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Feeding the World: How Changes in Biotech Regulation Can Jump-Start the Second Green Revolution and Diversify the Agricultural Industry

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FEEDING THE WORLD: HOW CHANGES IN BIOTECH REGULATION CAN JUMP-START THE SECOND GREEN REVOLUTION AND DIVERSIFY THE AGRICULTURAL INDUSTRY

JOHN A. ERWIN* & ROBERT GLENNON**

As the Earth's population climbs from 7.7 billion in 2019 to almost 10 billion by mid-century, farmers will need to increase food production by 70 percent. This Article analyzes the tools available to achieve this demanding goal. We assess changes in agriculture related to both the organic industry and the high-tech sector that are enabling farmers to become more efficient. Critically, biotechnology offers great promise to hasten the pace of increased agricultural efficiency through genetic engineering. While genetic modification has been controversial, we cannot exclude any viable policy option, especially one with so much promise. Yet the current regulatory environment impedes bringing to market new foods produced through biotechnology and acts as a barrier to diversity for both products and producers.

Our argument is straightforward: in a world of risk versus promise, the regulation of biotechnology must be correlated with the level of risk. We advocate for a system of regulation of crops based on risk—one that is tied to the product itself, not the process that created it. The complicated, expensive, and time-consuming process currently imposed on bringing genetically engineered crops to market is divorced from the potential risks these crops actually pose. We specifically suggest adopting a single-entry point to the regulatory system, creating a registry of genetically engineered products to avoid the public perception issues that genetically modified organisms ("GMOs") have faced to date, and shifting regulatory triggers to better associate the regulatory burden with the actual risks being put forth. Proposals by the Trump Administration in June 2019 may move regulation in the direction we have suggested, but these proposed rules present other issues. A second Green Revolution that embraces the most promising available technology can help free the future of agriculture from the control of dominant agrochemical companies and help feed the world.

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The first essential component of social justice is adequate food for all mankind.[1]

[T]he world has the technology that is either available or well advanced in the research pipeline to feed a population of 10 billion people. The more pertinent question today is: Will farmers and ranchers be permitted to use this new technology?[2]

–Dr. Norman Borlaug, Nobel Peace Prize Laureate (1970)

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[1] Norman Borlaug, The Green Revolution, Peace, and Humanity, Nobel Lecture (Dec. 11, 1970) (transcript available at https://www.nobelprize.org/prizes/peace/1970/borlaug/lecture/ [https://perma.cc/73BA-ZTC8]).
[2] Norman E. Borlaug, *Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry*, 124 PLANT PHYSIOLOGY 487, 490 (2000).

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INTRODUCTION

As the Earth's population climbs from 7.7 billion in 2019 to almost 10 billion by mid-century,[3] the United Nations Food and Agriculture Organization estimates that farmers will need to increase crop production by up to 70 percent.[4] The most recent IPCC report paints an equally bleak picture—demonstrating that our land and water resources are being exploited at "unprecedented rates."[5] Achieving this goal will require an unparalleled commitment of human energy, imagination, resources, and empathy.[6]

Over the last half century, farmers made extraordinary progress in becoming more efficient and increasing production.[7] Consumers, especially in the United States, have benefitted from food prices that have never been so low.[8] The fate of hundreds of millions of people, many in the developing world, depend on farmers being able to do it again. And they must do so in the face of enormous challenges.

Water shortages currently exist across broad swaths of the planet.[9] Diversions have dried up many rivers.[10] Industrial and agricultural

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[3] U.N. DEP'T OF ECON. & SOC. AFFAIRS, WORLD POPULATION PROSPECTS 2019: DATA BOOKLET 1 (2019) [hereinafter U.N. REPORT].

[4] Mitchell C. Hunter et al., *Agriculture in 2050: Recalibrating Targets for Sustainable Intensification*, 67 BIOSCIENCE 386, 386–87 (2017).

[5] *See* INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, IPCC SPECIAL REPORT ON CLIMATE CHANGE, DESERTIFICATION, LAND DEGRADATION, SUSTAINABLE LAND MANAGEMENT, FOOD SECURITY, AND GREENHOUSE GAS FLUXES IN TERRESTRIAL ECOSYSTEMS: SUMMARY FOR POLICYMAKERS 2 (Aug. 7, 2018), https://www.ipcc.ch/site/assets/uploads/2019/08/4.-SPM_Approved_Microsite_FINAL.pdf [https://perma.cc/2NMQ-PYD7] [hereinafter IPCC]; Christopher Flavelle, *Climate Change Threatens the World's Food Supply, United Nations Warns*, N.Y. TIMES (Aug. 8, 2019), https://www.nytimes.com/2019/08/08/climate/climate-change-food-supply.html [https://perma.cc/844N-JJ3U].

[6] *See generally* AMANDA LITTLE, THE FATE OF FOOD: WHAT WE'LL EAT IN A BIGGER, HOTTER, SMARTER WORLD (2019).

[7] *International Agricultural Productivity*, ECON. RES. SERV., USDA, https://www.ers.usda.gov/data-products/international-agricultural-productivity/ [https://perma.cc/W87G-3KUH] (last updated Nov. 21, 2019).

[8] ROBERT GLENNON, UNQUENCHABLE: AMERICA'S WATER CRISIS AND WHAT TO DO ABOUT IT 276 (2009).

[9] Somini Sengupta & Weiyi Cai, *A Quarter of Humanity Faces Looming Water Crises*, N.Y. TIMES (Aug. 6, 2019), https://www.nytimes.com/interactive/2019/08/06/climate/world-water-stress.html [https://perma.cc/3EFP-V824].

[10] Katherine Nightingale, *World's major rivers 'drying up,'* SCIDEV.NET (Apr. 22, 2009),

chemicals have polluted entire water systems.[11] Groundwater pumping greatly exceeds sustainable quantities.[12] Climate change will worsen conditions in already-stressed areas, and more water will be required to replicate today's level of production. To compound matters, farmers face competition for water from municipal and industrial users.[13] Population growth is causing a conversion of agricultural land into residential, commercial, and industrial buildings.

The arithmetic is not complicated: farmers need to almost double production with less water and less land!

These conditions have unleashed a global competition to acquire more farmland,[14] which exacerbates political instability. Food security is becoming national security. The good news is that we have a toolkit of viable policy options to help us address these challenges.

Solutions include water conservation, which remains the lowest-hanging fruit. Reuse of the water we already have must be an important part of the future. We should use price signals to encourage conservation and market forces to encourage investment in water infrastructure. We need to preserve high-quality agricultural land from development. Improved agricultural practices, such as "no till," can help increase crop yields.[15] The high-tech sector needs to be engaged to create disruptive technologies that harness the power of data to give farmers the information they need to become more efficient. Education should play a critical role in helping to lower birth rates, thus reducing the pace of population growth.

Critically, the allure of biotechnology offers great promise to hasten the pace of increased agricultural efficiency. Yes, "GMOs" are controversial in some quarters. But, with a problem of this scale, we cannot exclude any viable policy option, especially those with such great potential. Yet the current regulatory environment impedes bringing to market new

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https://www.scidev.net/global/watr/news/world-s-major-rivers-drying-up-.html [https://perma.cc/W66K-T28Q].

[11] *World Water Day 2001: Pollution from Industry, Mining and Agriculture*, WORLD HEALTH ORG. (May 2002), https://www.who.int/water_sanitation_health/en/industrypollution.html [https://perma.cc/26UM-3DM4].

[12] Sengupta & Cai, *supra* note 9.

[13] LESTER R. BROWN, PLAN B 4.0: MOBILIZING TO SAVE CIVILIZATION 41–42 (2009).

[14] *See* THE GLOBAL FARMS RACE: LAND GRABS, AGRICULTURAL INVESTMENT, AND THE SCRAMBLE FOR FOOD SECURITY 2, 4 (Michael Kugelman & Susan L. Levenstein eds., 2012) [hereinafter THE GLOBAL FARMS RACE].

[15] Stefanie Spears, *What is No-Till Farming?*, REGENERATION INT'L (June 24, 2018), https://regenerationinternational.org/2018/06/24/no-till-farming/ [https://perma.cc/52KX-RLEC].

foods produced through biotechnology and perpetuates an oligopolistic market of well-heeled companies.

This Article, first, will examine the challenges to meeting the U.N. goal of increasing food production by 70 percent. Second, it will explore the solutions or policies that can help meet that goal. Third, it will consider the debate over biotechnology, by examining the benefits and the resistance to using genetic modification for manipulating our food supply. Fourth, we will examine the current state of regulations relating to genetic engineering, focusing both on traditional GMOs and novel gene editing ("GE") techniques such as CRISPR/Cas. Fifth, we will propose modifications to help guide us towards these lofty goals for food production and compare our proposal to the most recent proposed rules put forth by the Trump Administration.

Our argument is straightforward: in a world of risk versus promise, the risk involved in allowing greater access to biotechnological products does not warrant the complicated, expensive, and time-consuming process currently imposed on bringing genetically engineered crops to market. The desire to protect against unknown perils has generated unintended consequences that profoundly limit the capacity of genetic engineering to solve the world's food crisis. The transition from traditional transgenic methods of genetic modification to the modern methods of genetic editing has already begun to open up new markets and new loopholes to regulation, and now is clearly the time to address these issues. When both the Obama Administration and the Trump Administration agree that the regulatory system needs updating, it is past time to revise the process.[16]

We advocate for a system of regulation of crops based on risk—one that is tied to the specific and innate qualities of each product, not the specter of harm associated with the process that created it.[17] This risk-based system would incorporate novelty and use the agencies' extensive experience with certain kinds of products to reduce superfluous review of products that are substantially similar to those already reviewed and to catch novel products that can slip through the cracks under the current

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[16] For the Obama era memorandum, see Memorandum from John P. Holdren et al. on Modernizing the Regulatory System for Biotechnology Products to the Heads of Food and Drug Administration, Environmental Protections Agency, and Department of Agriculture (July 2, 2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf [https://perma.cc/5YZN-ET55] [hereinafter Obama Memorandum]. For the Trump era Executive Order, see Exec. Order No. 13,874, 84 Fed. Reg. 27,899 (2019).

[17] *See* Gregory Conko et al., *A Risk-Based Approach to the Regulation of Genetically Engineered Organisms*, 34 NATURE BIOTECHNOLOGY 493, 495 (2016).

regulatory scheme. We suggest streamlining and unifying entry into the regulatory system by creating a single-entry system. We also suggest modifying current regulatory triggers to better incorporate risk and to close loopholes to current regulation. Finally, while the 2019 draft regulations put forth by the Trump Administration are positive steps forward, we will highlight the pitfalls in them.

In light of the rise and proliferation of gene editing technologies,[18] the next phase of biotechnology regulation should serve as a springboard for the Green Revolution 2.0. Dr. Norman Borlaug is credited with saving over a billion people through applying cutting edge biotechnology to create crops that could feed the world.[19] But in the years subsequent to Dr. Borlaug's revolution, agriculture moved from the realm of land grant universities and philanthropic contributions to a corporate world that is the modern agricultural industry—with Big Agriculture ("Big Ag") and its GMOs squaring off in the ring of public opinion against the rising tide of organic farming.[20] But gene editing has the potential to change everything. With proper regulation, we could witness the immense promise of genetic engineering, a promise that GMOs have by largely failed to realize.

I. CHALLENGES

Looking at a graph of the Earth's population growth offers a stark insight.[21] Humans have populated the planet for nearly two million years, but the increase from four billion to seven billion took less than forty years.[22] As demographers sketch population growth rate scenarios, from rapid to slow, the next couple billion people will join us in a very short period of time.[23] Move a couple of variables in the model a decimal point and the numbers look positively catastrophic. The point is not that this gloomy, Malthusian forecast will come true, but that population growth is now an urgent problem that threatens human health and life and is generating political instability and conflict.

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[18] Ashley P. Taylor, *Companies Use CRISPR to Improve Crops*, SCIENTIST MAG. (Feb. 1, 2019), https://www.the-scientist.com/bio-business/companis-use-crispr-to-improve-crops-65632 [https://perma.cc/EXA4-RWXF].

[19] Kenneth M. Quinn, *Extended Biography*, WORLD FOOD PRIZE (2009), https://www.worldfoodprize.org/en/dr_norman_e_borlaug/extended_biography/ [https://perma.cc/98ZB-9PPV].

[20] *See* GEORGE R. MCDOWELL, LAND-GRANT UNIVERSITIES AND EXTENSIONS: INTO THE 21ST CENTURY 84–89 (2001).

[21] *See* Figure 1.

[22] Max Roser et al., *World Population Growth*, OUR WORLD DATA (May 2019), https://ourworldindata.org/world-population-growth [https://perma.cc/Y7ZF-BU32].

[23] *Id.*

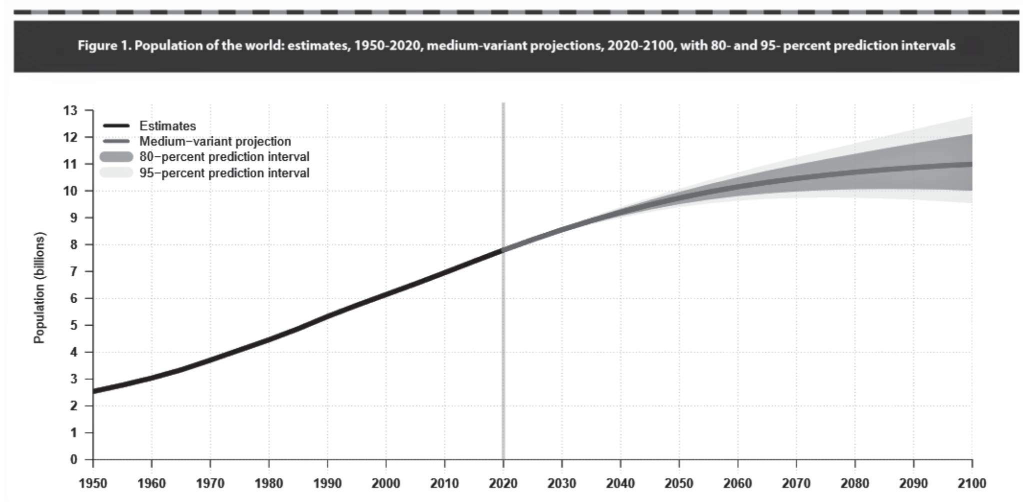

Figure 1: Population of the world: estimates, 1950–2020, medium-variant projections, 2020–2100, with 80–95 percent prediction intervals from the United Nations' World Population Prospects 2019: Data Booklet[24]

As the temperature of the Earth increases, it will require farmers to use *more* water to produce the *same* amount of food.[25] Warmer temperatures impede seed germination, alter seasonal patterns for some crops, and introduce unknowns into the process of being a farmer.[26] Climate change will compromise water supplies in some areas with lower levels of precipitation by reducing snow packs in mountains (which serve as storage areas in the American West), and by causing higher rates of evaporation due to earlier runoff.[27] Our infrastructure for storing water was built on a model of seasonal rainfall that is no longer accurate. The Oroville Dam crisis in California in 2016 vividly demonstrated that the American West needs to prepare for higher runoff levels due to more precipitation coming from rain than from snow.[28] Catastrophic forest fires recently destroyed an entire town, Paradise, CA, and burned over one hundred thousand acres

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[24] U.N. REPORT, *supra* note 3, at 1.

[25] Bureau of Reclamation, U.S. Dep't of the Interior, *Colorado River Basin Water Supply and Demand Study,* RECLAMATION, Dec. 2012, at 7, 25.

[26] USDA, CLIMATE CHANGE AND AGRICULTURE IN THE UNITED STATES: EFFECTS AND ADAPTATION 4–5 (2013).

[27] GLENNON, *supra* note 8, at 61–64.

[28] Noah S. Diffenbaugh, *What California's Dam Crisis Says About the Changing Climate*, N.Y. TIMES (Feb. 14, 2017), https://www.nytimes.com/2017/02/14/opinion/what-californias-dam-crisis-says-about-the-changing-climate.html [https://perma.cc/KZL4-EU4T].

of land that store water as snowpack.[29] The fires will result not only in horrendous quantities of ash to wash into rivers and lakes, but also impair the capacity of forests to store water for municipal and agricultural uses.

Were these challenges not enough, our current water use is unsustainable. This is particularly true with respect to excessive groundwater pumping.[30] Groundwater has accumulated in underground geological formations over thousands of years, but in parts of the world, we've exhausted this supply in mere decades.[31] Nowhere is this more acute than in China and India, the two countries with the largest populations.[32] Unrestricted access to a finite resource has created a classic "tragedy of the commons."[33]

Less water will be available when farmers need more water. And farmers are facing competition for the water they currently use. As an illustration, consider the growth in the production of biofuels, especially ethanol. Produced from corn, ethanol takes a lot of water.[34] And farmers and food processors would have used most of this corn as feed for animals, as corn syrup in soft drinks, or as an ingredient in pretty much everything that comes in a can or a jar.[35] In 2014, farmers across the globe dedicated more than 155 million acres to production of biofuels.[36]

A bright aspect of recent global economic history has been the rise of emerging economies in Brazil, Russia, India, and China, known as the

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[29] Jack Nicas & Thomas Fuller, *Wildfire Becomes Deadliest in California History*, N.Y. TIMES (Nov. 12, 2018), https://www.nytimes.com/2018/11/12/us/california-fires-camp-fire.html [https://perma.cc/48YR-5RYC].

[30] Alexandra S. Richey et al., *Quantifying Renewable Groundwater Stress with GRACE*, 51 WATER RESOURCES RES. 5217, 5218 (2015); Alexandra S. Richey et al., *Uncertainty in Global Groundwater Storage Estimates in a Total Groundwater Stress Framework*, 51 WATER RESOURCES RES. 5198, 5198–99 (2015).

[31] Dennis Dimick, *If You Think the Water Crisis Can't Get Worse, Wait Until the Aquifers Are Drained*, NAT'L GEOGRAPHIC (Aug. 21, 2014), https://www.nationalgeographic.com/news/2014/8/140819-groundwater-california-drought-aquifers-hidden-crisis/ [https://perma.cc/8DS3-5ASR].

[32] *See The struggle over water in India and China*, ECONOMIST (Jan. 5, 2019), https://www.economist.com/books-and-arts/2019/01/05/the-struggle-over-water-in-india-and-china [https://perma.cc/3SFM-KSDY] (reviewing SUNIL AMRITH, UNRULY WATERS: HOW RAINS, RIVERS, COASTS AND SEAS HAVE SHAPED ASIA'S HISTORY (2018)).

[33] Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243, 1244–45 (1968).

[34] GLENNON, *supra* note 8, at 51–56.

[35] *Id.* at 52.

[36] *How much Farmland is used for Biofuel?*, HUNGER MATH (Oct. 29, 2015), https://hungermath.wordpress.com/2015/10/29/how-much-farmland-is-used-for-biofuel/ [https://perma.cc/SVR6-W2ZH]; *see also* Jonathan A. Foley et al., *Solutions for a Cultivated Planet*, 478 NATURE 337, 341 (2011).

BRIC countries or economies. These and other emerging economies have seen a rising standard of living as per capita incomes have dramatically risen.[37] Accompanying this economic growth has been a change in diets. As people become more affluent, their taste for meat products increases. Economists predict that due to increased consumption of meat products, the production of pork, beef, and poultry will double globally by 2020.[38]

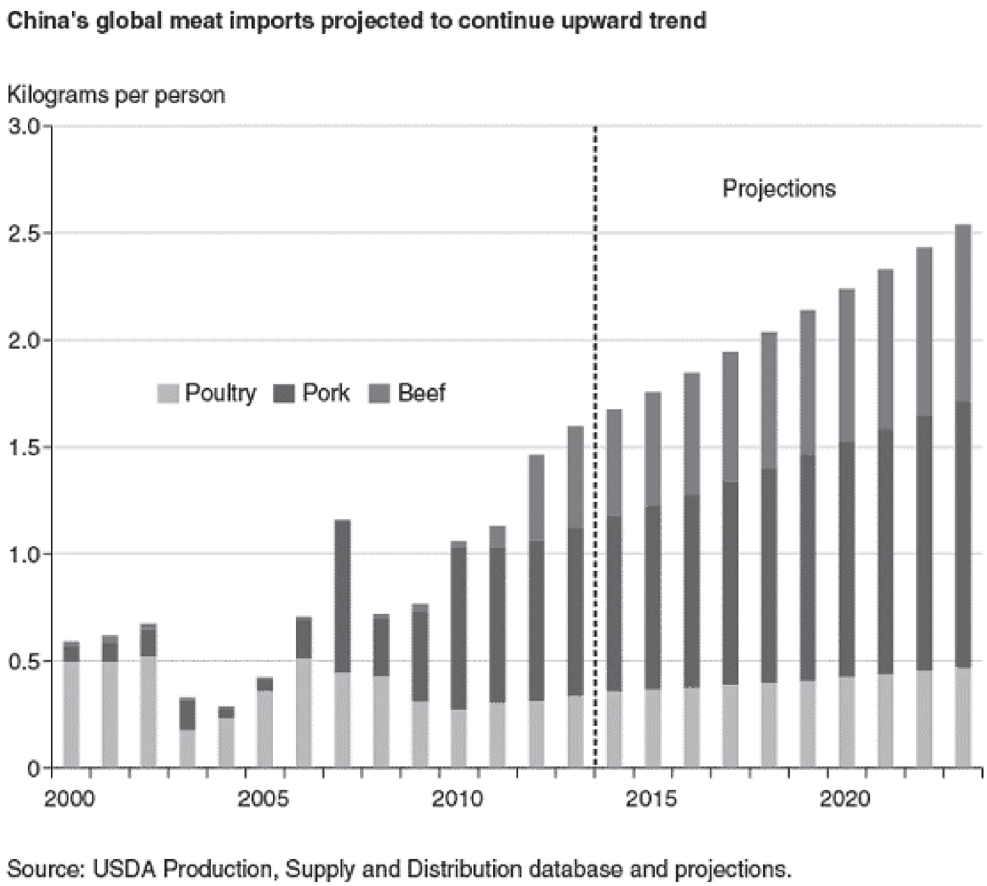

Figure 2: China's global meat imports are projected to more than double from 2010 to 2020 and this is an example of the growing trend of worldwide

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[37] *See* NEW DEV. BANK, THE ROLE OF BRICS IN THE WORLD ECONOMY & INTERNATIONAL DEVELOPMENT 11, 18–19, 44 (2017); *BRICS countries well placed for a leadership role in helping eradicate global hunger and poverty by 2030*, U.N. FOOD & AGRIC. ORG. (June 16, 2017), http://www.fao.org/americas/noticias/ver/en/c/896244/ [https://perma.cc/R66F-RTDG].

