers within the next two or three years. While not a genetic engineering technique, per se, marker-assisted breeding makes traditional breeding more efficient. Maize varieties that are both drought-tolerant and insect-protected are being developed using both advanced breeding and transgenic approaches and could be available to farmers in the latter part of the decade. *See* www.monsanto.com/ourcommitments/pages/water-efficient-maize-for-africa.aspx.

Rice is a matter of life to much of the world. Every year, about 4 million tons of rice are lost due to flooding—enough to feed 30 million people. A flood-resistant gene discovered thirteen years ago in a low-yield Indian rice variety may hold the key to reversing such losses. By introducing the gene into rice crops with better yields, researchers at the University of California have developed rice that can withstand submersion in water for extended periods. Field trials have demonstrated the potential for three-to-five-fold increases in yield, allowing farmers to produce more food for consumption.

Policy Recommendations

Climate change is not likely to be halted in any meaningful way in the immediate future and, even if governments could manage to reduce GHG emissions in significant ways, temperatures and sea level would continue to rise for several more years based on lingering effects from the historic creation and sequestration of GHGs. NAS 2014 Report on Climate Change, p 22. Agricultural strategies, thus, will be needed to produce more food under more agronomically stressful conditions than we experience at present, with a smaller overall carbon footprint. Traditional approaches almost certainly will be insufficient alone to effectively and efficiently manage the supply of food needed to feed a growing worldwide population. Here are three initiatives to integrate agricultural biotechnology into the response to climate change.

Worldwide, transparent and democratic conversations should be undertaken on effective governance of agricultural biotechnology to mitigate climate change.

The Cartagena Protocol on Biosafety defines "modern biotechnology" narrowly as the application of:

1. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
2. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in

traditional breeding and selection.

Secretariat of the Convention on Biological Diversity, 2000, *available at* http://bch.cbd.int/protocol/publications/cartagena-protocol-en.pdf.

This definition has been adopted with a fair degree of consistency by regulators around the globe, many of which have demanding premarket approval regimes.

The precision and versatility of biotechnology will, if given the opportunity, permit nations throughout the world to be ready to respond to both extended periods of drought and more severe rainfall conditions. Yet currently, certain civil society organizations, or nongovernmental organizations (NGOs), are critical of biotechnology. Many of these groups focus on the threat that biotechnology will be misused. But misuse of biotechnology can be policed and prevented by appropriate regulation. The threat to the world's food supply from climate change will not be mitigated unless all stakeholders, including NGOs, focus on the benefits that agricultural biotechnology can provide to preserve and enhance food supplies on a warming planet.

NGOs and those governments with highly restrictive policies that discourage the introduction of any biotechnology products regardless of safety face an ethical dilemma. The responsible use of agricultural biotechnology promotes both human rights and environmental protection. There are moral implications in marginalizing one of the most promising ways of ensuring an adequate food supply for a growing global population facing effects from climate change that will be transformative. Continued education is essential to develop the support that may be needed to allow advances in agricultural biotechnology to meet societal values of fighting poverty and starvation and promoting food nutrition and security.

A coordinated international approach is needed to harness the potential of emerging technologies to take on the challenges of climate change.

The National Academy of Sciences calls climate change "one of the defining issues of our time." NAS 2014 Report on Climate Change, Forward. In 2008, the top CO2 emitters due to industrial and energy-related activities were China, the United States, the European Union, India, the Russian Federation, Japan, and Canada. Together, these sources represent a large proportion of total global emissions. At the same time, tropical deforestation in Africa, Asia, and South America is largely contributing to total GHG emissions attributable to land-use change.

Each of these countries is a member of the UNFCCC, an organization that has international cooperation on addressing climate change as its focus. By participating in UNFCC, countries agree to (1) gather and share information on GHG emissions, national policies, and best practices; (2) launch national strategies for addressing GHG emissions, including the provision of financial and technological support to developing countries; and (3) cooperate in preparing for changes required to adapt to the effects of climate change. In 1995, negotiations to strengthen the global response to climate change led to the adoption of the Kyoto Protocol. The major feature of the Kyoto Protocol is binding GHG reduction targets for thirty-seven industrialized countries and the European community. The Protocol's first commitment period started in 2008 and ended in 2012. The second commitment period began on January 1, 2013, and will end in 2020. There are now 195 Parties to the UNCFCC and 192 Parties to the Kyoto Protocol.

UNFCC has a track record of supporting private-sector initiatives designed to help crops adapt to changing climates. The organization clearly recognizes that biotechnology has a role in addressing climate change, stating the following in one of its reports:

> One of the main focuses of international research for adaptation to climate change will be the search for a new generation of crop varieties. Much of the increase in yields in recent decades resulted from improved management practices, irrigation and increased use of fertilizers or other inputs, but around half was due to genetic improvements in crop varieties.

Technologies for Adaption to Climate Change, UNFCCC, p. 24 (2006).

These recent advances in agriculture have climate tradeoffs. In its March 2014 report, the FAO points to emissions generated during the application of synthetic fertilizers as the fastest-growing emission source in agriculture, accounting for 13 percent of agricultural emissions in 2011.