[38] Zoran Petrovic et al., *Meat Production and Consumption: Environmental Consequences*, 5 PROCEDIA FOOD SCI. 235, 235–36 (2010).

meat consumption; data made available by the USDA Production, Supply and Distribution database and projections[39]

The downside is that it takes more land and more water to produce meat than it does grains and other foodstuffs.[40] These dietary shifts add another component to the challenge facing farmers to increase production by 70 percent.

As a population grows, cities need more land for housing and more water for various domestic, municipal, and industrial uses—including power production. When cities and industry need more water, the best and cheapest place to find it is in agriculture. Farmers use between 70 and 80 percent of the world's water,[41] often to grow low-value crops, such as alfalfa.[42] Hence, they are the natural potential source of new water for other users.

The conversion of high-quality agricultural land to municipal and industrial uses poses a vexing problem for farmers to meet the U.N. goal of 70 percent more food by 2050. From the Central Valley in California to the Punjab in India, a frightening amount of farmland is being converted to other uses.[43]

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[39] James Hansen & Fred Gale, *China in the Next Decade: Rising Meat Demand and Growing Imports of Feed*, ECON. RES. SERV., USDA (Apr. 7, 2014), https://www.ers.usda.gov/amber-waves/2014/april/china-in-the-next-decade-rising-meat-demand-and-growing-imports-of-feed/ [https://perma.cc/Y8Q7-B4WA] (with data sourced from the USDA Production, Supply and Distribution database, and projections).

[40] *Meat and greens*, ECONOMIST (Dec. 31, 2013), https://www.economist.com/feast-and-famine/2013/12/31/meat-and-greens [https://perma.cc/7HHC-6UHM].

[41] IPCC, *supra* note 5, at 2.

[42] Robert Glennon, *Water Scarcity, Marketing, and Privatization*, 83 TEX. L. REV. 1873, 1887–88 (2005).

[43] *See, e.g.*, Shefali Anand, *Maximum Money: Is Agricultural Land a Good Investment?*, WALL ST. J. (Oct. 4, 2011), https://www.wsj.com/articles/SB10001424052970204612504576609964115831284 [https://perma.cc/3YJH-Y39W]; Jose A. Del Real & Nicholas Bogel-Burroughs, *A Southern California Without Orange Groves? One of the Last Could Soon Be Gone*, N.Y. TIMES (July 11, 2019), https://www.nytimes.com/2019/07/11/us/southern-california-orange-grove.html [https://perma.cc/U56F-P77V]; *see also* Figure 3.

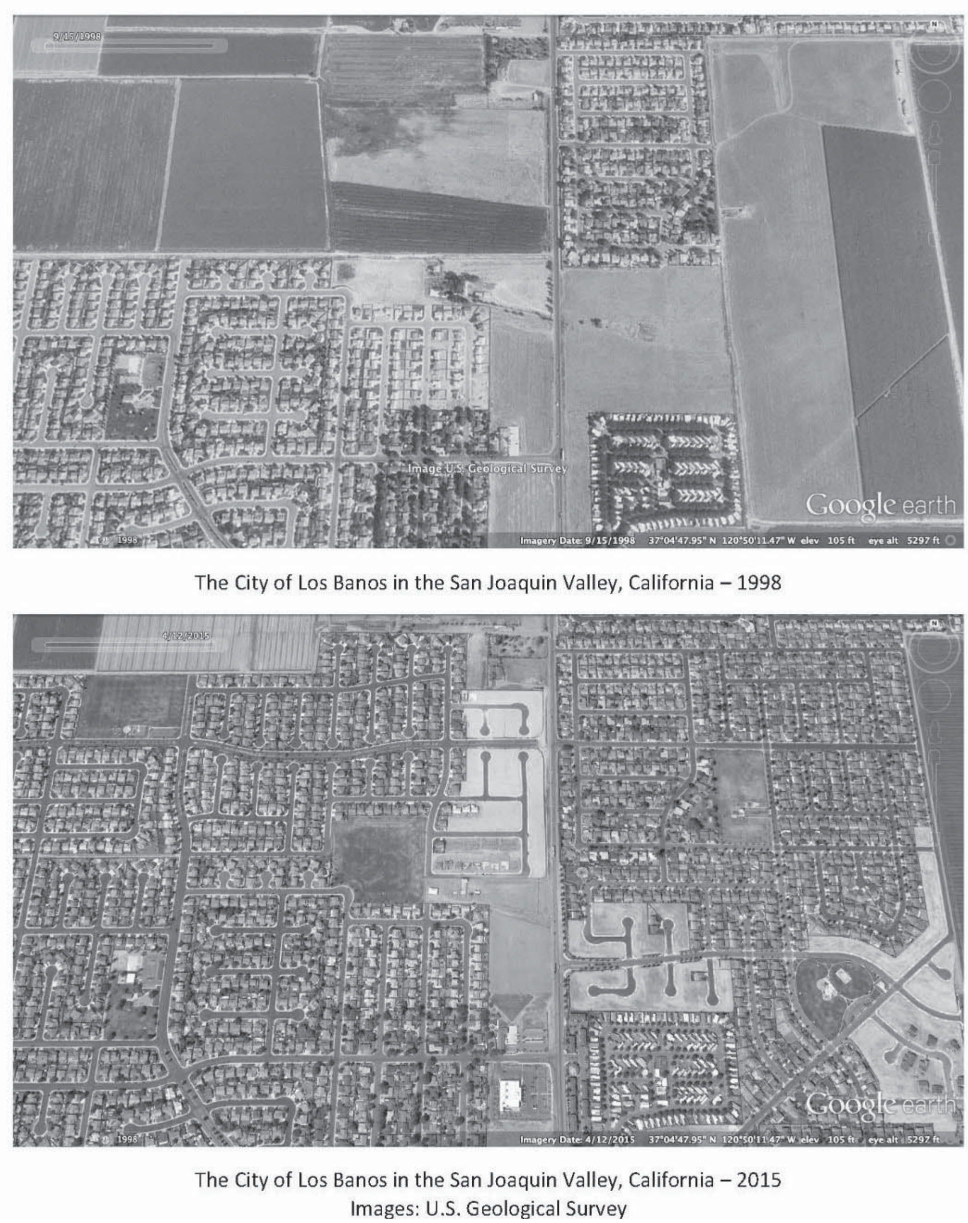

Figure 3: Overview of the city of Los Banos in the San Joaquin Valley, California of the same location in 1998 and in 2015, sourced from Google Earth using data from the United States Geological Survey[44]

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[44] *City of Los Banos in 1998,* GOOGLE EARTH*; City of Los Banos in 2015*, GOOGLE EARTH.

The mix of population growth and water scarcity has driven up the value of farmland and encouraged a worldwide competition to secure land (and water rights).[45] In the United States, foreign investors have increased their purchases of real estate. The amount of farmland in the United States owned by foreign interests doubled in the last twenty years to nearly thirty million acres.[46] Across the globe, this competition pits wealthy countries, such as Saudi Arabia, China, and India, against some of the poorest countries, especially in sub-Saharan Africa. It also has created a largely ignored moral problem: how does the international community react as weak or corrupt regimes sell out their own people by allowing the massive export of water embedded in crops from countries that already face water-shortage-driven famine? Recent developments in South Asia, the Middle East, and North Africa have exposed water as a national security issue that is driving the dislocation of desperate people. In South Asia, for example, India and Bangladesh are squabbling over water from the Brahmaputra River, which runs from India into Bangladesh.[47]

The challenge is sharply etched. Farmers need both more water and more land at a time when they may have less of each. Yet, at the same time, we expect farmers to almost double production by 2050.[48]

II. SOLUTIONS

To achieve the U.N. goal, we must marshal our energies, resources, political will, and moral courage to act. We have, fortunately, an array of policy tools, which if used collectively, can avert what could be a catastrophe by mid-century. No single policy holds the silver bullet of a global fix to food production. But combined, they offer a sustainable path forward.

To begin, let's look at how we use water. In the United States, lush lawns and gardens are common in cities across the arid West, including

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[45] THE GLOBAL FARMS RACE, *supra* note 14, at 4.

[46] *See* Lauren Markham, *Who keeps buying California's scarce water? Saudi Arabia*, GUARDIAN (Mar. 25, 2019), https://www.theguardian.com/us-news/2019/mar/25/california-water-drought-scarce-saudi-arabia [https://perma.cc/G9DR-QFLG]; Renee Wilde, *'American Soil' Is Increasingly Foreign Owned*, NPR (May 27, 2019), https://www.npr.org/2019/05/27/723501793/american-soil-is-increasingly-foreign-owned [https://perma.cc/YD2A-QLZ7].

[47] Brian Wang, *Bangladesh, China and India Could Have Conflicts Over the Brahmaputra River*, NEXT BIG FUTURE (Aug. 2, 2019), https://www.nextbigfuture.com/2019/08/asianwaterwars.html [https://perma.cc/ZA7K-T93L].

[48] *See* U.N. REPORT, *supra* note 3, at 1; *Feeding the world in 2050*, U.N. FOOD & AGRIC. ORG., http://www.fao.org/tempref/docrep/fao/meeting/018/k6021e.pdf [https://perma.cc/BHN8-9X9A] (last visited Dec. 3, 2019).

Los Angeles, San Diego, Las Vegas, Phoenix, Salt Lake City, and Denver.[49] Of the millions of acres of cropland, more than half are flood irrigated—the least efficient form of irrigation.[50] Conservation remains the low hanging fruit, ripe for the picking to save water. Conservation programs take many forms, from voluntary to incentivized to mandatory.[51] Each can play a role in encouraging wiser use of this precious resource.[52]

Second, all the water that is available currently exists.[53] We can no more create water than destroy it. Therefore, we must aggressively reuse the water we already have. In one way, we have always reused water. Indeed, we are drinking the same water as the dinosaurs.[54] Only now we have technological capacity to turn wastewater into drinking water.[55] Instead, many cities treat their water just to dump it into a nearby river or ocean.[56]

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[49] *See* Taylor W. Anderson, *Salt Lake City tells couple who replaced lawn with wood chips, rocks, and plants to add vegetation or face fines*, SALT LAKE TRIB. (Oct. 6, 2017), https://www.sltrib.com/news/politics/2017/10/06/salt-lake-city-tells-a-couple-who-replaced-lawn-with-wood-chips-rocks-and-plants-they-broke-the-law-and-must-add-vegetation-or-face-fines/ [https://perma.cc/6N8K-UF3A]; Kevin Beaty, *Denverites use up to 120 million gallons a day to water their lawns*, DENVERITE (May 6, 2019), https://denverite.com/2019/05/06/denverites-can-use-120-million-gallons-a-day-to-water-their-lawns/ [https://perma.cc/7GER-YNWP]; Rory Carroll, *Sod it: Californians turn back to grass lawns as drought shaming ebbs*, GUARDIAN (Nov. 2, 2016), https://www.theguardian.com/us-news/2016/nov/02/california-drought-lawns-grass-sod [https://perma.cc/6LPC-KLJY]; Esme E. Deprez, *Despite water rationing, California's wealthy keep lawns lush*, DULUTH NEWS TRIB. (Apr. 16, 2015), https://www.duluthnewstribune.com/news/3724432-despite-water-rationing-californias-wealthy-keep-lawns-lush [https://perma.cc/98LZ-735U]; Bret Jaspers, *Arizona HOAs strive to balance lush grass with conserving water*, AZCENTRAL, https://www.azcentral.com/story/news/local/gilbert/2018/08/11/homeowners-groups-must-balance-growing-grass-saving-water/949274002/ [https://perma.cc/JPG5-2R27] (last updated Aug. 12, 2018); Ted Robbins, *In Las Vegas, Lawns Are The Biggest Water Waster*, NPR (Jan. 30, 2014), https://www.npr.org/2014/01/30/268685253/in-las-vegas-lawns-are-the-biggest-water-waster [https://perma.cc/4JZH-VNDS].

[50] Eduardo Porter, *The Risks of Cheap Water*, N.Y. TIMES (Oct. 14, 2014), https://www.nytimes.com/2014/10/15/business/economy/the-price-of-water-is-too-low.html [https://perma.cc/2P5H-MXWR].

[51] GLENNON, *supra* note 8, at 171–81.

[52] *Id.*

[53] *Freshwater Crisis*, NAT'L GEOGRAPHIC, https://www.nationalgeographic.com/environment/freshwater/freshwater-crisis/ [https://perma.cc/LWT3-A3RD] (last visited Dec. 3, 2019).

[54] *Id.*

[55] Joe McCune, *Missouri S&T researcher cleans wastewater*, MO. U. SCI. & TECH. (Feb. 20, 2015), https://news.mst.edu/2015/02/missouri-st-researcher-cleans-wastewater/ [https://perma.cc/6ZGX-G43U]; Kieron Monks, *From toilet to tap: Getting a taste for drinking recycled waste water*, CNN (Nov. 17, 2015), https://www.cnn.com/2014/05/01/world/from-toilet-to-tap-water/index.html [https://perma.cc/3PM2-4EQ5].

[56] Lei Yang et al., *Natural Disinfection of Water in Marine Outfall Fields*, 34 WATER RES. 743, 743 (2000).

As the world faces worsening water shortages, we need to rethink the concept of "wastewater" and to consider it as reclaimed water or, as Singapore does, as "new" water.[57] Some cities, such as Tucson, already reuse water for watering golf courses, parks, cemeteries, and highway medians.[58] Some global corporations, such as Alphabet, are using reclaimed water to even cool their data centers.[59] Reclaimed water provides a fine supply for cooling electrical power plants.[60] And one day, we may even drink it. The technology to do so safely already exists, but the "Yuck!" factor response in the public discourages water managers from getting out in front on this sensitive issue.[61] But times are changing.

In 2007, the Orange County Water District ("OCWD") brought online an indirect potable reuse system that reclaims water from treatment plants, subjects it to additional filtration processes, and recharges it to aquifers for later recovery and delivery to homes and businesses.[62] In 2019, the city of Los Angeles followed OCWD's lead and announced it would reclaim water from its Hyperion Water Reclamation Plant that it previously dumped into the Pacific Ocean.[63] This move will reuse 190 million gallons of water a day—equal to the volume in the seventh largest river in the United States.[64]

Third, we need a program to discourage the conversion of prime agricultural land. As these lands get converted, sometimes other lands come under cultivation. But most often the newly cultivated plots are the

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[57] *Singapore Water Story*, PUB. UTIL. AGENCY: SINGAPORE'S NAT'L WATER AGENCY, https://www.pub.gov.sg/watersupply/singaporewaterstory [https://perma.cc/LC96-QCZK] (last updated Oct. 22, 2019).

[58] Dan Kraker, *Desert City Uses Water then Uses it Again*, MPR NEWS (May 27, 2014), https://www.mprnews.org/story/2014/05/27/ground-level-beneath-the-surface-tucson-water-reuse [https://perma.cc/PP4J-M8LM].

[59] Todd Woody, *Google Greens Up Data With Recycled Water For Cooling*, FORBES (Mar. 15, 2012), https://www.forbes.com/sites/toddwoody/2012/03/15/google-greens-up-data-center-with-recycled-water-for-cooling/#404f08377186 [https://perma.cc/7N2L-5WCA].

[60] Robert A. Hendel et al., *Using Reclaimed Water in Power Plant Cooling Applications,* POWER (Mar. 1, 2017), https://www.powermag.com/using-reclaimed-water-power-plant-cooling-applications/ [https://perma.cc/WB36-K5UX].

[61] *See* Jennifer Vettel, *Reclaimed Water: Safe to Drink*?, EARTH INST. (June 23, 2009), https://blogs.ei.columbia.edu/2009/06/23/reclaimed-water-safe-to-drink/ [https://perma.cc/XC7K-HZYS] (including comments addressing the "yuck" factor).

[62] GLENNON, *supra* note 8, at 166, 169.

[63] *Mayor Garcetti: Los Angeles Will Recycle 100% of City's Wastewater by 2035*, LAMAYOR.ORG (Feb. 21, 2019), https://www.lamayor.org/mayor-garcetti-los-angeles-will-recycle-100-city%E2%80%99s-wastewater-2035 [https://perma.cc/U5FC-36HU].

[64] Robert Glennon, *The genius of toilet to tap: California is discovering that wastewater has incredible value*, L.A. TIMES (Mar. 7, 2019), https://enewspaper.latimes.com/infinity/article_share.aspx?guid=6b0976db-7404-444d-9362-6e2e0ea7a87d [https://perma.cc/8KJ9-APAV].

consequence of the destruction of virgin rain forests.[65] Not only is that undesirable as a matter of climate change, but hacked down or burned forest lands are on the low end of quality farmland. No one should be naïve enough to think that even the highest-quality farmland will not get paved over if it is located in the path of urban development. But a system of incentives should require developers to set aside other prime farmland located away from urban development. Other vehicles to save farmland include land trusts, which create property tax incentives for owners and prospective purchasers to keep land in agriculture.[66]

Fourth, we need to confront the reality that there is virtually no financial incentive to use less water, because the price of water is so low. In the United States, we pay less for water than we do for cable television or for cell phone service.[67] Water bills that arrive every three months and charge a flat rate for the water used reinforce the idea that water is plentiful rather than a scarce resource. Without a strong financial incentive to change behavior, many people will continue to water lawns excessively until the sprinkler water runs down the street. If we are to meet the U.N. goal, we need creative engineers and inventors to develop better water mousetraps. In fact, many have already done so. But few of them have viable business models because the price of water is so low.

That said, the affordability of water has become a major problem for millions of Americans. We should not ignore the plight of persons of modest means who are having a tough time paying their water bills.[68] Instead, we should recognize a human right to water for basic needs and ensure that everyone is served.[69] No exceptions. The water needed for cooking, drinking, and sanitation constitutes only 1 percent of the water Americans use each day.[70] Let us set that water aside and begin a serious

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[65] *See* Henry Fountain, *A Respite From Record Losses, but Tropical Forests Are Still in Trouble*, N.Y. TIMES (Apr. 25, 2019), https://www.nytimes.com/2019/04/25/climate/tropical-forest-deforestation.html?searchResultPosition=1 [https://perma.cc/V8DJ-LGS5].

[66] Kayleigh Kulp, *These Tax Credits Make Land Conservation a Steal*, CNBC (July 10, 2016), https://www.cnbc.com/2016/07/08/these-tax-credits-make-land-conservation-a-steal.html [https://perma.cc/JNY7-DHAF].

[67] *See* GLENNON, *supra* note 8, at 223.

[68] *See* Robert Glennon, *Moral Stewardship of Our Most Precious Resource: Water*, *in* CASCADING CHALLENGES IN THE GLOBAL WATER CRISIS 14 (Gerard Magill & James Benedicts eds., 2019); Jose A. Del Real, *They Grow the Nation's Food, but They Can't Drink the Water*, N.Y. TIMES (May 21, 2019), https://www.nytimes.com/2019/05/21/us/california-central-valley-tainted-water.html [https://perma.cc/B6P6-ZMVM]; Jose A. Del Real, *What's All This About a Water Tax?,* N.Y. TIMES (May 13, 2019), https://www.nytimes.com/2019/05/13/us/california-today-water-tax.html [https://perma.cc/LPG3-Y3AF].

[69] Glennon, *supra* note 68, at 14.

[70] GLENNON, *supra* note 8, at 229.

conversation on how to price the other 99 percent. A good start would be volume-based rates that have increasing block rates: the more you use, the more you'll pay for that final unit of water.[71]

Fifth, we need to use market forces to encourage investment in water infrastructure. In some countries, including the United States, laws and regulations have created property rights to water.[72] In the American West, a system of prior appropriation protects the first person to use water against subsequent users.[73] This system initially encouraged development but more recently has served as an impediment to development.[74] One problem is that it locks in all existing rights without regard to whether they use water in an efficient way.[75] For farmers, who consume almost 80 percent of water in the West,[76] this has enabled flood irrigation to continue long past the time it made any sense.[77] But it is completely unrealistic to expect farmers to foot the bill to install efficient, but very expensive, irrigation systems so that municipal and industrial interests can use the water saved. Far better would be to remove impediments to water rights transfers.[78] Allow farmers to work with urban interests, which have the money, and need water. A system of transferrable rights would allow cities and industry to finance modernization of agricultural irrigation infrastructure in exchange for getting some of the water conserved. It is a win-win system: farmers continue to grow as much product with less water, and urban interests get an additional supply.

III. CHANGES IN FARMING

The agricultural sector is the best place for technological advances to make a real difference in water consumption, which in turn will increase

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[71] *Id.* at 226.

[72] Erin Wilcox, *Water, property rights and the public trust doctrine*, DAILY J. (Jan. 30, 2019), https://www.dailyjournal.com/articles/351033-water-property-rights-and-the-public-trust-doctrine [https://perma.cc/9HA5-KTQD].

[73] *Water Appropriation Systems*, ENERGY & ENVTL. RES. CTR., https://undeerc.org/Water/Decision-Support/Water-Law/pdf/Water-Appr-Systems.pdf [https://perma.cc/PXH9-XGBG] (last visited Dec. 3, 2019).

[74] PETER W. CULP ET AL., SHOPPING FOR WATER: HOW THE MARKET CAN MITIGATE WATER SHORTAGES IN THE AMERICAN WEST 14–16, 29–30 (2014); ROBERT GLENNON, WATER FOLLIES: GROUNDWATER PUMPING AND THE FATE OF AMERICA'S FRESH WATERS 14, 18 (2002).

[75] CULP ET AL., *supra* note 74, at 16.

[76] *Id.* at 10.

[77] U.S. GEOLOGICAL SURVEY, ESTIMATED USE OF WATER IN THE UNITED STATES IN 2015 30 (2015) [hereinafter USGS SURVEY].

[78] CULP ET AL., *supra* note 74, at 11–15.

food production. Farmers have recently made significant changes to historic agricultural practices. Consider the long tradition of tilling fields between growing seasons. When a farmer uses animals or machinery to turn over a field, it often causes soil compaction, loss of organic matter, disruption of beneficial microbes and other organisms (such as earthworms), and water loss through evaporation.[79] Though some farmers have employed no-till practices for a half century, the movement has recently exploded as farmers have come to appreciate that no-till reduces irrigation, saves labor and fuel costs, and may increase yield.[80]

Other changes in farm cultivation practices, promoted especially by organic farmers,[81] include: increased use of cover crops in order to retain moisture to stimulate growth of organic matter; reducing or eliminating use of chemical fertilizers or pesticides; and adding compost to restore organic matter.[82] By one estimate, each one percent increase of organic matter retains twenty thousand gallons of water per acre.[83] The potential water savings in a single state like California adds up to trillions of gallons.[84]

A major shift is under way in how farmers irrigate their fields. Woefully inefficient flood irrigation is gradually being replaced by micro- or

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[79] James J. Hoorman, *The Biology of Soil Compaction*, CROPS & SOIL 4, 5 (2011), https://www.nrcs.usda.gov//Internet/FSE_DOCUMENTS/nrcs144p2_045780.pdf [https://perma.cc/7U5Y-E3YA].

[80] Brad Plumer, *No-till farming is on the rise. That's actually a big deal*, WASH. POST (Nov. 9, 2013), https://www.washingtonpost.com/news/wonk/wp/2013/11/09/no-till-farming-is-on-the-rise-thats-actually-a-big-deal/ [https://perma.cc/8K2W-XRQW].

[81] As a note, we do not advocate for organic farming over traditional farming or vice versa—both have pros and cons, and this is heavily dependent on the crops and system in which they are implemented. A recent meta-study of environmental impacts on agricultural production found that generally organic farming utilized more land to reach similar yields and had higher impacts when it came to the potential for polluting aquatic systems, through both eutrophication and acidification. On the other hand, energy usage was generally lower in organic farms. Greenhouse gas emissions were similar between the two methods, but they varied widely by crop type. There is no silver bullet for ecologically friendly agriculture. *See* Michael Clark & David Tilman, *Comparative Analysis of Environmental Impacts of Agricultural Production Systems, Agricultural Input Efficiency, and Food Choice*, 12 ENVTL. RES. LETTERS 1, 3–5 (2017).

[82] Stephanie Strom, *Paying Farmers to Go Organic, Even Before the Crops Come In*, N.Y. TIMES (July 14, 2016), https://www.nytimes.com/2016/07/15/business/paying-farmers-to-go-organic-even-before-the-crops-come-in.html [https://perma.cc/88GF-G43J].

[83] Lara Bryant, *Organic Matter Can Improve Your Soil's Water Holding Capacity*, NAT. RESOURCES DEF. COUNCIL (May 27, 2015), https://www.nrdc.org/experts/lara-bryant/organic-matter-can-improve-your-soils-water-holding-capacity [https://perma.cc/2QZM-5M9C].

[84] *Point Positive: Water Solutions That Protect Our Rivers*, FRIENDS RIVER, https://www.friendsoftheriver.org/our-work/point-positive-solutions/ [https://perma.cc/64LX-M6WD] (last visited Dec. 3, 2019).

drip-irrigation, which uses emitters to deliver precisely the amount of water a plant needs.[85] It is highly efficient because it eliminates both evaporation loss and excess water percolating into the soil. These irrigation methods have been successfully used for row crops and fruit trees.[86] An Israeli company, Netafim, has pioneered a system of subsurface drip irrigation, which can be used on commodity crops, such as alfalfa.[87] The water savings can reach 30 percent, and the farmer can deliver liquid fertilizer through the same pipes that deliver water.[88]

A potentially disruptive technology is hydroponic agriculture, growing plants in greenhouses in water rather than soil.[89] Hydroponic agriculture has found a commercial niche in producing microgreens in urban "vertical farms" in places such as Brooklyn, New York.[90] Stacked trays with LED lighting enable urban farmers to supply high-quality, locally grown produce to chefs and home cooks.[91]

The question organic farming faces is whether it can feed a world of nine billion people. The answer may be "yes" according to Joel K. Bourne, Jr, author of a wonderful book, *The End of Plenty: The Race to Feed a Crowded World*.[92] The transition from conventional to organic farming initially causes a decline in yield as farmers eliminate the application of synthetic fertilizers, but yields bounce back and exceed those in conventional farming after the process of farming organically builds up organic matter in the soil.[93] The challenge for organic farming will be to expand beyond vegetable and fruit crops to disrupt the market for commodity crops—corn, soybeans, wheat, and rice. These crops feed the world. One recent study actually found that the world could be fed from

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[85] USGS SURVEY, *supra* note 77, at 28, 54, 60.

[86] *Drip Irrigation*, U.N. FOOD & AGRIC. ORG., http://www.fao.org/3/S8684e07.htm [https://perma.cc/T5H8-PKCM] (last visited Dec. 3, 2019).

[87] *Crop Knowledge: Alfalfa*, NETAFIM, https://www.netafim.com/en/crop-knowledge/alfalfa/ [https://perma.cc/H392-FDWT] (last visited Dec. 3, 2019).

[88] *Water Use Efficiency with Precision Irrigation*, NETAFIM, https://www.netafim.com/en/precision-Irrigation/water-use-efficiency/ [https://perma.cc/7EE8-VFC7] (last visited Dec. 3, 2019).

[89] *See* Eilene Zimmerman, *Growing Greens in the Spare Room as 'Vertical Farm' Start-Ups Flourish*, N.Y. TIMES (June 29, 2016), https://www.nytimes.com/2016/06/30/business/smallbusiness/growing-greens-in-the-spare-room-as-vertical-farm-start-ups-flourish.html [https://perma.cc/JQ57-KXPR].

[90] *Id.*

[91] *Id.*

[92] *See* JOEL K. BOURNE, JR., THE END OF PLENTY: THE RACE TO FEED A CROWDED WORLD 258–59 (2015).

[93] *Id.*

a shift to 100 percent organic agricultural system, yet their model has been heavily criticized and required a universal conversion to vegetarianism![94]

But vertical agriculture and organic farming cannot, and probably should not, displace large farms and commodity crops. According to Jayson Lusk, author of *Unnaturally Delicious: How Science and Technology Are Serving Up Super Foods to Save the World*, large farmers "are among the most progressive, technologically savvy growers on the planet."[95] The scale of their operations enables them to employ precision agriculture, half-million-dollar combines with sophisticated GPS systems, drones to monitor crop yields and insect infestations, and "variable rate applicators," which apply fertilizer only to the parts of a field that need it.[96] The cost of these and other innovative tools is well beyond the means of most small farmers.[97] But thanks to these innovations, crop production in the United States has doubled since 1970 even though farmers are using 16 percent less land.[98]

"Vegetables aren't the answer" to feeding the world, argues *Washington Post* food writer, Tamar Haspel.[99] While it is great to have farmers' markets and organic produce, vegetable acreage is a tiny percentage of total agricultural land: four million acres out of 330 million.[100] We could dramatically expand vegetable production, as we should because so few of us eat enough vegetables, but most of the world's calories and protein comes from commodity crops: corn, soybeans, wheat, and rice.[101]

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[94] *See* Adrian Muller et al., *Strategies for Feeding the World More Sustainably With Organic Agriculture*, 8 NATURE COMM.1290 (2017). *But see* Mark Lynas, *Organic farming can feed the world—until you read the small print*, CORNELL ALLIANCE FOR SCI. (Nov. 22, 2017), https://allianceforscience.cornell.edu/blog/2017/11/organic-farming-can-feed-the-world-until-you-read-the-small-print/ [https://perma.cc/YMP8-JNF7].

[95] Jason Lusk, *Why Industrial Farms Are Good for the Environment*, N.Y. TIMES (Sept. 23, 2016), https://www.nytimes.com/2016/09/25/opinion/sunday/why-industrial-farms-are-good-for-the-environment.html [https://perma.cc/7RR3-6BU6] [hereinafter Lusk, *Why Industrial Farms Are Good for the Environment*]; *see* JASON LUSK, UNNATURALLY DELICIOUS: HOW SCIENCE AND TECHNOLOGY ARE SERVING UP SUPER FOODS TO SAVE THE WORLD (2016) [hereinafter LUSK, UNNATURALLY DELICIOUS].

[96] Lusk, *Why Industrial Farms Are Good for the Environment, supra* note 95.

[97] *See* LUSK, UNNATURALLY DELICIOUS, *supra* note 95, at 190–91.

[98] *Id. at* 191.

[99] Tamar Haspel, *We need to feed a growing planet. Vegetables aren't the answer.*, WASH. POST (Dec. 15, 2016), https://www.washingtonpost.com/lifestyle/food/we-need-to-feed-a-growing-planet-vegetables-arent-the-answer/2016/12/15/f0ffeb3e-c177-11e6-8422-eac61c0ef74d_story.html [https://perma.cc/J599-7TD5].

[100] *Id.*

[101] *Id.*; *What the World Eats*, NAT'L GEOGRAPHIC, https://www.nationalgeographic.com/what-the-world-eats/ [https://perma.cc/9B3U-S2RZ] (last visited Dec. 3, 2019).

The core of a healthy diet consists of whole grains and legumes, including beans, peanuts, and lentils.[102] Commodity agriculture feeds the world because these crops, especially corn and soy, are nutritious, grow abundantly on small plots, and store well.[103] Vegetables are expensive for the calories delivered and require special handling (refrigeration) to keep from spoiling.[104] Finally, as we think about meeting the U.N.'s goal, vegetables require more land to produce calories than, say, corn.[105] Haspel estimates that an acre of broccoli delivers approximately two million calories compared to corn's fifteen million.[106]

IV. SILICON VALLEY MEETS THE CENTRAL VALLEY

"Feeding the world through math" is the way Erik Andrejko, the former director of Monsanto Corporation's data science center, described the company's mission.[107] In 2013, the realization that better data could help farmers achieve higher yields led Monsanto to acquire Climate Corporation.[108] The San Francisco weather-data company had begun using data on weather, farm inputs, and soil maps to create algorithms, which would give farmers precise information on important decisions, such as spacing between rows, the kind of microbes needed for soil health, and the levels of nitrogen to apply.[109] Monsanto also invested in Blue River Technology, a Silicon Valley firm specializing in helping farmers reduce their use of the exact chemicals Monsanto sells.[110] It seemed an odd investment, but *Fortune Magazine*'s Beth Kowitt persuasively argues that "big data is slowly shifting [Monsanto] from a product maker to a service provider: 'seed as a service,' if you will."[111] This new mission so meshed with the direction of Germany's pharmaceutical and agricultural giant, Bayer AG, that it acquired Monsanto in 2016.[112] Bayer's Crop

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[102] Haspel, *supra* note 99.
[103] *Id.*
[104] *Id.*
[105] *Id.*
[106] *Id.*
[107] Beth Kowitt, *Can Monsanto Save the Planet?*, FORTUNE (June 6, 2016), https://fortune.com/longform/monsanto-fortune-500-gmo-foods/ [https://perma.cc/CV9U-ZU3F] (quote from Erik Andrejko, director of Monsanto Corporation's data science center).
[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] *Bayer Closes Monsanto Acquisition*, MONSANTO (June 7, 2018), https://monsanto.com/news-releases/bayer-closes-monsanto-acquisition/ [https://perma.cc/8N8F-P3NH].

Science division promotes "digital farming," using remote sensing to drive "decision farming."[113]

Bayer Crop Science has competition in this space, including from Dupont and John Deere.[114] As one example, consider a Google (Alphabet)-funded startup, Granular, which gathers data from aircraft, self-driving tractors, and remote sensors to give farmers better tools for a myriad of decisions on-farm.[115] Sid Gorham, CEO and co-founder of Granular, described what his company does as giving farmers Enterprise Resource Planning software, which industrial and retail firms have used to make great efficiency strides.[116] It is an exciting time to be in farming. Where "precision ag" will lead remains unclear. But data-enabled farming gives hope for a second Green Revolution.

Even so, modern monitoring and modeling can only take us so far—at some point you hit the edge of what is biologically possible with the crop strains we have been "perfecting" for ages. Biotechnology has the potential to change everything. The field of biotechnology involves the manipulation of living organisms or their components to produce more useful products, such as pest resistant crops or novel pharmaceuticals.[117] Manipulation of the genetic code of life is the cornerstone of biotechnology.

V. GENETIC ENGINEERING

Everything we eat has been genetically modified.[118] The forces of mutation and selection have been changing the genomes of every living

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[113] *Digital Farming Technology*, BAYER, https://www.cropscience.bayer.com/en/stories/2018/digital-farming-technology [https://perma.cc/6FE2-TNXB] (last visited Dec. 3, 2019).

[114] *Software and Digital Services*, CORTEVA, https://www.corteva.us/products-and-solutions/software-and-digital-solutions.html [https://perma.cc/5W4E-GDUQ] (last visited Dec. 3, 2019); *Agrinomic Research,* JOHN DEERE, https://www.deere.com/en/agriculture/agronomic-research/ [https://perma.cc/RPG3-N9ZD] (last visited Dec. 3, 2019).

[115] Christopher Mims, *To Feed Billions, Farms Are About Data as Much as Dirt*, WALL ST. J. (Aug. 9, 2015), https://www.wsj.com/articles/to-feed-billions-farms-are-about-data-as-much-as-dirt-1439160264 [https://perma.cc/2SH6-KLUZ].

[116] *Id.*

[117] *Biotechnology*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/biotechnology [https://perma.cc/V623-XZ5G] (last visited Dec. 3, 2019).

[118] While other commentators have taken umbrage with this characterization (see Glenn Davis Stone, *CRISPR and the Monsanto Problem (GMO, be some other name!)*, FIELDQUESTIONS (Feb. 23, 2016), https://fieldquestions.com/2016/02/23/crispr-and-the-monsanto-problem-gmo-be-some-other-name/ [https://perma.cc/88XR-ERSV]), we feel that Norman Borlaug put it better than we ever could: "The fact is that genetic modification started long before humankind started altering crops by artificial selection. Mother Nature did it, and often in a big way." Borlaug, *supra* note 2, at 489.

organism since time immemorial.[119] Genetic modification is the natural order. Millennia before Darwin and Wallace set forth the theory of evolution, human beings were already manipulating these forces for our own benefit. Selective breeding of animals, such as horses and dogs, or of foods, such as corn, wheat, and rice, has occurred for centuries.[120] Genetic modification through selective breeding has produced varieties of food that would likely never have arisen under the forces of natural selection, many of which the world could not survive without. Take corn. There is no wild corn.[121] Our redirection of natural forces has created foods with increased nutritional value and reduced health risk (e.g., vegetable oil with less fatty acids).[122]

Our manipulation of nature began with only blunt tools and techniques: breeding plants en masse, continuing to breed those that we liked, and discarding those that did not serve our purposes.[123] With no control over the underlying DNA itself, we were largely at the whim of capricious nature to create novel traits, phenotypes, of which the vast majority would provide no discernable benefit to humanity.[124]

By the eighteenth century, we knowingly began to cross-breed more distantly related plants, thus exerting a higher level of control over the outcome—aiming to combine specific traits from different species of plants.[125] What we would later learn is that hybrid offspring are often more fit than either of their progenitors, a process known as hybrid vigor or heterosis.[126] Hybridization was the backbone of Nobel Laureate Norman

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[119] CHARLES DARWIN, THE ORIGIN OF SPECIES 71 (J.W. Burrow ed., Penguin Classics 1985) (1859).

[120] *Id.*

[121] Corn was domesticated, through artificial selection, from teosinte, a process beginning over 4,200 years BC! *See* George W. Beadle, *The Ancestry of Corn*, 242 SCI. AM. 112 (1980); Bruce F. Benz, *Archaeological Evidence of Teosinte Domestication from Guilá Naquitz, Oaxaca*, 98 PROC. NAT'L ACAD. SCI. 2104 (2001).

[122] Ghent U., *GMOs With Health Benefits Have a Large Market Potential*, SCIENCEDAILY (Jan. 13, 2015), https://www.sciencedaily.com/releases/2015/01/150113090428.htm [https://perma.cc/L676-B7YF].

[123] Jeffrey Ross-Ibarra et al., *Plant Domestication, a Unique Opportunity to Identify the Genetic Basis of Adaption*, 104 PROC. NAT'L ACAD. SCI. 8641, 8642 (2007).

[124] *Id.*

[125] Thomas Fairchild would develop the first artificial plant hybrid known to science in 1717 by cross-breeding a carnation pink with a Sweet William resulting in what was dubbed "Fairchild's Mule." *See* Matthew Wilson, *Thomas Fairchild: the man who created the first hybrid plant—and changed science*, FIN. TIMES (Mar. 17, 2017), https://www.ft.com/content/64451cc4-07f3-11e7-ac5a-903b21361b43 [https://perma.cc/L452-B7L6].

[126] Famed maize geneticist George Harrison Shull would discover hybrid vigor. *See* George H. Shull, *The Composition of a Field of Maize*, 4 J. HEREDITY 296, 296–300 (1908).

Borlaug's Green Revolution, which is credited with saving over a billion people from starvation.[127] Yet, ultimately these hybridization techniques still produced many unexpected and undesirable plants, making it a time consuming and labor-intensive process.[128]

In the early 20th century, future Nobel Laureate Hermann Joseph Muller gained acclaim for bombarding fruit flies with X-rays—in the process discovering the mutagenic property of radiation.[129] Not long after that, horticulturalists took up X-rays, and eventually other mutagens, in an attempt to speed up the process of developing novel crops.[130] Because they could not manipulate the actual genetic material, the next best thing was to manipulate the mutation rate.[131] The natural process of mutation is extremely slow, so by using outside forces to increase the number of mutations each generation, novel traits will be found that can be bred into currently existing stocks.[132] This is a scattershot approach and there is no way to control what changes will occur or what phenotypes will arise.[133] Today, thousands of varieties of crops have been created through mutagenic processes.[134] Modern biotechnology sprouted from these foundations, allowing us to gain unprecedented levels of control over the process.

After molecular biologists developed recombinant DNA-based technologies, they no longer needed to experiment with cross-breeding and X-rays until, by trial and error, they arrived at a better apple. With recombinant DNA, they could insert specific pieces of genetic material from one species into another.[135] With the techniques of genetic engineering,

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[127] Josh Coomey, *Building better plants—Norman Borlaug and the Green Revolution*, THAT'S LIFE SCI. (July 11, 2016), http://thatslifesci.com.s3-website-us-east-1.amazonaws.com/2016-07-11-Building-better-plant-Norman-Borlaug-and-the-Green-Revolution_JCoomey/ [https://perma.cc/3ZC6-6J5J].