With the need to adapt and mitigate the effects of climate change, a coordinated, "wise-use" public policy approach to biotechnology, one that makes full use of the benefits of biotechnology while working to understand and manage any associated potential risks, should be advanced at the international government level. The UNFCCC offers an important platform for countries and the private sector to cooperate on agricultural biotechnology research within the specific context of climate change. A formal UNFCCC policy statement dedicated to the positive role of, and need for, advances in biotechnology to address climate change would be beneficial for both agriculture and our climate.

Ensure that emerging technologies with negligible net atmospheric and environmental impact are not subject to unnecessary regulation.

Modern biosafety guidelines have as their common origin the 1975 Asilomar Conference on Recombinant DNA, an influential conference held in California that was organized to discuss the potential biohazards and regulation of biotechnology. The highly respected and widely adopted US National Institutes of Health (NIH) Biosafety Guidelines emerged from the work that began at Asilomar. Since that time, voluntary adoption of the NIH guidelines and its international counterparts have been a primary oversight tool for research affiliated with universities, government institutions, and private firms involving biotechnology. Overlaying these biosafety principles are a complex and diverse set of national regulatory frameworks. After almost twenty years of worldwide regulatory approvals and safe human consumption, it is clear that GE crops should be subject to a science-based regulatory process rather than a politically driven one. The science strongly supports the safe use and consumption of the GE crops on the market in addition to their carbon reduction potential, and current regulatory schemes are far stricter than is justified. It is important for there to be coordination and harmonization of regulations if biotechnology is to be used effectively as one of the critical tools to address climate change.

A memorandum issued by the US Office of Science and Technology Policy (OSTP) in 2011 includes the need for science-based principles in the governance of emerging technologies. The OSTP guiding set of principles offers a blueprint to advance a more harmonized regulatory approach. Mar. 11, 2011 Memorandum for The Heads Of Executive Departments and Agencies, Principles for Regulation and Oversight of Emerging Technologies. In it, the US government is challenged to "encourage coordinated and collaborative research across the international community" and to "clearly communicate the regulatory approaches and understanding of the United States to other nations." This includes promoting informed choices and sharing information with respect to the benefits and costs of regulation and oversight. Among the regulatory principles to be advanced are the following: (1) Decisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency; (2) Regulations should be developed with a firm commitment to fair notice and to public participation; (3) The benefits of regulation should justify the costs (to the extent permitted by law and recognizing the relevance of uncertainty and the limits of quantification and monetary equivalents);(4) Where possible, regulatory approaches should promote innovation while also advancing regulatory objectives, such as protection of health, the environment, and safety; (5) When no significant oversight issue based on a sufficiently distinguishing attribute of the technology or the relevant application can be identified, agencies should consider the option not to regulate; and (6) Where possible, regulatory approaches should be performance-based and provide predictability and flexibility in the face of fresh evidence and evolving information.

As a practical matter, these principles could be adopted in the form of a globally harmonized framework system of rules that foster the development of agricultural biotechnology products with negligible net atmospheric and environmental impact, so that they are not subject to an unnecessary and lengthy degree of oversight regulation prior to their introduction. For example, products obtained through emerging novel genetic technologies and breeding techniques should be excluded from typical regulatory oversight applicable to GE organisms if the genetic material of the final commercial plants and their offspring do not contain any inserted foreign DNA (transgenes), when the alteration in the final commercial plant (intended and unintended) induced by the technique could be produced by a traditional technique, natural process, or technique exempt from regulatory GE definitions, and when the final commercial plant cannot be distinguished from non-GE strains. Policies that ensure that new technologies do not encounter unnecessary government roadblocks, such as repeated notification requirements for identical products, should be encouraged and coordinated as far in advance as possible.

Conclusion

National climate change policies consistently recognize agriculture as a key climate-sensitive sector. The significant changes to existing climate conditions that are predicted to occur by 2050 will take place at approximately the same time as the planet's population reaches nine billion people. In the interest of food security alone, agriculture needs to be climate-ready. The preponderance of evidence indicates that agricultural biotechnology will be an indispensable tool against the extremes of climate change. President Barack Obama, in a recent letter to the granddaughter of Dr. Norman Borlaug, an American biologist and Nobel laureate honored for his work to increase agricultural production worldwide, clearly expressed the policy of the United States to continue to investigate, promote, and implement science-based agricultural solutions for the challenges of climate change:

> While I was running for President, your grandfather wrote to me about the importance of agricultural development. I share his belief that investment in enhanced biotechnology is an essential component of the solution to some of our planet's most pressing agricultural problems. Through our new regional climate change hubs, we will use the sorts of technologies pioneered by your grandfather to help farmers and ranchers face the climate challenges ahead. And I will continue to work with the Department of Agriculture and others to explore innovative solutions to address food security challenges and mitigate the effects of climate change.

See Pres. Barack H. Obama, Letter to Ms. Julie Borlaug (Apr. 11, 2014), *available at* www.agri-pulse.com/uploaded/Borlaug_Letter.pdf.

Led by the United States and other nations with objective, science-based approaches to agricultural biotechnology, the world must harness the spirit of international cooperation in the face of the challenges posed by climate change and fully recognize the important role of agricultural biotechnology in addressing and mitigating these challenges. Enhancing agriculture's ability to respond through advances in biotechnology must be part of an integrated, resilient, and international approach to climate change.