[128] *See* Borlaug, *supra* note 2, at 487–88.

[129] *See* Kevin M. Gleason, *Hermann Joseph Muller's Study of X-rays as a Mutagen, (1926–1927)*, EMBRYO PROJECT ENCYCLOPEDIA, https://embryo.asu.edu/pages/hermann-joseph-mullers-study-x-rays-mutagen-1926-1927 [https://perma.cc/2CUR-B38Z] (last visited Dec. 3, 2019).

[130] Lewis Stadler would be the first to demonstrate this same mutagenic process in corn. *See* Lewis J. Stadler & George F. Sprague, *Genetic Effects of Ultra-violet Radiation in Maize: I. Unfiltered Radiation*, 22 PROC. NAT'L ACAD. SCI. 572, 572–73 (1936).

[131] Yusuff Oladosu, et al., *Principle and Application of Plant Mutagenesis in Crop Improvement: A Review*, 30 BIOTECHNOLOGY & BIOTECHNOLOGICAL EQUIPMENT 1, 2, 4 (2016).

[132] *Id.* at 2.

[133] *Id.*

[134] B.S. Ahloowalia et al., *Global Impact of Mutation-Derived Varieties*, 135 EUPHYTICA 187, 187 (2004).

[135] Recombinant DNA is essentially when different pieces of DNA are combined. Paul Berg is credited with creating the first recombinant DNA molecule when he inserted DNA from a lambda phage into DNA from Simian Virus 40. He shared the 1980 Nobel

they could create novel variants that could never exist in nature, such as a plant species with a gene from bacteria that made the new organism resistant to a specific disease or pest.[136]

Conventional biotechnology has become so ingrained in our food supply that we scarcely give it a thought.[137] But, to many, GMOs are another thing altogether. Opposition to GMOs seems partly based on a fear of mutant plants overwhelming our world and destroying us. Even the term "Genetically Modified Organisms" suggests something unnatural, a thing or a monster out of a bad sci-fi film. As Michael Specter puts it, "by cutting DNA from one species and splicing it into another, we have crossed an invisible line and created forms of life unlike anything found in 'nature.'"[138] Arguments against GMOs on these grounds rest on philosophical or theological premises, not on scientific or empirical bases. This seems a particularly hypocritical stance, as there is nothing particularly natural about wide hybridization or mutagenic techniques either. Artificial selection is literally, by definition, unnatural. Somehow these techniques manage to avoid the wrath of the activists, and, in fact, mutagenic and hybridized plants can be classified as "organics."[139]

Further, the world's leading scientific organizations are agreed that foods derived from GMO crops are as safe to eat as other foods. These prestigious groups include the American Association for the Advancement of Science, the World Health Organization, England's Royal Society, France's Academy of Sciences, and the European Commission.[140] In 2016, the National Academy of Sciences' Committee on Genetically Engineered Crops released a comprehensive report on genetic engineering that analyzed what we have learned in the last few decades of developing and

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Prize in Chemistry for this discovery. *See* David A. Jackson et al., *Biochemical Method for Inserting New Genetic Information into DNA of Simian Virus 40: Circular SV40 DNA Molecules Containing Lambda Phage Genes and the Galactose Operon of Escherichia coli*, 69 PROC. NAT'L ACAD. SCI. 2904, 2904–05 (1972).

[136] The first "GMO" was created shortly after Paul Berg's initial discovery when Herbert Boyer and Stanley Cohen successfully transferred an antibiotic resistant gene by creating novel plasmids. *See* Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROC. NAT'L ACAD. SCI. 3240, 3240, 3242–44 (1973).

[137] Joanna K. Sax, *Biotechnology and Consumer Decision-Making*, 47 SETON HALL L. REV. 433, 435 (2017).

[138] Michael Specter, *Seeds of Doubt*, NEW YORKER (Aug. 18, 2014), https://www.newyorker.com/magazine/2014/08/25/seeds-of-doubt [https://perma.cc/UD3F-6HFY].

[139] Carol Lynn Curchoe, *Frankenfoods!! Found in the Organic Aisle*, MEDIUM (Apr. 17, 2016), https://medium.com/the-method/frankenfoods-created-by-science-found-in-the-organic-aisle-77d33a750ad3 [https://perma.cc/Q2C8-8YF2].

[140] Specter, *supra* note 138.

using these technologies.[141] The committee found no differences to human health from GE foods when compared to other foods.[142] Additionally, the committee "found no evidence of cause-and-effect relationships between GE crops and environmental problems."[143]

While scientists may overwhelmingly believe that GMOs are safe (88 percent in a Pew Poll), only 37 percent of the public does.[144] While there has been a strong trend in recent years to combat misinformation and gaps between science and policy through increased public communication and education, increasing research on public opinion of genetic modification has yielded mixed results as to the efficacy of increased education.[145] One recent study actually found that while the most extreme GMO opponents tended to know the least about science and genetics they believed they knew the most![146] The Internet has become a source of widely spread misinformation largely propagated as part of an aggressive anti-GMO campaign by some environmental groups and by the organic food industry.[147]

But that insults the intelligence of people who have legitimate qualms about GMOs, especially those with concerns about some of the leading corporations that produce GMOs. Monsanto, for many a name

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[141] NAT'L ACADS. OF SCIS., ENG'G, & MED., GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS (2016) [hereinafter NAS].

[142] *Id.* at 19, 225, 236. Opponents to GMOs seized on one finding of the report to try to undermine its central point about food safety. The Committee noted that there were no long-term epidemiological studies about food safety. *See National Academy of Sciences Releases Report on GMOs*, WHOLEFOODS MAG. (May 18, 2016), http://www.wholefoodsmagazine.com/news/main-news/national-academy-sciences-releases-report-gmos/ [https://perma.cc/AJ5D-PFS4]. This is true, of course, for the obvious reason that GMOs have only been in the food supply for a couple of decades.

[143] NAS, *supra* note 141, at 154.

[144] *An Elaboration of AAAS Scientists' Views*, PEW RES. CTR. (July 23, 2015), https://www.pewinternet.org/wp-content/uploads/sites/9/2015/07/Report-AAAS-Members-Elaboration_FINAL.pdf [https://perma.cc/FP5V-9LZE].

[145] Philip M. Fernbach et al., *Extreme Opponents of Genetically Modified Foods Know the Least but Think They Know the Most*, 3 NATURE HUM. BEHAV. 251, 255 (2019).

[146] *Id.* at 254.

[147] MARK LYNAS, SEEDS OF SCIENCE: WHY WE GOT IT SO WRONG ON GMOS 60–61, 198–99 (2018); Joanna K. Sax & Neal M. Doran, *Ambiguity and Consumer Perceptions of Risk in Various Areas of Biotechnology*, 42 J. CONSUMER POL'Y 47, 48–49, 51, 56 (2019); Michelle Miller, *Who funds the grassroots anti-GMO movement*?, GENETIC LITERACY PROJECT (Sept. 15, 2016), https://geneticliteracyproject.org/2016/09/15/funds-grassroots-anti-gmo-movement/ [https://perma.cc/J9J8-KRGG]; William Saletan, *Unhealthy Fixation*, SLATE (July 15, 2015), http://www.slate.com/articles/health_and_science/science/2015/07/are_gmos_safe_yes_the_case_against_them_is_full_of_fraud_lies_and_errors.html [https://perma.cc/HSK9-4GAK].

synonymous with GMOs, is so detested that, after Climate Corp agreed to be acquired by Monsanto, Climate Corp's founder wrote his employees suggesting that they could expect to get emails from friends asking: "Do you REALLY want to work at the MOST EVIL COMPANY IN THE WORLD??!!"[148]

Monsanto's track record does not inspire confidence in the reports that it has conducted in-house or financed. Recent news stories of lingering concerns about links between Roundup and risks of cancer, and about Monsanto commissioning favorable studies and papers without acknowledging potentially critical academic papers, further cements the perception that the company's claims should not be accepted without independent confirmation.[149] As *The New Yorker*'s Michael Specter puts it: "The all-encompassing obsession with Monsanto has made rational discussion of the risks and benefits of genetically modified products difficult."[150]

The years 2018–2019 have been difficult ones for Bayer, which acquired Monsanto in 2018. Three of the thousands of lawsuits against Monsanto for harms allegedly caused by its weedkiller, Roundup, went to trial. Each resulted in judgments for the plaintiffs: one for $289.2 million; another for $80.3 million.[151] In May 2019, Monsanto lost again, this time for more than $2 billion.[152] Bayer's stock has plummeted from $29.85 when it acquired Monsanto on June 7, 2018, to $19.52 on November 8, 2019.[153]

As Michael Specter and Joel K. Bourne, Jr. have demonstrated, the chief beneficiaries to date from GMOs have been biotech companies and large farmers.[154] There are legitimate concerns with the way these

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[148] Kowitt, *supra* note 107.

[149] *See* Dan Charles, *Monsanto Attacks Scientists After Studies Show Trouble For Weedkiller Dicamba*, NPR (Oct. 26, 2017), https://www.npr.org/sections/thesalt/2017/10/26/559733837/monsanto-and-the-weed-scientists-not-a-love-story [https://perma.cc/LQ5P-QKUP].

[150] Specter, *supra* note 138.

[151] *See* Jacob Bunge & Ruth Bender, *Roundup, the World's Best-Selling Weedkiller, Faces a Legal Reckoning*, WALL ST. J. (Apr. 8, 2019), https://www.wsj.com/articles/roundup-the-weedkiller-that-changed-farming-faces-a-reckoning-11554735900 [https://perma.cc/P6M8-RYNS]; Mihir Zaveri, *Monsanto Weedkiller Roundup Was 'Substantial Factor' in Causing Man's Cancer, Jury Says*, N.Y. TIMES (Mar. 19, 2019), https://www.nytimes.com/2019/03/19/business/monsanto-roundup-cancer.html [https://perma.cc/9ZBF-LQTC].

[152] *See* Ellen M. Gilmer & Ariana Figueroa, *Monsanto lost again on Roundup. What's next for glyphosate?*, ENV'T & ENERGY NEWS (May 14, 2019), https://www.eenews.net/stories/1060332679 [https://perma.cc/3HCY-NYU4].

[153] *Bayer Aktiengesellschaft (BAYRY)*, YAHOO! FIN., https://finance.yahoo.com/quote/BAYRY/history?period1=1417842000&period2=1575608400&interval=1d&filter=history&frequency=1d [https://perma.cc/7FCK-7PPP] (last visited Dec. 3, 2019).

[154] BOURNE, *supra* note 92, at 243–44; Specter, *supra* note 138.

agrochemical companies operate and have implemented GMO technology. There has been a strong pushback against monoculture in agriculture[155]: nine species of commodity crops make up nearly two-thirds of total crop production[156]—and many argue that GMOs have accelerated the monocultural shift that occurred post–Green Revolution.[157] Despite the promise of genetic engineering, 99 percent of GMO crops planted today are either *Bt* insect-resistant crops or Roundup Ready herbicidal GMO crops.[158] Concerns over the way the agrochemical companies control farmers and the current patent system abound.[159] These issues need to be addressed, but at the end of the day, these are problems with the agriculture industry, not with the technology of genetic engineering. Current regulations perpetuate this system, and thus we need to modify regulation, especially with the advent of genetic editing, to decouple the technologies from "Big Ag."

As we strive to achieve the U.N.'s goal of increasing food production by 70 percent by 2050, genetic engineering offers a tool whose potential eclipses all others.[160] Imagine GMO crops that tolerate drought, ward off pests, achieve greater yields, promote better nutrition, require less land and less water, reduce pesticide and herbicide use, encourage conservation tilling, and help offset climate change by reducing CO_2 emissions.[161] Scientists have engineered crops that accomplish all of the above, but most have yet to reach market due to regulatory processes that are complicated, extensive, and expensive.[162]

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155 Jack Hitt, *Michael Pollan on the Links Between Biodiversity and Health*, YALE ENV'T 360 (May 28, 2013), https://e360.yale.edu/features/michael_pollan_on_the_links_between_biodiversity_and_health [https://perma.cc/6TBC-J83M] ("I still feel the great evil of American agriculture is monoculture.").

156 U.N. FOOD & AGRIC. ORG., THE STATE OF THE WORLD'S BIODIVERSITY FOR FOOD AND AGRICULTURE 114 (J. Belanger & D. Pilling eds., 2019).

157 *Do GMOs encourage monoculture cropping and reduce biodiversity?*, GENETIC LITERACY PROJECT, https://gmo.geneticliteracyproject.org/FAQ/do-gmos-encourage-monoculture-cropping-and-reduce-biodiversity/ [https://perma.cc/A22G-R9WQ] (last visited Dec. 3, 2019).

158 Janet E. Carpenter, *Peer-Reviewed Surveys Indicate Positive Impact of Commercialized GM Crops*, 28 NATURE BIOTECHNOLOGY 319, 319 (2010).

159 *See, e.g.*, Dan Barber, *Save Our Food. Free the Seed.*, N.Y. TIMES (June 7, 2019), https://www.nytimes.com/interactive/2019/06/07/opinion/sunday/dan-barber-seed-companies.html?mtrref=www.google.com&gwh=41D925F212BD0491B0FBC7FC0F19D486&gwt=pay&assetType=REGIWALL [https://perma.cc/5DSU-JWBV].

160 For a new book that makes a similar argument, see LITTLE, *supra* note 6, at 57–87.

161 *See, e.g.*, David Biello, *Coming to a Cornfield Near You: Genetically Induced Drought-Resistance*, SCI. AM. (May 13, 2011), https://www.scientificamerican.com/article/corn-genetically-modified-to-tolerate-drought/ [https://perma.cc/TW6C-S923].

162 *See Restrictions on Genetically Modified Organisms: United States*, LIBR. CONGRESS,

Consider GMO rice. Rice feeds about half the world and vitamin A deficiency affects 250 million children whose diet consists mostly of rice.[163] In 2000, two European scientists discovered that they could insert genes into rice, which would produce beta-carotene, the source of vitamin A.[164] This "golden rice" offers a huge improvement in public health.[165] The owners of the patents on the seeds, including Monsanto, agreed to donate the patents to a non-profit foundation, which would give farmers the seeds for free.[166] After nearly twenty years, not including the nearly two decades of research that went into the discovery, golden rice is only approved for cultivation in countries where it is unlikely to be needed (Canada, United States, Australia, and New Zealand).[167] The same fate has befallen drought and pest-resistant GMO corn, the most common staple crop in Africa.[168]

GMO critics derive comfort in this cumbersome process. The fear of the unknown powerfully drives resistance. This reluctance to take a chance epitomizes the application of the precautionary principle, albeit a logically erroneous application.[169] If an activity poses a perceived risk of harm to the environment or human health, precautionary measures are seen as warranted even if science has not conclusively determined some cause-and-effect relationships.[170] GMO critics would not argue that every harm merits application of the principle. Their concern is catastrophic horror brought on by releasing a freakish organism into the environment that wreaks havoc with basic biology.[171]

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https://www.loc.gov/law/help/restrictions-on-gmos/usa.php [https://perma.cc/WPJ7-8GLZ] (last updated June 9, 2015).

[163] BOURNE, *supra* note 92, at 237–38.

[164] Xudong Ye et al., *Engineering the Provitamin A (β-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm*, 287 SCI. 303, 303–04 (2000).

[165] Matt Ridley, *GM Crops Like Golden Rice Will Save the Lives of Hundreds of Thousands of Children*, QUILLETTE (Dec. 1, 2019), https://quillette.com/2019/12/01/gm-crops-like-golden-rice-will-save-the-lives-of-hundreds-of-thousands-of-children/ [https://perma.cc/7766-ERBN].

[166] BOURNE, *supra* note 92, at 238.

[167] Andy Coghlan, *GM golden rice gets approval from food regulators in the US*, NEW-SCIENTIST (May 30, 2018), https://www.newscientist.com/article/mg23831802-500-gm-golden-rice-gets-approval-from-food-regulators-in-the-us/ [https://perma.cc/P7C2-QTP4].

[168] Specter, *supra* note 138.

[169] Conko et al., *supra* note 17, at 493.

[170] *Wingspread Statement on the Precautionary Principle*, WORLD HEALTH ORG. (Jan. 20, 1998), http://www.who.int/ifcs/documents/forums/forum5/wingspread.doc [https://perma.cc/6TWS-V8ZD].

[171] Mark Lynas, *Time to call out the anti-GMO conspiracy theory* (Apr. 29, 2013), http://marklynas.org/2013/04/time-to-call-out-the-anti-gmo-conspiracy-theory/ [https://perma.cc/F2K8-JV4J].

This message has been heard by regulators in the United States and, especially, in Europe, which has extremely stringent regulations on GMO crops. The regulatory framework has built in layers of review to guard against imperfectly understood or even unknown risks to the environment or human health.[172] The consequence, is that it takes thirteen years and $136 million on average to bring a GMO product to market.[173]

Two important yet unintended consequences flow from the length and cost of regulatory compliance. First, the staggering costs of research virtually preclude university, non-profit organizations, and public-sector researchers from using genetic engineering to improve crops for farmers.[174] Only well-capitalized private companies have pockets deep enough to underwrite GMO research.[175]

Second, the well-heeled corporate labs concentrate only on commodity crops, those with potential application to millions of acres for crops such as corn, soybeans, cotton, and canola.[176] Only commodity crops offer a potential seed market at a scale that warrants committing hundreds of millions of dollars on studies that may, in the end, not produce a new GMO crop.[177] It is a high-stakes game, not for the faint of heart or the modestly capitalized. As important as commodity crops are to feed the planet, it is a tragedy that regulatory costs create disincentives for research into improving fruit and vegetable crops. This has only furthered concerns about agricultural monoculture and the lack of genetic diversity within our food crops.

VI. REGULATION OF GMO CROPS

A. *The Coordinated Framework*

If anything proves the inadequacy of the byzantine system of regulation of GMOs, it is that three separate agencies were put in charge of GMO regulation during the 1980s and little has changed since. Dubbed

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[172] Jose R. Prado et al., *Genetically Engineered Crops: From Idea to Product*, 65 ANN. REV. PLANT BIOLOGY 769, 770–71 (2014).
[173] *Id.* at 770.
[174] Conko et al., *supra* note 17, at 502.
[175] BOURNE, *supra* note 92, at 239 (suggesting that this may be changing as the costs of conducting genetic research have dramatically declined); Nina Fedoroff et al., *Radically Rethinking Agriculture for the 21st Century*, 327 SCI. 833, 833 (2010) (recommending the establishment of a public facility within the USDA to engage in safety testing of GMO crops to enable university and public-sector researchers to conduct some research).
[176] *How GMO Crops Hurt Farmers*, FOOD & WATER WATCH (Jan. 9, 2015), https://www.foodandwaterwatch.org/insight/how-gmo-crops-hurt-farmers [https://perma.cc/5TQZ-H9GM].
[177] *See id.*

the "Coordinated Framework for Regulation of Biotechnology," the regulation of GMO crops is split among the Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA"), and the Department of Agriculture ("USDA").[178] Each agency has its own statutory mandate to fulfill; each regulates different aspects of biotechnology. This Coordinated Framework was promulgated by the Reagan Administration's Office of Science and Technology Policy ("OSTP") when site-specific gene editing was merely science fiction.[179] When OSTP decided to deal with this novel issue of biotechnology, they simply co-opted laws and agencies already in existence to deal with the issue.[180]

On its face, the Coordinated Framework seems to embrace sensible regulation. It was well intentioned and aimed to regulate the product, not the process. This product versus process dichotomy has become a major talking point in the regulation of GMOs and biotechnology in general.[181] The European Union remains mired in a system of process-based regulation and they continue to tighten the regulatory screws on biotechnological methods.[182] Under a process-based regulatory scheme, the mere use of genetic engineering or biotechnological agricultural techniques results in an increased level of regulatory scrutiny and burden, regardless of the crop being produced.[183] The Coordinated Framework appears to take the opposite approach, that of regulating the products irrespective of the mechanisms used to create them. Regulation is tied to negative phenotypes of the products, such as weediness, toxicity, or allergenicity.[184] A regulatory system where the dangers posed are commensurate with the likelihood of them occurring seems to be what the authors of the Coordinated Framework intended; unfortunately, such a risk-based regulatory system only exists in the minds of the drafters.

B. EPA Regulation of GMOs

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") gives EPA regulatory authority to oversee genetically modified products

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[178] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf [https://perma.cc/3ETT-Y89E] [hereinafter Coordinated Framework].
[179] *Id.*
[180] *Id.*
[181] *See* Giovanni Tagliabue, *Product, Not Process! Explaining a Basic Concept in Agricultural Biotechnologies and Food Safety*, 13 LIFE SCI., SOC'Y & POL'Y 1, 1–3 (2017).
[182] *See infra* Section VII.D.
[183] *See* Conko et al., *supra* note 17, at 493–94, 496.
[184] *Id.* at 495, 500.

that involve pesticides of any sort, this includes pesticidal compounds created by the plants themselves.[185] One might assume that EPA, tasked with protecting the environment, would have the most authority over GMO crops, especially as many of the concerns raised about GMOs are environmental in nature. However, the agency's actual regulatory role is quite limited under FIFRA, which gives the Administrator the power to regulate "distribution, sale, or use" of pesticides to the "extent necessary to prevent unreasonable adverse effects on the environment."[186] These unreasonable, adverse effects extend to both "man or the environment."[187] This is judged by a balancing test that "tak[es] into account the economic, social, and environmental costs and benefits of the use of any pesticide."[188] "Dietary risk[s]" from pesticidal residues that run afoul of the Federal Food, Drug, and Cosmetics Act ("FFDCA") are also considered "unreasonable adverse effects."[189] And while EPA's role may be limited solely to pesticidal GMOs, insect-resistant crops still make up a sizeable portion of GMOs produced.[190]

To pull GMOs into the realm of FIFRA, EPA created the "plant-incorporated protectant[s]" ("PIPs") category, defined as substances plants produce for protection against pests and the genetic material necessary to produce these substances.[191] Thus, crops that are genetically engineered to produce toxins or other pesticides fall under EPA's gamut. The EPA performs its regulatory duty through a registration and permitting process. For an application to be approved, it requires "a full description of the tests made and the results thereof upon which the claims are based."[192] This essentially requires the producers to verify that the toxin is safe for the environment and to conduct safety analyses to ensure the transferred protein is not allergenic.[193] PIPs can be exempted from these registration regulations if: (1) the crop is a food and the pesticide residues it creates are exempted under the FFDCA;[194] (2) the PIP is listed by EPA as an inert ingredient;[195] or, (3) the PIP comes from another plant species

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[185] Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y (2012).
[186] 7 U.S.C. § 136a(a).
[187] 7 U.S.C. § 136(bb).
[188] *Id.*
[189] *Id.*
[190] Carpenter, *supra* note 158, at 319.
[191] 40 C.F.R. § 152.3 (2019).
[192] 7 U.S.C. § 136a(c)(1)(F).
[193] *Id.*
[194] 40 C.F.R. § 174.21(b).
[195] 40 C.F.R. § 174.21(c).

that is sexually compatible with the modified plant.[196] Often EPA attaches significant post-market obligations to the granting of registrations.[197]

The EPA system for regulating PIPs is a prime example of a process-based regulation masquerading as product-based. On its face, it appears as if EPA is only regulating based on the pesticidal properties of the crops created. In reality, it is not the pesticidal qualities that triggers regulation, it is whether those pesticidal qualities were created or enhanced through a transgenic process.[198] Crops produced through traditional agricultural practices are not put through this rigorous system requiring pre- and post-market regulatory requirements equivalent to those agrochemical companies must go through for biotechnologically derived products, even if they are producing the exact same pesticidal compounds in similar concentrations.[199] The EPA regulatory scheme has led to problems for buyers, sellers, and importers down the line, such as unexpected fines and delays for importing products and difficulties bringing fruit plants labeled as "pesticides" to markets.[200]

C. FDA Regulation of GMOs

The FDA is the agency responsible for GMOs that are food products to be consumed by humans or animals.[201] The FDA wrangled GMOs under its regulatory wing using the aforementioned FFDCA, which charges FDA with controlling "adulterated foods."[202] Adulterated foods are those which "contain[ ] any poisonous or deleterious substance which may render it injurious to health" or those which "bear . . . any food additive that is unsafe."[203] Food additives are substances that "becom[e] a component or otherwise affect[ ] the characteristics of any food," which includes transgenic proteins, and these additives will require approval

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[196] 40 C.F.R. § 174.25.

[197] 7 U.S.C. § 136f (permit inspection by EPA personnel and maintenance of records of production and distribution); 7 U.S.C. § 136d(a)(2), (b) (submit additional information related to unreasonable adverse effects or that EPA otherwise needs to maintain its registration); 7 U.S.C. § 136a(g) (registrations are re-evaluated every 15 years).

[198] Conko et al., *supra* note 17, at 495.

[199] *Id.*

[200] *See id.*; Steven H. Strauss & Joanna K. Sax, *Ending Event-Based Regulation of GMO Crops*, 34 NATURE BIOTECHNOLOGY 474, 474–76 (2016).

[201] *Consumer Info About Food from Genetically Engineered Plants*, FDA, https://www.fda.gov/food/food-new-plant-varieties/consumer-info-about-food-genetically-engineered-plants [https://perma.cc/W4PQ-TD3J] (last updated Jan. 4, 2018).

[202] Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301–399 (2012).

[203] 21 U.S.C. § 342(a)(1).

from FDA to go to market.[204] Additives can avoid pre-approval if they are "generally recognized as safe" ("GRAS"), meaning they have been "adequately shown through scientific procedures . . . or experience based on common use in food" to be safe.[205]

In 1992, FDA published a policy to treat foods derived by genetic modifications similarly to foods derived from traditional agricultural practices.[206] Additionally, the added genetic material is presumed to be GRAS.[207] Ultimately, this should allow the producers to determine if their product was GRAS, and thus exempt from pre-approval, based on its characteristics.[208] However, FDA may still intervene and require premarket approval if the GMO product "differs significantly in structure, function, or composition from substances currently found in food."[209] Additionally, FDA established a voluntary consulting process to review determinations of "substantial equivalence" before the crop moves to marketing.[210] As part of this consultation process, FDA looks for changes such as "significantly increased levels of plant toxicants or anti-nutrients, reduction of important nutrients, new allergens, or the presence in the food of an unapproved food additive."[211]

Although the consultation process is voluntary, it has been heavily criticized as a "*de facto* approval requirement" which, despite universally approving foods to date, has often prolonged by years the march to the market.[212] No company, especially in the current social climate for GMOs, is willing to risk going to market just to be sanctioned or see FDA remove

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[204] 21 U.S.C. § 321(s).
[205] *Id.*
[206] *See* FDA, Statement of Policy—Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 1992) ("Under this policy, foods . . . developed by the new methods of genetic modification are regulated within the existing framework of the act, . . . utilizing an approach identical in principle to that applied to foods developed by traditional plant breeding. The regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use of the food (or its components). . . . [T]he key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.").
[207] *Id.*
[208] *Id.*
[209] *Id.*
[210] *See* Conko et al., *supra* note 17, at 496.
[211] *Consultation Procedures under FDA's 1992 Statement of Policy for Foods Derived from New Plant Varieties*, FDA, https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/consultation-procedures-under-fdas-1992-statement-policy-foods-derived-new-plant-varieties [https://perma.cc/563Q-MEJS] (last updated Sept. 20, 2018).
[212] *See* Conko et al., *supra* note 17, at 496.

their product from the stream of commerce. This is yet another example of a product-based regulation warping into a process-based one. In theory, the regulation of new products that are significantly different than what is already on the market is a product-based regulation, but the *de facto* review for all products created by a biotechnological process flips that on its head.

D. USDA Regulation of GMOs

Lastly, USDA's Animal and Plant Health Inspection Services ("APHIS") regulates GMOs under the Plant Protection Act of 2000.[213] APHIS has the authority to regulate the "importation, entry, exportation, or movement in interstate commerce of any plant . . . if . . . necessary to prevent the . . . dissemination of a plant pest."[214] Any GMO plant that has a gene transferred into its genome from any "plant pest" falls under APHIS's authority as a "regulated article."[215] The term regulated article includes "[a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated" as a plant pest.[216] A plant pest is a wide-ranging term, which encompasses organisms that "indirectly injure or cause disease or damage in or to any plants" and includes "insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof [and] viruses."[217]

This is clearly a comprehensive standard, not even considering the fact that all "naturally" grown crops would technically qualify thanks to the likes of horizontal gene transfer.[218] As others have pointed out, the

[213] Plant Protection Act, 7 U.S.C. §§ 7701–7786 (2000).
[214] 7 U.S.C. § 7712(a).
[215] 7 C.F.R. § 340.1 (1987).
[216] *Id.*
[217] *Id.*
[218] Horizontal gene transfer is a process through which genetic material is transferred across species' boundaries naturally. Most of our genetic material is transferred vertically, from parent to offspring, but species will pick up small amounts of exogenous DNA and incorporate it into their own genomes. We are just now beginning to understand more fully the role horizontal gene transfer has played in shaping eukaryotic genomes, but genes have been demonstrated to enter plant genomes from viruses, arthropods, fungi, nematodes, and protozoa (all of which fall under the plant pests category). *See* Caihua Gao et al., *Horizontal Gene Transfer in Plants*, 14 FUNCTIONAL & INTEGRATIVE GENOMICS 23, 23–24 (2014); Huiquan Liu et al., *Widespread Horizontal Gene Transfer from Double-Stranded RNA Viruses to Eukaryotic Nuclear Genomes*, 84 J. VIROLOGY 11,876, 11,876 (2010).

vast majority of genetically modified crops include either bacterial or viral DNA or vectors that are listed on the plant pest list.[219] Thus, GMO crops must work through the labyrinthian APHIS bureaucracy. There are essentially three paths to market through the APHIS red tape: (1) a petition for determination of nonregulated status; (2) a permit for release into the environment; and (3) a notification procedure.[220] One option is that producers can "petition APHIS for a determination that a regulated article does not present a plant pest risk and therefore should not be subject to the applicable regulations."[221] Nonregulated status will release the product from any post-market requirements.[222] Additionally, there is an extension system where producers can petition APHIS to extend a determination of nonregulated status to new products that are sufficiently similar;[223] however, this extension system has been rarely used and is nearly as burdensome as the petition.[224] If products do not qualify for deregulation, permits may be doled out by APHIS for organisms that pose a plant pest risk.[225] These permits involve both pre-market and post-market oversight.[226] A notification process exists to act as an abbreviated version of the permitting process. This notification procedure is only available for products that meet six somewhat stringent requirements: it cannot be a noxious weed under the PPA; the genetic material must be "stably integrated"; the function of the genetic material must be known; the genetic material cannot be toxic to nontarget organisms; the genetic sequences must not pose a risk of creating new plant viruses; and it cannot contain genetic material from animal or human pathogens.[227] As a result, very few GMOs successfully go through this process, as it

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[219] Conko et al., *supra* note 17, at 496.
[220] 7 C.F.R. §§ 340.3, 340.4, 340.6.
[221] Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139, 145 (2010); *see also* 7 C.F.R. § 340.6.
[222] 7 C.F.R. § 340.6.
[223] 7 C.F.R. § 340.6(e); ANIMAL & PLANT HEALTH INSPECTION SERV., USDA, REQUEST TO EXTEND NONREGULATED STATUS FROM A PREVIOUS DETERMINATION: EXTENSION GUIDANCE FOR DEVELOPERS 3 (Feb. 22, 2016), https://www.aphis.usda.gov/brs/aphisdocs/guidance_ext_nonreg.pdf [https://perma.cc/6VJQ-VUEB].
[224] There have been a total of twenty-four extensions granted out of 128 deregulations. *Petitions for Determination of Nonregulated Status*, ANIMAL & PLANT HEALTH INSPECTION SERV., USDA, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status [https://perma.cc/VC3V-CK5U] (last updated Sept. 26, 2019); *see also* Strauss & Sax, *supra* note 200, at 475.
[225] 7 C.F.R. § 340.4.
[226] *Id.*
[227] 7 C.F.R. § 340.3(b)(1)–(6).

effectively precludes *Bt* insecticides and herbicide-resistant crops, which make up the vast majority of GMOs currently on the market.[228]

On the one hand, the APHIS regulations may be the most product-based of the lot, though they are triggered only by products created through bioengineering processes. APHIS sets out to regulate products that pose a specific threat as pests. There is a clear risk involved with propagating and spreading potential pests that could do substantial damage to agriculture or wild ecosystems. On the other hand, the way this APHIS regulation is applied is inconsistent with our modern understanding of evolutionary biology and genetics. Simply because a gene comes from a so-called "pest" species does not inherently endow any species given that gene with those same pest-like qualities. Phenotypes are complex, especially phenotypes for noxiousness or weediness, and the addition of a single gene with a known, expected function is not going to recreate those phenotypes solely because of its evolutionary origin.[229] This rings even truer when the sequence added is simply a promoter sequence, or some other non-coding sequence, as the addition of this genetic material merely increases the expression of already present genes creating proteins that are endogenous to the plant, not the plant pest.[230]

E. Updates to the Coordinated Framework

After decades of following the Coordinated Framework, in 2015 the Obama Administration ostensibly began a process to modernize these regulations.[231] The OSTP, in addition to tasking the National Academy to commission a study, pushed FDA and USDA to draft new guidelines and rules.[232] Released in 2017, this update was more clarification than modernization.[233] Though the OSTP reiterated a commitment to product-based risk-related regulation, few if any substantive changes were actually included in this update. Largely the update focuses on clarifying the

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[228] Paul Enriquez, *CRISPR GMOs*, 18 N.C. J.L. & TECH. 432, 490–91, 501–02 (2017).
[229] Conko et al., *supra* note 17, at 497–98, 501.
[230] Kent J. Bradford et al., *Regulating Transgenic Crops Sensibly: Lessons from Plant Breeding, Biotechnology and Genomics*, 23 NATURE BIOTECHNOLOGY 439, 440–41 (2005).
[231] Obama Memorandum, *supra* note 16, at 1.
[232] *Id.* at 3, 5.
[233] FDA, MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 56–58 (2017), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf [https://perma.cc/FJV8-8NPR].

distinct regulatory roles of each agency.[234] It uses a variety of hypotheticals to demonstrate how certain biotechnological products would be subject to the various statutes in effect.[235] However, little of substance changed and many, on both sides of the debate on biotechnology, feel that this was a missed opportunity rather than a success.[236]

F. NEPA for GMOs

Outside the three core agencies, additional laws require compliance for GMO crops. The National Environmental Protection Act ("NEPA") is implicated anytime a federal agency makes any "major Federal action significantly affecting the quality of the human environment."[237] Each of the three agencies have their own regulations and rules with respect to which decisions will trigger the preparation of an Environmental Assessment ("EA") or Environmental Impact Statement ("EIS").[238] This was a key issue in one of the few cases on GMO regulation to be heard by the Supreme Court, *Monsanto Co. v. Geertson Seed Farms*.[239] In this case, as in nearly every other legal challenge against the three agencies over GMOs, the Court ultimately deferred to the agencies in these admittedly technical and scientific areas of regulation.[240]

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[234] *Id.* at 1–2, 5–8, 59.
[235] *Id.* at 39–51.
[236] Professor Jennifer Kuzma at the NC State Genetic Engineering and Society Center was quoted as saying "I thought it was a missed opportunity." Brooke Borel, *The U.S. Regulations for Biotechnology Are Woefully Out of Date*, SLATE (Apr. 21, 2017), https://slate.com/technology/2017/04/u-s-biotechnology-regulations-are-woefully-out-of-date.html [https://perma.cc/N66T-696N]. Jaydee Hanson, a policy analyst at the Center for Food Safety, was quoted as saying "The Obama Administration really missed the mark on an opportunity to update the framework for oversight of biotechnology to match the monumental changes that have occurred in the field." *Federal Biotech Updates Too Little, Too Late*, CTR. FOR FOOD SAFETY (Jan. 6, 2017), https://www.centerforfoodsafety.org/press-releases/4695/federal-biotech-updates-too-little-too-late [https://perma.cc/5MQ6-ZBHJ].
[237] National Environmental Policy Act, 42 U.S.C. § 4332(C).
[238] For APHIS, see National Environmental Policy Act Implementing Procedures, 7 C.F.R. § 372. For FDA, see Environmental Impact Considerations, 21 C.F.R. § 25. For EPA, see Procedures for Implementing the National Environmental Policy Act and Assessing the Environmental Effects Abroad of EPA Actions, 40 C.F.R. § 6.
[239] Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139 (2010).
[240] For a failed challenge against FDA's presumption of GRAS for GMOs, see All. for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000). For failed challenges against APHIS for deregulation of GMO products, see Ctr. for Food Safety v. Vilsack, 718 F.3d 829 (9th Cir. 2013); Ctr. for Food Safety v. Vilsack, 636 F.3d 1166 (9th Cir. 2011).

G. *Labeling of GMOs*

State and federal legislatures have recently debated whether to enact laws that would require the labeling of GMO products. A number of state legislatures, led by Vermont, required the labeling of GMO and GE products within their jurisdictions.[241] The specter of fifty different sets of standards prompted the federal government to enact a federal standard and to pre-empt the state statutes. In 2016, Congress passed the National Bioengineered Food Disclosure Standard which required food manufacturers to disclose the presence of bioengineered foods.[242] On December 21, 2018, USDA promulgated a final rule clarifying the new standards for labels for all bioengineered foods.[243] The act and subsequent rule defined bioengineered foods as those "(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature."[244] Essentially all foods with detectable amounts of genetically modified materials are required to be labeled; however, the second half of the definition for "bioengineered foods" is sufficiently vague that it is still unclear whether or not GE crops actually fit into this category of "bioengineered."[245] Terms like "found in nature" and "conventional breeding" are never actually defined leaving them open to interpretation.[246] Somewhat ironically, the statute "clarifies" that bioengineered crops "shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food."[247]

From our perspective, the jury is still out on the utility or necessity of labeling laws for products of genetic engineering. On the one hand, the science strongly supports the conclusion that the techniques utilized

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[241] At the time of passing the National Bioengineered Food Disclosure Standard in 2016, three states, Vermont, Connecticut, and Maine, had passed laws requiring the labeling of genetically engineered products. *See* Bob Kinzel, *Senate Moves Forward with Bill that Would Overturn Vermont's GMO Labeling Law*, CONN. PUB. RADIO (July 7, 2016), https://www.wnpr.org/post/senate-moves-forward-bill-would-overturn-vermonts-gmo-labeling-law [https://perma.cc/WNW8-3TEU].
[242] National Bioengineered Food Disclosure Standard, 7 U.S.C. § 1639 (2016).
[243] Agricultural Marketing Service, Final Rule: National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814 (2018) [hereinafter AMS Rule].
[244] 7 U.S.C. § 1639(1).
[245] *See id.*; AMS Rule, 83 Fed. Reg. at 65,814, 65,816; Greg Jaffe, *Biotech Blog: The Final National Bioengineered Food Disclosure Standard*, CTR. FOR SCI. PUB. INT. (Apr. 8, 2019), https://cspinet.org/news/biotech-blog-final-national-bioengineered-food-disclosure-standard [https://perma.cc/2CK6-52YT].
[246] Jaffe, *supra* note 245.
[247] AMS Rule, 83 Fed. Reg. at 65,825.

in the bioengineering of crops are safe.[248] Labeling products that are safe seems to send the exact opposite message—why would completely safe and equivalent products need specialty labels with scary words? For this reason, both the American Medical Association and the American Association for the Advancement of the Sciences have come out against labeling.[249] There is compelling evidence that the drive to label is largely being pushed by the organic industry in an effort to achieve a competitive advantage.[250] Ultimately, labeling simply adds one more, potentially costly, step on the long road to market.[251] On the other hand, some science groups and companies have stood up in support of some sort of labeling laws; there is a feeling that openness and transparency is the key to ultimately changing public opinion on GMOs.[252] Because there is nothing to hide, the cause is better served by showing the public the wide variety of safe products already on the market, especially when they see just how ubiquitous bioengineered food is in the foods they already buy regularly. Public acceptance of biotechnology is every bit as critical as a scientifically defensible regulatory scheme if we are going to feed the world. Though there is a wide range of research on the field of public acceptance of GMOs, and how labeling laws might affect that, it remains largely unclear what kinds of effects labeling will have on public acceptance of the agricultural industry.[253]

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[248] *See* NAS, *supra* note 141, at 2, 19.

[249] *American Medical Association: GMO Labeling Not Necessary*, HUFFINGTON POST (June 21, 2012), https://www.huffpost.com/entry/gmo-labeling-ama-american-medical-association_n_1616716 [https://perma.cc/DHQ5-HTP2]; *Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods*, AM. ASS'N FOR ADVANCEMENT SCI. (Oct. 20, 2012), https://www.aaas.org/sites/default/files/AAAS_GM_statement.pdf [https://perma.cc/4ECW-MTGE].

[250] Joanna K. Sax, *The GMO/GE Debate,* 4 TEX. A&M L. REV. 345, 354–55, 360–61 (2017).

[251] Jeff Gelski, *G.M.O. labeling alone may cost Americans $3.8 billion*, FOOD BUS. NEWS (Feb. 22, 2016), https://www.foodbusinessnews.net/articles/7433-g-m-o-labeling-alone-may-cost-americans-3-8-billion [https://perma.cc/753W-3DTZ].

[252] Holly Spangler, *Mark Lynas: Yes to GMOs, mandatory labeling*, FARMFUTURES (Jan. 11, 2016), https://www.farmprogress.com/story-mark-lynas-yes-gmos-mandatory-labeling-8-136103 [https://perma.cc/W9A7-YC82]; *Support of the Labeling of Genetically Modified Foods,* AM. PUB. HEALTH ASS'N (Jan. 1, 2001), https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/28/13/18/support-of-the-labeling-of-genetically-modified-foods [https://perma.cc/2N7L-ZXFL]; *Why We Support Mandatory National GMO Labeling*, CAMPBELL'S (Jan. 7, 2016), https://www.campbellsoupcompany.com/newsroom/news/2016/01/07/labeling/ [https://perma.cc/56Z9-5G4U].

[253] On one hand, you have research that suggests consumers associate GMO-labeled products as less healthy, safe, and environmentally friendly compared to other labels. *See* Joanna K. Sax & Neal Doran, *Food Labeling and Consumer Associations with Health, Safety, and Environment*, 44 J.L. MED. & ETHICS 630, 631–32, 635 (2016). On the other

Ultimately, the regulatory framework for genetically engineered crops needs a fundamental makeover. We have a system where the stringency of the regulation has become divorced from the risks the products actually pose. We think that the Coordinated Framework needs to move the three agencies away from focusing on the process used and instead to focusing on the product itself and the risk created by that product. Such an overhaul would simplify the regulatory system, shorten the time it takes to get a product to market, reduce the costs of GMO research, enable smaller governmental agencies and NGOs to participate in critical GE research, and encourage the "Big Ag" corporate labs to use genetic engineering for fruit and vegetable crops. In the end, genetic engineering is too valuable a tool for feeding the planet to allow overly complicated governmental oversight to stymy its utility. This becomes even more critical with the rise of gene editing technologies like CRISPR.

VII. GENE EDITING: WHY NOW IS THE TIME FOR REFORM

A. CRISPR

Gene editing has the potential to render the current U.S. regulatory system irrelevant.[254] Today CRISPR is the poster child for genetic editing technologies. The CRISPR/Cas system, short for Clustered Regularly Interspaced Short Palindromic Repeats, was originally discovered as an adaptive immunity system in bacteria.[255] When viruses attack bacteria, part of the bacterial immune response is to capture the viral DNA and insert it into its own genome at these CRISPR loci.[256] Then, the bacteria utilizes these captured DNA fragments along with CRISPR-associated ("Cas") proteins to bind to and cut up the invading viral DNA, thus protecting the bacteria from these viral infections.[257]

While none of this may sound like the key to solving world hunger and curing molecular genetic disease, scientists have co-opted this naturally occurring system to perform highly specific genetic editing.[258] When

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hand, a study found that labeling laws in Vermont actually improved attitudes towards GMO food. *See* Jane Kolodinsky & Jayson L. Lusk, *Mandatory Labels Can Improve Attitudes Towards Genetically Engineered Food*, 4 SCI. ADVANCES 1, 2 (2018).

[254] Enriquez, *supra* note 228, at 439, 513–14; Borel, *supra* note 236.

[255] *See* Ruud Jansen et al., *Identification of Genes that are Associated with DNA Repeats in Prokaryotes*, 43 MOLECULAR MICROBIOLOGY 1565, 1565 (2002).

[256] Philippe Horvath & Rodolphe Barrangou, *CRISPR/Cas, the Immune System of Bacteria and Archaea*, 327 SCI. 167, 167 (2010).

[257] *Id.*

[258] Le Cong et al., *Multiplex Genome Engineering Using CRISPR/Cas Systems*, 339 SCI.

applied to gene editing, this CRISPR/Cas system is placed into the organism's cells with synthetic molecules that match the target sequence, called guide RNAs.[259] The CRISPR/Cas complex will bind to the organism's DNA at the target site and will cut it, forcing the cell to repair itself.[260] From there, the system can be modified to "knockout" genes, insert sequences, or modify existing sequences.[261] The key is that when the cells repair the damage to the DNA strand, it uses the new sequences delivered with your CRISPR/Cas system as the new template, instead of the natural sequence.[262] If this is done to the cells in the germ line, then it will be heritable and will be passed on to the next generation, effectively acting like a new mutation in the population.[263] This allows scientists to edit genes with a high degree of specificity.[264]

While traditional GMOs are the product of inserting genes found in other species, genetic editing techniques instead change the composition of the genes.[265] Variations of the CRISPR/Cas system allow genes to be turned off, turned on, or modified at a single base or on a larger scale.[266] Imagine traditional genetic modifying technologies as the cut and paste function of your word processor; CRISPR is the find and replace function. We are no longer constrained to pull genes out of other species, but we can create truly novel variation instead.

B. CRISPR and the Agricultural Industry

CRISPR has already revolutionized how scientists study both basic and applied biology, yet its profound effects on the outside world are yet to

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819, 822 (2013); Martin Jinek et al., *A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCI. 816, 820 (2012).

[259] Rasmus O. Bak et al., *Gene Editing on Center Stage*, 34 TRENDS GENETICS 600, 600–01 (2018).

[260] *Id.* at 600.

[261] *Id.* at 600–01.

[262] *Id.* at 601.

[263] *Id.* at 602.

[264] *Id.*

[265] TALENs and zinc fingers are two slightly early genomic editing tools that have also been used to produce gene edited products. However, both are significantly more expensive, difficult to manage, and much less efficient at targeting than CRISPR, hence why the vast majority of focus for regulation of gene editing technology has been on CRISPR. *See* Jim Yeadon, *Pros and Cons Of ZNFs, TALENs, and CRISPR/Cas*, JACKSON LAB (Mar. 4, 2014), https://www.jax.org/news-and-insights/jax-blog/2014/march/pros-and-cons-of-znfs-talens-and-crispr-cas [https://perma.cc/RZD9-7L3G].

[266] Bak et al., *supra* note 259, at 604, 608.

come. This technology has the potential to revolutionize the biotech and agricultural industries.[267] As noted earlier, the agricultural industry has been dominated by the "Big Ag" companies, specifically Bayer, Corteva, BASF, and ChemChina.[268] Producing genetically modified crops traditionally has been a highly labor intensive and highly capital intensive process that only those companies with the deepest pockets could undertake.[269]

In a 2019 article for the *New York Times Magazine*, celebrity chef Dan Barber argued persuasively against this oligopoly in the seed market and argued that we needed to increase the seed diversity and development of novel foods.[270] Though he argued for an increase in government funding for research into organic farming and traditional crop breeding, these goals, and in many ways the goals of the organic movement, might be better served through the proliferation of gene edited crops. GMOs and GEs are almost universally excluded from the myriad of "organic" certifications around the world, but an adoption of GE technology by the organic movement would better help serve the goal of sustainable agriculture.[271]

The International Federation of Organic Agricultural Movements ("IFOAM") has four principles of organic farming: health, ecology, fairness, and care.[272] We believe that GE technology can absolutely meet all

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[267] *See, e.g.*, Kunling Chen et al., *CRISPR/Cas Genome Editing and Precision Plant Breeding in Agriculture*, 70 ANN. REV. PLANT BIOLOGY 667 (2019); Caixia Gao, *The Future of CRISPR Technologies in Agriculture*, 19 NATURE REVS. MOLECULAR CELL BIOLOGY 275 (2018).

[268] This has become even more pronounced through Bayer's acquisition of Monsanto and the recent Dow and DuPont merger and subsequent spinoff to create Corteva. "Thanks to a series of mergers and acquisitions over the last few years, four multinational agrochemical firms—Corteva, ChemChina, Bayer and BASF—now control over 60 percent of global seed sales." Barber, *supra* note 159.

[269] BOURNE, *supra* note 92, at 259.

[270] Barber, *supra* note 159.

[271] *See* Amjad M. Husaini & Muhammad Sohail, *Time to Redefine Organic Agriculture: Can't GM Crops Be Certified as Organics*?, 9 FRONTIERS PLANT SCI. 1, 2–4 (2018); Gerhart U. Ryffel, *I Have a Dream: Organic Movements Include Gene Manipulation to Improve Sustainable Farming*, 9 SUSTAINABILITY 392, 392, 394, 398 (2017).

[272] This is defined more specifically as (1) "Organic Agriculture should sustain and enhance the health of soil, plant[s], animal[s], [and] human[s] . . . as one and indivisible"; (2) "Organic Agriculture should be based on living ecological systems and cycles, work with them, emulate them and help sustain them"; (3) "Organic Agriculture should build on relationships that ensure fairness with regard to the common environment and life opportunities"; (4) "Organic Agriculture should be managed in a precautionary and responsible manner to protect the health and well-being of current and future generations and the environment." *Principles of Organic Agriculture*, INT'L FED'N ORGANIC AGRIC. MOVEMENTS, https://www.ifoam.bio/en/organic-landmarks/principles-organic-agriculture [https://perma.cc/E7LG-DPBY] (last visited Dec. 3, 2019).

four principles. Health and ecology are extremely trait dependent principles.[273] GE crops grown without a focus on the external application of non-organic pesticides and instead on nutritional value or climate change adaptation should easily satisfy this requirement. There is nothing inherently unhealthy or environmentally damaging about the process.[274] For fairness, no GE product is inherently fair or unfair—the laws and systems employing technology could be unfair. In this Article, we are arguing for a system that will make agriculture fairer and more diverse. Under the proper regulatory regime, fair GE products could be produced. Finally, care is simply a restatement of the precautionary principle, which sufficient testing of GE products should be able to address. In fact, the official IFOAM position paper on genetic engineering does not explicitly block genetic engineering techniques, stating that GMOs are organisms "in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."[275] There is an argument that gene editing with simple point mutations, novel DNA-free CRISPR techniques, or using gene silencing techniques actually fits this description.[276] Recently, USDA Under Secretary of Agriculture Greg Ibach testified before the House Agriculture Subcommittee and actually argued that gene-edited products perhaps should be included within the USDA's organic standards, so movement on this front seems possible.[277] Unfortunately, the organic industry in America seems diametrically opposed to any movement in this direction. A group of seventy-nine organic farm organizations submitted a letter of opposition to the agency in the wake of Undersecretary Ibach's testimony, rejecting "any dialogue about any form of genetic engineering into organics."[278]

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[273] *Id.*
[274] *Genetically engineered foods*, NAT'L INSTS. OF HEALTH, https://medlineplus.gov/ency/article/002432.htm [https://perma.cc/2MEP-ZHHB] (last visited Dec. 3, 2019).
[275] Council Directive 2001/18, art. 2, 2001 O.J. (L106) 7 (EC).
[276] Luca Lombardo & Samanta Zelasco, *Biotech Approaches to Overcome the Limitations of Using Transgenic Plants in Organic Farming*, 8 SUSTAINABILITY 497, 497, 499–501 (2016).
[277] Undersecretary Ibach stated: "I think there is the opportunity to open the discussion to consider whether it is appropriate for some of these new technologies that include gene-editing to be eligible to be used to enhance organic production and to have drought and disease-resistant varieties, as well as higher-yield varieties available." *Actuality: Should Gene Editing Be Part of Organic Production?*, USDA (July 17, 2019), https://www.usda.gov/media/radio/daily-newsline/2019-07-17/actuality-should-gene-editing-be-part-organic-production [https://perma.cc/QW98-HT9V].
[278] Press Release, Organic Farmers Ass'n, Organic Farmers, Ass'n Opposes Genetic Eng'g in Letter to Sec'y (Sept. 18, 2019), http://organicfarmersassociation.org/news/press-release

Unlike traditional genetic engineering methods, CRISPR is low cost and easy to use.[279] It is already being used in academic settings around the world and is assuredly infiltrating industry in all companies, big or small, for those same reasons.[280] While "Big Ag" has traditionally focused on the large scale commodity crops, CRISPR will open up new possibilities for boutique startups geared around traditionally neglected niche crops.[281] Much like Silicon Valley pioneers who built computers in their garages, biohackers can do the same with crops. CRISPR egalitarizes and diversifies the agricultural industry. If regulated in a fair and consistent manner, we have the chance to avoid the pitfalls experienced with GMOs. A wide range of crops and producers would help address the concerns of monoculture.

We are already beginning to see this development. At the time of writing, there have been fifteen inquiries that APHIS has dealt with related to CRISPR-related products including seven from university labs, one from a non-profit lab, and one from a government lab.[282] Two inquiries originated from Yield10 Scientific, a small biotech company with a share price less than a dollar.[283] Only three originated from "Big Ag" companies, two from a Corteva subsidiary, and one from Altria, one of the largest tobacco producers in the world.[284] Additionally, the fifteen inquiries represent

-organic-farmers-association-opposes-genetic-engineering-in-letter-to-secretary/ [https://perma.cc/27ZW-24BC].

[279] Mark Shwartz, *Target, delete, repair CRISPR is a revolutionary gene-editing tool, but it's not without risk*, STAN. MED., https://stanmed.stanford.edu/2018winter/CRISPR-for-gene-editing-is-revolutionary-but-it-comes-with-risks.html [https://perma.cc/SJ9J-9CWX] (last visited Dec. 3, 2019).

[280] *See* Caitlin Dewey, *The Future of Food*, WASH. POST (Aug. 11, 2018), https://www.washingtonpost.com/news/business/wp/2018/08/11/feature/the-future-of-food-scientists-have-found-a-fast-and-cheap-way-to-edit-your-edibles-dna/ [https://perma.cc/A72J-MUFU].

[281] *See* Taylor, *supra* note 18.

[282] *Regulated Article Letters of Inquiry*, ANIMAL & PLANT HEALTH INSPECTION SERV., USDA, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/regulated_article_letters_of_inquiry/regulated_article_letters_of_inquiry [https://perma.cc/88P8-UQC6] (last updated Aug. 8, 2019) [hereinafter *AIR List*]. As of August 8, 2019, fifteen total inquiries have been submitted. *Id.* Illinois State University, University of Minnesota, Yeild10 Bioscience, and DuPont Pioneer have submitted two inquiries each. *Id.* Penn State, Donald Danforth Plant Science Center, USDA Agricultural Research Service, the University of Florida, the Max Planck Institute for Chemical Ecology, Altria Client Services LLC, and Iowa State University have all submitted a single inquiry each. *Id.*

[283] As of August 2019, Yield10 Bioscience Inc. was trading around $0.90. *See Yield10 Bioscience, Inc. (YTEN)*, YAHOO! FIN., https://finance.yahoo.com/quote/YTEN/history?p=YTEN [https://perma.cc/G5S6-CX2A] (last visited Dec. 3, 2019).

[284] Jayson Derrick, *The Biggest Big Tobacco Companies*, YAHOO! FIN. (Jan. 18, 2017), https://finance.yahoo.com/news/biggest-big-tobacco-companies-154219354.html [https://perma.cc/THW8-C73B].

nine different crops species being modified: soybeans, corn, pennycress, camelina, tomatoes, mushrooms, coyote tobacco, and tobacco.[285] Already we are seeing the diversification of both producers and products, but regulatory uncertainly could derail the promise of gene editing.

C. Regulation of Genetic Editing in the United States

As of November 2019, it is difficult to know which regulations that apply to genetically modified organisms also apply to gene edited products.[286] When the 2017 Update to the Coordinated Framework was released, many hoped that it would clarify this potential legal quagmire.[287] It did no such thing, largely leaving the regulation of GE organisms as it was under the original Coordinated Framework.[288] At the moment, GE crops appear to be largely slipping through the proverbial regulatory cracks.[289] This could be problematic if crops that pose a serious risk are allowed to market without any associated regulation. On the other hand, applying the onerous regulations that transgenics currently go through could stunt this potential boom. "Big Ag" will be able to jump through the regulatory hoops, but applying the status quo regulations would continue to disproportionately affect the smaller start-up growers, largely removing many of the benefits these novel technologies promise.[290]

In 2017, APHIS proposed and then retracted a draft rule after it received hundreds of comments and held numerous public meetings.[291] Criticism of the rule came from all sides.[292] On the one hand, this rule

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[285] *AIR List*, *supra* note 282.
[286] *See* Dan Charles, *Will Gene-Edited Food Be Government Regulated?*, NPR (May 10, 2019), https://www.npr.org/sections/thesalt/2019/05/10/717273970/will-gene-edited-food-be-government-regulated [https://perma.cc/XL27-XJC8].
[287] Robbie Barbero et al., *Increasing the Transparency, Coordination, and Predictability of the Biotechnology Regulatory System*, OBAMA WHITE HOUSE ARCHIVES (Jan. 4, 2017), https://obamawhitehouse.archives.gov/blog/2017/01/04/increasing-transparency-coordination-and-predictability-biotechnology-regulatory [https://perma.cc/F7WK-PB28].
[288] Borel, *supra* note 236.
[289] Borel, *supra* note 236; Charles, *supra* note 286.
[290] *See* Edward L. Rubin & Joanna K. Sax, *Administrative Guidance and Genetically Modified Food*, 60 ARIZ. L. REV. 539, 593 n.264 (2018).
[291] Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms, 82 Fed. Reg. 7008 (proposed Jan. 19, 2017) (to be codified at 7 C.F.R. pt. 340); Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms, 82 Fed. Reg. 51,582 (proposed Nov. 7, 2017) (withdrawing the January 19 proposed rule).
[292] The agency received over 200 comments ranging from both sides of the GMO debate. *See* Jeff Gelski, *APHIS to take 'fresh look' at revising G.M.O. regulations*, FOOD BUS. NEWS

would have placed risk at the forefront, requiring risks to be identified before regulation would kick in.[293] On the other hand, it would have pulled GE organisms under APHIS's regulatory domain and was generally seen as increasing regulatory burdens.[294] As a result, the rule was withdrawn.[295]

Until such a rule is promulgated, APHIS does not have authority over most GE products.[296] Opponents of genetic engineering techniques were upset when it became clear that APHIS did not have statutory authority under the PPA to regulate most gene edited crops.[297] Under the PPA, APHIS uses the idea of "plant pests" as its hook for authority to regulate, yet crops modified using CRISPR technology do not include exogenous DNA from any plant pest.[298] Unless GE methods are utilized to modify plants that are already classified as plant pests, APHIS seemingly has no authority to regulate them. As mentioned above, APHIS regulates GMO products through either a notification procedure, a permitting procedure, or a petition for nonregulated status.[299]

Instead, "regulation" of CRISPR products, however, has occurred through an entirely different path. APHIS has a process, which they have dubbed "Am I Regulated?" ("AIR"), where groups can submit a letter of inquiry asking if their product meets the definition of a regulated article.[300] These letters are fairly short and contain a brief overview of the

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(Nov. 8, 2017), https://www.foodbusinessnews.net/articles/10859-aphis-to-take-fresh-look-at-revising-g-m-o-regulations [https://perma.cc/U93C-FSWU]; Jennifer Kuzma, *Politics "Trumps" Science in the Regulation of Genetically Engineered Crops*, GENETIC ENG'G & SOC'Y CTR., N.C. ST. U. (Nov. 7, 2017), https://research.ncsu.edu/ges/2017/11/politics-trumps-science-regulation-genetically-engineered-crops/ [https://perma.cc/56YC-UYJL]; Kelly Servick, *Trump's agriculture department reverses course on biotech rules*, SCI. MAG. (Nov. 6, 2017), https://www.sciencemag.org/news/2017/11/trump-s-agriculture-department-reverses-course-biotech-rules [https://perma.cc/RJB5-KDBR].

[293] Kuzma, *supra* note 292.

[294] *Id.*

[295] Press Release, USDA, USDA to Re-engage Stakeholders on Revisions to Biotechnology Regulations (Nov. 6, 2017), https://www.usda.gov/media/press-releases/2017/11/06/usda-re-engage-stakeholders-revisions-biotechnology-regulations [https://perma.cc/7WTH-UY48].

[296] Enriquez, *supra* note 228, at 500–01.

[297] Charles, *supra* note 286; *see* Jennifer Kuzma, *Regulating Gene-Edited Crops*, 35 ISSUES SCI. & TECH. 80, 83–84 (2018).

[298] Allan Eaglesham & Ralph W.F. Hardy, *New DNA-Editing Approaches: Methods, Applications and Policy for Agriculture*, *in* NABC REPORT 26—NEW DNA-EDITING APPROACHES: METHODS, APPLICATIONS AND POLICY FOR AGRICULTURE 10 (Allan Eaglesham & Ralph W.F. Hardy eds., 2015).

[299] 7 C.F.R. §§ 340.3, 340.4, 340.6.

[300] *Am I Regulated Under 7 CFR part 340?*, ANIMAL & PLANT HEALTH INSPECTION SERV., USDA, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated [https://perma.cc/P4T3-VC8N] (last updated Oct. 31, 2019).

product and the methods used to create the product including: the taxonomic description of the organism, the intended phenotype, the intended activity, the intended genetic changes, the description of the vector and the construct inserted, and a description of the methods used to confirm that the intended changes were achieved.[301] At the moment, this process might become as much a *de facto* regulation as the FDA consultation process, though fortunately it is much less onerous. Most producers seem to be more than happy to go through the AIR process in order to "build consumer trust."[302] That said, there is no statutory mandate requiring it and, at least one company, Cibus, is on the record as being willing to bypass these reviews.[303]

Thus far, APHIS has responded to fifteen different letters of inquiry related to CRISPR modified organisms.[304] Each time, they have concluded that "APHIS does not consider [the crop] described . . . to be regulated pursuant to 7 CFR part 340."[305] However, every letter has also stipulated that

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[301] *Am I Regulated (AIR) Process Guidance for Submission of AIR Inquiries*, ANIMAL & PLANT HEALTH INSPECTION SERV., USDA (Oct. 31, 2019), https://www.aphis.usda.gov/brs/pdf/AIR_Guidance.pdf [https://perma.cc/52HA-GS9F].

[302] Charles, *supra* note 286 (quoting Manooj Sahoo, Chief Commercial Officer for Calyxt).

[303] Cibus bypassed these voluntary review procedures for a strain of canola developed using mutagenic techniques and was quoted as saying that "if the company created this same kind of canola using newer gene-editing tools, it also would not require any formal government review." *Id.*

[304] There have been many more of these letters for other older gene-editing techniques like TALENs and ZFNs. *See* Enriquez, *supra* note 228, at 512; *AIR List*, *supra* note 282.

[305] Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Dr. Yinong Yang, Coll. of Agric. Scis. (Apr. 13, 2016), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-321-01_air_response_signed.pdf [https://perma.cc/8SBC-JCCJ] [hereinafter Firko Letter to Yang]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Dr. Daria H. Schmidt, Dir. Registration & Reg. Aff., DuPont Pioneer (Apr. 18, 2016), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-352-01_air_response_signed.pdf [https://perma.cc/DWD8-EH97] [hereinafter Firko Waxy Corn Letter to Schmidt]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, Dr. Thomas Brutnell, Dir. Enter. Inst. for Renewable Fuels, Donald Danforth Plant Sci. Ctr. (Apr. 7, 2017), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/16-066-01_air_response_signed.pdf [https://perma.cc/8KZP-WDD5] [hereinafter Firko Letter to Brutnell]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Dr. Karen Bohmert-Tatarev, Tech. Manager, Yield10 Bioscience, Inc., & Dr. Kristi D. Snell, VP of Research & CSO, Yield10 Bioscience, Inc. (Aug. 29, 2017), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/17-166-01_air_response_signed.pdf [https://perma.cc/NE2F-RHYX] [hereinafter Firko Letter to Bohmert-Tatarev]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Dr. Shaun Curtin, Res. Molecular Biologist, USDA-ARS (Oct. 16, 2017), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/17-219-01_air_response_signed.pdf [https://perma.cc/7SKV-ZT8T] [hereinafter Firko Letter to Curtin]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Dr. Daria H. Schmidt, Dir. Registration & Reg. Aff., DuPont

the genome-edited crop "may still be subject to other regulatory authorities such as FDA or EPA."[306] Further, in a 2018 press release, Secretary of Agriculture Sonny Perdue clarified that USDA would not "regulate plants that could otherwise have been developed through traditional

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Pioneer (Jan. 12, 2018), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/17-076-01_air_response_signed.pdf [https://perma.cc/Q4KV-V8B5] [hereinafter Firko LeafBlight Corn Letter to Schmidt]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Harry J. Klee, Univ. of Fla., Horticulture Scis. (May 14, 2018), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/18-051-01_air_response_signed.pdf [https://perma.cc/N7TK-U4SG] [hereinafter Firko Letter to Klee]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Dr. Patrick Schnable, Iowa State Univ. (July 12, 2018), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/18-110-01_air_response_signed.pdf [https://perma.cc/4MGM-MLDD] [hereinafter Firko Letter to Schnable]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Drs. John Sedbrook and Michaela McGinn, Ill. State Univ. (Aug. 6, 2018), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/18-036-01_air_response_signed.pdf [https://perma.cc/E9WQ-CCLF] [hereinafter Firko Letter to Sedbrook and McGinn]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Dr. Karen Bohmert-Tatarev, Tech. Manager, Yield10 Bioscience, Inc., & Dr. Kristi D. Snell, VP of Research &CSO, Yield10 Bioscience, Inc. (Sept. 7, 2018), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/18-142-01_air_response_signed.pdf [https://perma.cc/62BJ-XQLE] [hereinafter Firko Camelina Null Segregant Lines Letter to Bohmert-Tatarev]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Ian T. Baldwin, Professor, Max Planck Inst. for Chem. Ecology (Feb. 25, 2019), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/18-248-01_air_re sponse_signed.pdf [https://perma.cc/YCF4-Q5EJ] [hereinafter Firko Letter to Baldwin]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Dr. John Sedbrook, Ill. State Univ. (Apr. 19, 2019), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/18-337-01_air_response_signed.pdf [https://perma.cc/HLD7-27MZ] [hereinafter Firko Letter to Sedbrook]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Dr. Robert Stupar, Assoc. Prof., Univ. of Minn. (June 17, 2019), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/19-077-02_air_response_signed.pdf [https://perma.cc/W4M8-8ZJA] [hereinafter Firko Letter to Stupar]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Dr. Robert Stupar, Assoc. Prof., Univ. of Minn. (June 17, 2019), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/19-077-01_air_response_signed.pdf [https://perma.cc/GC7F-JSVT] [hereinafter Firko Line 68-5-10 Letter to Stupar]; Letter from Michael Firko, APHIS Deputy Adm'r, USDA, to Richard Jupe, VP Product Design & Maint., Altria Client Services LLC (July 31, 2019), https://www.aphis.usda.gov/bio technology/downloads/reg_loi/19-101-01_air_response_signed.pdf [https://perma.cc/X4ET-G2Z2] [hereinafter Firko Letter to Jupe].

[306] Firko Letter to Yang, *supra* note 305; Firko Waxy Corn Letter to Schmidt, *supra* note 305; Firko Letter to Brutnell, *supra* note 305; Firko Letter to Bohmert-Tatarev, *supra* note 305; Firko Letter to Curtin, *supra* note 305; Firko LeafBlight Corn Letter to Schmidt, *supra* note 305; Firko Letter to Klee, *supra* note 305; Firko Letter to Schnable, *supra* note 305; Firko Letter to Sedbrook and McGinn, *supra* note 305; Firko Camelina Null Segregant Lines Letter to Bohmert-Tatarev, *supra* note 305; Firko Letter to Baldwin, *supra* note 305; Firko Letter to Sedbrook, *supra* note 305; Firko Letter to Stupar, *supra* note 305; Firko Line 68-5-10 Letter to Stupar, *supra* note 305; Firko Letter to Jupe, *supra* note 305.

breeding techniques as long as they are not plant pests or developed using plant pests."[307]

Thus far, APHIS is the only agency to throw its hat into the ring to have its say on CRISPR modified crops. As mentioned above, EPA is primarily responsible for regulating pesticides, and, as such, GE plants that upregulate pesticidal genes or introduce pesticidal phenotypes would be subject to EPA regulations. Thus far, none of the products submitted for the APHIS AIR process qualify.[308]

The FDA, on the other hand, could additionally play the role of regulating CRISPR products if it felt so inclined.[309] The FDA has already made a splash by trying to drag CRISPR modified animals under its regulatory thumb as an "animal drug."[310] Though FDA regulations are product-based on their face, and GE crops would not face extra scrutiny for how they are engineered, in practice, the *de facto* voluntary consultation process would likely be utilized, similar to what has happened with GMOs. To date, little has come from FDA relating to CRISPR modified plants and it remains to be seen if they will be roped into regulation in the same manner.

Tellingly, despite the first CRISPR products being given the go ahead by APHIS in 2016, three years later none have come to market.[311] Though Dr. Yinong Yang, a Penn State professor and the developer of the first CRISPR product to be put in front of a regulatory agency, believed that FDA approval was not required, he also thought it "prudent" and stated that FDA consent "could give the public more assurance and peace

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[307] Press Release, USDA, Secretary Perdue Issues USDA Statement on Plant Breeding Innovation (Mar. 28, 2018), https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation [https://perma.cc/3DRR-ZBL3].

[308] Firko Letter to Yang, *supra* note 305; Firko Waxy Corn Letter to Schmidt, *supra* note 305; Firko Letter to Brutnell, *supra* note 305; Firko Letter to Bohmert-Tatarev, *supra* note 305; Firko Letter to Curtin, *supra* note 305; Firko LeafBlight Corn Letter to Schmidt, *supra* note 305; Firko Letter to Klee, *supra* note 305; Firko Letter to Schnable, *supra* note 305; Firko Letter to Sedbrook and McGinn, *supra* note 305; Firko Camelina Null Segregant Lines Letter to Bohmert-Tatarev, *supra* note 305; Firko Letter to Baldwin, *supra* note 305; Firko Letter to Sedbrook, *supra* note 305; Firko Letter to Stupar, *supra* note 305; Firko Line 68-5-10 Letter to Stupar, *supra* note 305; Firko Letter to Jupe, *supra* note 305.

[309] Enriquez, *supra* note 228, at 503.

[310] *See Regulation of Intentionally Altered Genomic DNA in Animals; Draft Guidance for Industry; Availability*, 82 Fed. Reg. 6561 (Jan. 19, 2017); Alison Van Eenennaam et al., *Proposed U.S. Regulation of Gene-Edited Food Animals Is Not Fit for Purpose*, 3 NPJ SCI. FOOD 1, 2 (2019); Alison Van Eenennaam, *FDA regulates gene-edited animals like drugs, not food. That's a mistake.,* NEW FOOD ECON. (Mar. 5, 2019), https://newfoodeconomy.org/gene-edited-food-regulations-drugs-livestock/ [https://perma.cc/T9HM-W9FA].

[311] Taylor, *supra* note 18.

of mind."[312] It is impossible to say whether or not the other CRISPR products heeded Dr. Yang's prudence and submitted to FDA or not, but this at least seems likely.[313] Interestingly, only two gene-edited products from earlier non-CRISPR/Cas methods have publicly come to market, one underwent both the USDA AIR procedure and the FDA consultation process while the other did neither.[314]

D. The European Union Reaction to Gene Editing

The European Union, unfortunately, has taken the exact opposite approach to gene-edited foods. The Court of Justice of the European Union ruled in July 2018 that "organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive."[315] The court essentially defines mutagenesis as any process that "alter[s] the genetic material of an organism in a way that does not occur naturally."[316] Of course, like the GMO Directive itself, the court takes a hypocritical view of mutagenesis stating that "the GMO Directive . . . does not apply to organisms obtained by means of certain mutagenesis techniques, namely those which have conventionally been used in a number of applications and have a long safety record."[317] A pilot project growing

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[312] Sandy Bauers, *Genetically modified mushroom stirs debate*, PHILA. INQUIRER (May 26, 2016), https://www.inquirer.com/philly/health/20160529_Genetically_modified_mushroom_stirs_debate.html [https://perma.cc/XK7L-STJ8] (quoting Dr. Yang).

[313] The FDA has a list of the responses to all consultations that it publishes on its website. Unfortunately, it does not publish that it has received consultation requests, only the final results are published. None of the CRISPR products that have made it through the APHIS AIR procedure have seemingly made it through FDA's "voluntary" consultation or they simply did not submit to FDA and instead have yet to come to market for other reasons. *See Consultations on Food from New Plant Varieties*, FDA, https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=Biocon&sort=FDA_Letter_Dt&order=DESC&startrow=1&type=basic&search= [https://perma.cc/NMV3-HNSR] (last updated Oct. 11, 2019).

[314] *See generally* Greg Jaffe, *Biotech Blog: A Call for a National Registry of Gene-Edited Agricultural Crops*, CTR. FOR SCI. PUBLIC INT. (Apr. 22, 2019), https://cspinet.org/news/biotech-blog-national-registry-gene-edited-crops [https://perma.cc/6BVA-BLQD]. Calyxt used TALENS to modify soybeans to make their oil profile more healthy for consumption and went through both processes. *See Calyxt Doubles 2018 High Oleic Soybean Acres*, CALYXT (Jan. 22, 2019), https://calyxt.com/calyxt-doubles-2018-high-oleic-soybean-acres/ [https://perma.cc/AC8B-Q782]. Cibus used a proprietary gene-editing process to create a herbicide-tolerant canola and did not go through either process. *See Our Crops*, CIBUS, https://cibus.com/crops.php [https://perma.cc/H3R5-VRZ8] (last visited Dec. 3, 2019).

[315] European Union Court of Justice Press Release 111/18, Organisms Obtained by Mutagenesis are GMOs and are, in Principle, Subject to the Obligations Laid Down by the GMO Directive (July 25, 2018).

[316] *Id.*

[317] *Id.*

GE Camelina was approved by the Department of Environment, Food, and Rural Affairs ("DEFRA") and had begun in the UK, skirting these regulations.[318] Biotechnology producers were hopeful that the European Court of Justice ruling would allow for GE plants to be approved and grown. Instead, they were significantly delayed until they could go through the strict GMO regulations present in the UK.[319] With Brexit looming, it is unclear how much longer the UK will persist under the GMO Directive of the EU. Prime Minister Boris Johnson has vowed to "liberate the UK's extraordinary bioscience sector from anti-genetic modification rules."[320]

These artificial distinctions between natural versus unnatural are counterproductive to sensible regulation. A plant is not inherently more dangerous because it uses "unnatural" means of production.[321] Even more importantly, the EU distinction between what is natural and what is artificial makes even less sense. There is nothing "natural" about the artificial selection we have used for millennia to bend the forces of evolution to our whims.[322] There is nothing natural about bombarding plants with X-rays in hopes of causing beneficial mutations.[323] It is asinine to argue that X-rays and cross-breeding plants so distantly related that they would never hybridize in the wild is more "natural" than using molecular techniques to make specific modifications, many of which could easily arise naturally given enough time.[324] The European Union has again shown the folly of process-based regulation and this ruling will stunt the progress of GE technologies and their proliferation within the EU.[325]

The approach the EU has chosen to take is short-sighted and detrimental to both innovation and humanity. It also negatively affects American growers as it creates issues related to the import and export of crops. If these gene-editing techniques are not regulated in the United

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[318] Charles Hymas, *Exclusive: Gene-edited super-crops to be grown in UK for the first time*, TELEGRAPH (May 22, 2018), https://www.telegraph.co.uk/global-health/science-and-disease/exclusive-gene-edited-super-crops-grown-uk-first-time/ [https://perma.cc/VHB2-NF4V].

[319] Jean-Denis Faure & Johnathan A. Napier, *Europe's first and last field trial of gene-edited plants?*, 7 ELIFE (Dec. 18, 2018), https://elifesciences.org/articles/42379 [https://perma.cc/Z73T-WS3L]; Arthur Nelsen, *Gene-edited plants and animals are GM foods, EU court rules*, GUARDIAN (July 25, 2018), https://www.theguardian.com/environment/2018/jul/25/gene-editing-is-gm-europes-highest-court-rules [https://perma.cc/7GT9-AJ6U].

[320] Éanna Kelly, *Boris Johnson vows to ditch EU rules on GM crops,* SCI. BUS. (July 25, 2019), https://sciencebusiness.net/news/boris-johnson-vows-ditch-eu-rules-gm-crops [https://perma.cc/L7Z2-AQEB] (quoting Prime Minister Boris Johnson).

[321] NAS, *supra* note 141, at 173.

[322] *See id.* at 173–78; *supra* Part VI.

[323] *See* NAS, *supra* note 141, at 23, 58, 67; *supra* Part VI.

[324] *See* NAS, *supra* note 141, at 58; *supra* Part VI.

[325] Faure & Napier, *supra* note 319, at 5.

States, but they undergo extensive regulation in the EU, it blocks off a substantial market, reducing the value of these crops.[326] Additionally, it might actually be impossible to differentiate gene-edited crops from those produced by currently allowed mutagenic techniques, exasperating the trade issues.[327] Crops that are unregulated and unlabeled in the United States while being undetectable at the genomic level sound like a nightmare for the EU to deal with under their current strict import regulations.[328]

But it should be abundantly clear that, like with traditional GMOs, there are significant issues in our current regulatory system for GE products. We need a system that regulates GE products in a manner that supports technological innovation and adaptation. The long, expensive march to market required for GMO products should not be repeated for GE products—if we have any illusions of feeding the world. At the same time, GE products should not automatically be allowed to slip through the cracks sans regulation just due to the process that created them; instead the regulation of both GMO and GE products should be tied to risk.

VIII. EMBRACING RISK-BASED REGULATION FOR GENETIC ENGINEERING

A. *Tying Regulation to Risk*

All sides of the debate over GMOs have criticized the current regulatory system.[329] Government regulations should only be as intrusive as is necessary in order to protect the general welfare, whether that's human health or the environment. When a regulatory system becomes detached from the dangers it was designed to regulate, when there is a lack of correlation between the products regulated and the dangers posed, the system should be changed. A very promising reform would be to truly incorporate the concept of "risk" into the realm of regulation.[330] Rather than regulating based on the technique used to create the plant or even genotypic changes, regulation would focus on the risk of the phenotype

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[326] Gregory Jaffe, *EU will regulate gene-edited organisms as GMOs*, CORNELL ALLIANCE FOR SCI. (July 26, 2018), https://allianceforscience.cornell.edu/blog/2018/07/eu-will-regulate-gene-edited-organisms-gmos/ [https://perma.cc/BM8W-ZYWW].
[327] *Id.*
[328] *Id.*
[329] *See, e.g.*, Bradford et al., *supra* note 230, at 439; Dana Carroll et al., *Regulate Genome-Edited Products, Not Genome Editing Itself,* 34 NATURE BIOTECHNOLOGY 477, 479 (2016); Fedoroff et al., *supra* note 175, at 833; Steven H. Strauss, *Genomics, Genetic Engineering, and Domestication of Crops*, 300 SCI. 61, 61–62 (2003); Strauss & Sax, *supra* note 200, at 474.
[330] *See* Conko et al., *supra* note 17, at 493, 502.

of the regulated plant and how this phenotype might interact in its proposed environment given its intended use as a product.[331] This idea of risk-based regulation would get us back to the original intent of the "coordinated framework" by being product-based instead of process-based.

The idea of better correlating risk with regulatory scrutiny has been around for nearly as long as the debate over biotechnology. In a recent article, Dr. Conko and his colleagues[332] suggested applying the "Stanford Model" for accomplishing this goal.[333] Originally proposed by a collaborative group in the 1990s to act as a framework for biotechnological regulation, its adaptive structure makes it still applicable today, despite intervening changes in technology.[334]

Essentially all biotechnological, or even all agricultural products, can be stratified into different risk categories.[335] Risk is calculated by multiplying "the [likelihood] that the genetic modification will lead to harm and the magnitude of the resulting harm."[336] The "risk" category for each organism is therefore based upon "the intrinsic properties of the plant, the nature of any new or altered traits, and the environment into which the crop would be introduced."[337] Products with a higher likelihood of causing harm will be in higher-risk categories than those that have a lower likelihood of causing harm;[338] likewise, products with the potential to cause more

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[331] *Id.*

[332] The authors of this article are an impressive multidisciplinary team. Gregory Conko is a senior fellow at the Competitive Enterprise Institute. Drew L. Kershen is Earl Sneed Centennial Professor of Law Emeritus at the University of Oklahoma College of Law. Henry I. Miller was the Robert Wesson Fellow in Scientific Philosophy and Public Policy at the Hoover Institute at Stanford University. Wayne A. Parrot is a professor at the Institute for Plant Breeding Genetics and Genomics at the University of George. *Id.* at 493; *Gregory Conko Returns to CEI as Senior Fellow*, COMPETITIVE ENTERPRISE INST. (Nov. 18, 2019), https://cei.org/content/gregory-conko-returns-cei-senior-fellow [https://perma.cc/D8B9-4KDX].

[333] Conko et al., *supra* note 17, at 493.

[334] *See* John Barton et al., *A Model Protocol to Assess the Risks of Agricultural Introductions*, 15 NATURE BIOTECHNOLOGY 845, 845–48 (1997).

[335] Conko et al. utilized four different risk categories: Negligible, Low, Moderate, and High. *See* Conko et al., *supra* note 17, at 498. Strauss et al. utilized three: Low, Medium, and High. *See* Strauss, *supra* note 329, at 61–62. Barton et al. used a numbering system, where 1 is the lowest safety concern and 5 is the greatest safety concern. *See* Barton et al., *supra* note 334, at 846. The exact number of categories is less important than the way in which the categories are applied.

[336] Conko et al., *supra* note 17, at 499 (emphasis omitted).

[337] *Id.* at 498.

[338] Likelihood is broken down into four categories: Very Low ("expected to happen only in very rare cases"), Low ("expected in some cases"), High ("expected in many cases"), and Very High ("expected in most cases"). *Id.* at 499.

serious harm would be in a higher-risk category than those with the potential to only cause minor harm.[339] To determine harm, regulators should consider the "object[s] of protection," which can include: "food safety, . . . prevention of enhanced weediness, loss of biodiversity from gene flow and harm to plants that are important to agriculture or ecosystems."[340] Conko and his colleagues suggest that this harm analysis should be done as a balancing test, with potential benefits to biodiversity, such as decreased pesticide usage or decreased conversion of natural landscapes into agricultural ones, being weighed against the potential harms caused.[341] In our current system, benefits are rarely considered when determining the appropriate level of regulatory scrutiny.[342]

The agencies already use a variety of strategies to regulate GMO and GE crops that could be adapted to stratify products by stringency and assign each to the commensurate risk level. The APHIS regulatory domain contains a variety of pre-market and post-market regulatory mechanisms, permits, notifications, inquiries, and petitions.[343] The systems of pre-market field trials and testings and post-market review are already in place and could likely be reframed as well as allocated to different risk categories.[344] Though some have suggested that all authority for genetically modified organisms be brought under a single regulatory agency's purview, this seems unlikely to happen without a major rewrite of our laws.[345]

B. Single Entry Process

Instead, we recommend utilizing a system similar to APHIS's "Am I Regulated" procedure as a unified first step for all agencies.[346] Producers can submit short inquiries with information on the product, expected traits, and the mechanism-of-action ("MOA") to the agencies all at once. If the

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[339] Magnitude of harm is broken down into four categories: Marginal ("harm is negligible or too small to measure"), Minor ("harm is reversible and limited to a given time"), Great ("harm can be widespread but is reversible"), and Major ("harm is extensive, long-term, or permanent"). *Id.*
[340] *Id.* at 498.
[341] *Id.* at 498–99.
[342] Conko et al., *supra* note 17, at 498; *see also* Rod A. Herman et al., *Risk-Only Assessment of Genetically Engineered Crops is Risky*, 24 TRENDS PLANT SCI. 58, 58 (2019).
[343] *See supra* Section VI.D.
[344] *Cf.* Conko et al., *supra* note 17, at 496.
[345] *See* Strauss & Sax, *supra* note 200, at 476.
[346] For AIR procedure description, see *supra* notes 300–03 and accompanying text; *see supra* Section VII.C.

risk is not apparent from this first-look inquiry, then the crops would be exempted from regulation, essentially fitting into the lowest risk category. If the kinds of risks that each agency is tasked with regulating are apparent, then a risk level can be assigned, and recommendations can be made on which regulations are required. This risk assessment should provide producers with a clear step-by-step pathway through the morass of regulation. This could also replace the "*de facto* voluntary" review that FDA currently undertakes for GMO products.[347] Ideally, all novel crops would be subject to this step, whether they are developed with mutagenic techniques, transgenic techniques, or genetic editing techniques—thus ensuring its grounding in "product not process." APHIS would be the obvious agency to house this single entry, and then, if it determined risks that would trigger FDA or EPA regulation, producers would be funneled to those agencies to meet the requirements associated with the assigned risk category. This would require actual coordination between the agencies to form this unified front for dealing with agricultural products, which meets the original vision of the coordinated framework.

This preliminary review should heavily rely on novelty—specifically, the novelty of the traits, not the novelty of the methods used to produce the traits.[348] New traits in new hosts should obviously trigger higher levels of regulation than inserting the same trait in the same host with the same mechanism of action, but under our current system, each insertion is treated independent, requiring review (dubbed event-based regulation).[349] Modifications that are identical to modifications that have been approved before should be fast-tracked to approval again. Ultimately, novelty is just a function of risk—as, with an appropriate application of the precautionary principle, unknown products should be subject to increased scrutiny than those for which the risks are by now apparent.[350] Regulation needs to be based on the risk the product creates to the environment and human health, not on how specific modification events occur.

C. Registry of Biotechnological Products

Additionally, this single entry into the regulatory process would allow for another major update—a database of biotechnological products on the market. This is especially needed in combination with the proliferation

[347] Conko et al., *supra* note 17, at 496.
[348] *See* Strauss & Sax, *supra* note 200, at 475–77.
[349] *Id.* at 474–76.
[350] Conko et al., *supra* note 17, at 493, 498–99.

of genetic editing techniques. If gene editing is to gain mainstream acceptance and realize its full potential, then public acceptance is a necessity.[351]

Greg Jaffe, the director at the Center for Science in the Public Interest, has been arguing for a registry specifically for GE products because it will create transparency in the system, hopefully leading to this public acceptance that is so vital to the mainstream success of GEs.[352] By attaching it to the single entry process above, we kill two birds with one stone. Essentially, the results of this entry process would simply be published and added to the database, thus creating the registry without extra work for the producers or agencies. The necessary information for the public would be made available, such as the kind of crop being modified, the modification made, the technology used, the molecular mechanisms that create the expected phenotype, and even the risks and subsequent required regulations the agencies assign.

Though this does go against the product-based mantra we are arguing for, much like with labeling laws, public acceptance must be considered, especially when the process-based requirement would be so minimal. This database of products and their traits also serves a second purpose—the agencies will now have the tools in hand to combat event-based regulation. If the determinations of regulation are truly risk-based, then products with a history of low risk host-trait-MOA combinations should be maintained to help make these risk determinations.

D. *Modifying Regulatory Triggers*

The Coordinated Framework intended that the regulation of genetically modified products be product-based and not process-based. A shift in regulatory triggers for some of the agencies is needed to facilitate this paradigm shift. Currently, we regulate when there is the presence of a "plant pest," when there is a risk to food safety, or when there are "pesticides."[353] The future of biotechnology will likely produce products that exist completely outside the realm of these three triggers but could pose environmental or other risks. Instead of regulating any product with genetic material from a "plant pest," APHIS should instead regulate products with plant pest phenotypes. If a product is noxious or weedy, then

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[351] *See generally* Kuzma, *supra* note 297.

[352] Jaffe, *supra* note 245.

[353] *See generally* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986) (explaining the federal policy for regulating the development and introduction of biotechnology products).

it should be regulated accordingly by APHIS, regardless of the genetic material or the processes involved in creating the product. This would reduce regulation on a wide variety of GMO and GE plants, and, at the same time, it would plug the gap that would potentially allow actual plant pests through sans regulation. Similarly, EPA would do well to regulate based on toxicity and other risks associated with pesticides—not on the mere presence of what they currently label a PIP. Plants that are not producing pesticidal compounds, but have simply had their own immune systems boosted, are being labeled and regulated as pesticides, despite the fact that there are no perceived risks associated with these changes.[354] It is asinine that EPA is trying to label plants as "pesticides," based on boosted immune systems, when in reality these kinds of modifications will drastically reduce actual pesticide usage, which should be EPA's actual mission. This is not how a risk-based system would operate. Only by modifying the regulatory triggers for APHIS and EPA will we be able to move towards a scientifically defensible system based on risk.

Ultimately, we believe that applying the same risk-based criteria to GEs and GMOs is the best possible strategy for regulation. When crops have a high potential to cause harm, they should be regulated accordingly; without evidence of risk, there should be no regulation.

IX. TRUMP ADMINISTRATION PROPOSALS

Though the Obama era changes were largely superficial,[355] the Trump Administration appears interested in making more substantive changes. In June 2019, President Trump signed an executive order aimed at further deregulation of GMO crops by simplifying the so-called "regulatory maze."[356] At this point, it is unclear what effect this order will ultimately have, but the substance and tone of the order have led commentators to characterize it as an attempt to either weaken protections

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[354] A sterling example of this was that of the HoneySweet plum. In an effort to increase resistance to plum pox virus (PPV), scientists inserted a gene PPV coat gene. The insertion of this gene from the virus will cause the plant's natural RNA interference pathways to provide high levels of resistance to the virus. The plants do not create chemical pesticides of any kind. This methodology affects the immune system of the plants, not chemical defenses that you would assume would qualify as a PIP. *See* Michel Ravelonandro et al., "*HoneySweet" Plum—A Valuable Genetically Engineered Fruit-Tree Cultivar*, 4 FOOD & NUTRITION SCI. 45, 45–46, 48 (2013).

[355] For the Obama era rule, see *supra* Section VI.E.

[356] Candice Choi, *Trump orders simpler path for genetically engineered food*, ASSOCIATED PRESS (June 11, 2019), https://www.apnews.com/2895e0f0ef344d16bfcf6f457ed2e759 [https://perma.cc/RXT3-NPHE]; *see* Exec. Order No. 13,874, 84 Fed. Reg. 27,899 (June 11, 2019).

or reduce burdensome regulation, depending on each commentator's biases.[357] As a clear swipe at the recent European Union GE ruling and its effect on trade, the Executive Order wants to "promote trade . . . by urging trading partners to adopt science- and risk-based regulatory approaches."[358]

Coinciding with the 2019 Executive Order, APHIS put forth a novel rule for public comment.[359] Guided by the tagline "SECURE" (standing for Sustainable, Ecological, Consistent, Uniform, Responsible, and Efficient), this new APHIS rule would actually substantially change the way the agency regulates GMO and GE plants.[360] This proposed rule is, in many ways, an important first step in reforming biotechnological regulation in favor of a more risk-based and product-based approach.[361] The proposed rule actually incorporates a number of the proposals we have made in this Article.

First, the trigger for regulation would shift away from the inclusion of genetic material from plant pests with the agency finally recognizing that "genetically engineering a plant with a plant pest as a vector, vector agent, or donor does not in and of itself result in a GE plant that presents a plant pest risk."[362] Further, the proposed rule highlights the potential regulatory gap gene editing has created by admitting that "GE techniques have been developed that do not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents yet may result

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[357] *See, e.g.*, Press Release, Ctr. for Food Safety, Trump Signs Exec. Order to Further Gut Fed. GMO Oversight (June 13, 2019), https://www.centerforfoodsafety.org/press-releases/5624/cfs-statement-trump-signs-executive-order-to-further-gut-federal-gmo-oversight [https://perma.cc/2TAY-MKY2]; Mike Dorning & Jennifer A. Dlouhy, *Trump Orders Federal Agencies to Ease Approval of New GMO Crops*, BLOOMBERG (June 11, 2019), https://www.bloomberg.com/news/articles/2019-06-11/trump-plans-to-sign-order-to-ease-approval-of-new-gmo-crops [https://perma.cc/WQ89-UJVB]; Jennifer Kuzma, *Biotechnology Oversight Gets an Early Make-Over by Trump's White House and USDA: Part 1—The Executive Order*, GENETIC ENG'G & SOC'Y CTR., N.C. ST. U. (June 18, 2019), https://research.ncsu.edu/ges/2019/06/ag-biotech-oversight-makeover-part-1-eo/#_edn1 [https://perma.cc/4978-5DXU].

[358] 84 Fed. Reg. at 27,900.

[359] Movement of Certain Genetically Engineered Organisms, 84 Fed. Reg. 26,514 (June 6, 2019) (to be codified at 7 C.F.R. pts. 340, 372) [hereinafter SECURE].

[360] Press Release, Animal & Plant Health Inspection Serv., USDA, USDA Proposes New SECURE Biotechnology Regulations to Protect Plant Health & Promote Agric. Innovation (June 5, 2019), https://www.aphis.usda.gov/aphis/newsroom/news/sa_by_date/sa-2019/biotech-secure-regulations [https://perma.cc/U4LQ-X66P].

[361] "The approach we are proposing would differ from the current regulatory framework in that regulatory efforts would focus on the properties of the GE organism itself rather than on the method used to produce it." SECURE, 84 Fed. Reg. at 26,516.

[362] *Id.* at 26,515.

in GE organisms that pose a plant pest risk."[363] As such, the "regulated article" terminology would be dropped entirely and, instead, regulation will kick in when crops actually exhibit "plant pest risks," defined as "[t]he possibility of harm to plants resulting from introducing or disseminating a plant pest or exacerbating the impact of a plant pest."[364] This fits in with our suggestions above about shifting regulatory triggers.

Second, it takes novelty into consideration and attempts to discard APHIS's current event-based regulatory approach.[365] APHIS will now look at the biochemical basis for traits, the "plant-trait-mechanisms of action (MOA) combination[]," when determining whether or not to regulate.[366] APHIS will decline to regulate "GE plants with plant-trait-MOA combinations that we have already determined are not subject to these regulations."[367] APHIS will maintain an online database of the plant-trait-MOA combinations to assist producers in determining whether their novel organism fits under this exception.[368] Essentially, plants that are substantially equivalent to ones that have been previously deregulated, because they posed no risk, are also placed in this no risk category and deregulated. Even though this rule does not incorporate defined risk categories like the Stanford model, this part of the rule truly incorporates risk-based regulation.

Another group of GE plants will also be exempted from regulation if this new rule is finalized. This rule, following up on Secretary Perdue's 2018 statements, would exempt GE crops that could have been produced through traditional breeding methods.[369] The proposal specifically mentions that this portion of the rule is "intended to provide regulatory relief to developers."[370] In this category of "traditional breeding methods," they include: "a deletion of any size," "a single base pair substitution," introductions of "nucleic acid sequences from within the plant's natural gene pool or from editing nucleic acid sequences in a plant to correspond to a sequence known to occur in that plant's natural gene pool," and "offspring of a GE plant" that do "not retain the genetic modification in the GE plant parent."[371] This step disregards the product-based system APHIS

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[363] *Id.*
[364] *Id.* at 26,524, 26,538.
[365] *Id.* at 26,517.
[366] *Id.*
[367] SECURE, 84 Fed. Reg. at 26,517.
[368] *Id.*
[369] *Id.* at 26,519.
[370] *Id.* at 26,516.
[371] *Id.* at 26,519.

claims to be instilling and actually decouples risk and regulation. It makes an assumption that the process of insertion or deletion is similar enough to conventional breeding, and thus does not need to be regulated, disregarding the nature of the product itself. As a class, these processes are no more dangerous or safe than any other, including transgenics.[372] Under our suggested system, these products would go through the single-entry system, and if the products do not possess risks, then they will quickly be exempted based on that lack of risk.

Finally, this rule would usher in what APHIS is calling a regulatory status review ("RSR") to determine at the first step of the process if the organism should be regulated by APHIS.[373] They describe RSR as "objective, rapid, and based on transparent predetermined criteria."[374] It will be essentially a hybrid between the functionally similar AIR process and the more stringent petition for the nonregulated status procedure.[375] The RSR will require more detailed information on the genetic changes and genetic sequences than they require for the current AIR procedure.[376] However, the field test requirement currently in place for petitions would be dropped for the RSR; APHIS believes that field trials are unnecessary to determine potentially deleterious effects.[377] Additionally, the requirement for notice and comment in the Federal Register that is used for petitions is not being carried over to the RSRs.[378] This will effectively create a two-step process. First, under the RSR, if the organism is not a plant pest risk, or fits under one of the above exemptions, then it will be

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[372] Jennifer Kuzma, *Biotechnology Oversight Gets an Early Make-Over by Trump's White House and USDA: Part 2—The USDA-APHIS Rule*, GENETIC ENG'G & SOC'Y CTR., N.C. ST. U. (July 2, 2019), https://research.ncsu.edu/ges/2019/07/ag-biotech-oversight-makeover-part-2-usda-aphis-rule/ [https://perma.cc/ERG3-WDPJ].
[373] SECURE, 84 Fed. Reg. at 26,524.
[374] *Id.* at 26,527.
[375] *See id.* at 26,524.
[376] *Id.* at 26,525.
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> To date, APHIS has authorized more than 100,000 field trials—a single permit or notification may authorize multiple trials—and APHIS has not received a report of unintended deleterious effects on plants, non-target organisms, or the environment. Based on the risk assessments we have performed in accordance with the petition process over 30 years, we have determined that, in many cases, we would have been able to evaluate the plant pest risks associated with a GE organism without field-test data. Rather, the Agency has discovered that the introduced trait of the GE organism provides the most reliable indicator of the organism's potential for deleterious effects on plants and plant products.

Id.
[378] *See id.* at 26,527.

able to proceed without additional regulation. If the RSR shows that there is a plant pest risk, then the producer can begin the application for a permit.[379] APHIS is also withholding the right to initiate a review or a re-review products when necessary.[380] Additionally, producers can skip the RSR procedure entirely and self-determine if their product falls into one of the exception categories, allowing them to move to market without any oversight from APHIS.[381]

This RSR process possesses a number of similarities to our suggested regulatory framework. The move to further embrace a process similar to the AIR is a good move that should responsibly reduce regulatory burden. We argue that extending this process across all three agencies in the form of a single-entry point for regulation would be the next step. However, the ability to self-determine is potentially troubling. The database of plant-trait-MOA combinations could have been a good start on creating a registry of GE products, but ultimately it falls short because so many products will simply self-determine without ever filling out an RSR.[382] As the RSR does not require field testing,[383] the burden of completing the RSR is fairly minimal. The increased burden from having to submit an RSR for every new product (not every single event but every novel product) is minimal in comparison to the potential benefits to transparency and public acceptance.[384]

CONCLUSION

The risk of any activity should drive a sensible regulatory system. But so too should consideration of the reward the activity may produce. If we are to meet the U.N. goal of increasing food production by 70 percent by 2050, we must utilize every tool in the toolkit, especially one as potentially transformative as genetic engineering.[385] The opportunity for GE to help farmers use less water to grow drought tolerant crops is a benefit so grand that government regulations should encourage, rather

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[379] The notification procedure is also being scrapped and streamlined back into the permitting procedure. SECURE, 84 Fed. Reg. at 26,527.
[380] *Id.* at 25,525.
[381] *Id.* at 26,517.
[382] Kuzma, *supra* note 372.
[383] *Id.*
[384] *See id.*
[385] *See generally* TIM SEARCHINGER ET AL., WORLD RES. INST., CREATING A SUSTAINABLE FOOD FUTURE: A MENU OF SOLUTIONS TO FEED NEARLY 10 BILLION PEOPLE BY 2050 1, 2, 7, 41 (Dec. 2018).

than stifle, scientists to create crops with these characteristics. It might be too late to truly change the regulation and the public perception of transgenics, but we simply cannot afford to go down that same dark road with genetic editing.

This is not a problem for the future, this is a problem for today. Climate change is here, and it is not going away any time soon.[386] Scientists have already begun to heed the charge. One recent study argued that adaptation of genetic engineering is needed to produce enough corn to combat the effects of climate change.[387] Drought-tolerant crops are being grown using these novel gene-editing techniques.[388] There are published studies where researchers used CRISPR to increase drought-tolerance, heat-resistance, or other abiotic resistances in corn,[389] tomatoes,[390] *Arabidopsis*,[391] rice,[392] and cassava.[393] Further, drought tolerant soybeans developed by the Agricultural Research Service, the research agency under APHIS, have already gone through the AIR procedure.[394] The techniques are viable and necessary, but the regulatory framework must change to give these products a fighting chance. The current framework blocks innovation when it comes to drought-tolerant and other engineered crops.[395] Even when they are developed in university labs or small firms, it is too expensive and time consuming to bring them to market.[396] The system must change.

Moving forward, we envision an agricultural landscape completely different to what we have today. We envision a new Green Revolution,

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[386] *See generally* IPCC, *supra* note 5.
[387] *See generally* Ariel Ortiz-Bobea & Jesse Tack, *Is Another Genetic Revolution Needed to Offset Climate Change Impacts for US Maize Yields?*, 13 ENVTL. RES. LETTERS 1 (2018).
[388] For a general overview of gene editing in crops, see Deepa Jaganathan et al., *CRISPR for Crop Improvement: An Update Review*, 9 FRONTIERS PLANT SCI. 1 (2018).
[389] Jinrui Shi et al., *ARGOS8 Variants Generated by CRISPR-Cas9 Improve Maize Grain Yield Under Field Drought Stress Conditions*, 15 PLANT BIOTECHNOLOGY J. 207, 207 (2017).
[390] Liu Wang et al., *Reduced Drought Tolerance by CRISPR/Cas9-Mediated SlMAPK3 Mutagenesis in Tomato Plants*, 65 J. AGRIC. FOOD CHEMISTRY 8674, 8674 (2017).
[391] Joaquin Felipe Roca Paixao et al., *Improved Drought Stress Tolerance in Arabidopsis by CIRSPR/dCas9 Fusion with a Histone AcetylTransferase*, 9 SCI. REP. 1, 1 (2019).
[392] Hui Zhang et al., *The CRISPR/Cas9 System Produces Specific and Homozygous Targeted Gene Editing in Rice in One Generation*, 12 PLANT BIOTECHNOLOGY J. 797, 797 (2014).
[393] Wenjun Ou et al., *Genome-Wide Identification and Expression Analysis of the KUP Family under Abiotic Stress in Cassava (Manihot esculenta Crantz)*, 9 FRONTIERS PHYSIOLOGY 1, 1 (2018).
[394] Firko Letter to Curtin, *supra* note 305 ("Confirmation that a *Glycine max* (soybean) line mutagenized using CRISPR-Cas9 is not a regulated article.").
[395] Conko et al., *supra* note 17, at 493.
[396] *See id.*

one that would make Dr. Borlaug proud. This revolution is technology-focused, bringing together advancements in water conservation, organic farming, data-driven agriculture, and biotechnology. We envision celebrity chefs engineering and serving up vegetables, from their vertical urban farms, tasting and looking like formerly rare heirlooms. We see a world where GE products have diversified the agricultural field in terms of products and producers, working in collaboration with organic and agroecological movements. And ultimately, we see a world being fed, but it all starts with sensible regulation.