ValpoScholar

Valparaiso University Law Review

Volume 51
Number 2 *Symposium: Continuing to Fight Today's Environmental Challenges: Climate Change, Health Concerns, Energy, and Food Supply*

*pp.*483-517

Symposium: Continuing to Fight Today's Environmental Challenges: Climate Change, Health Concerns, Energy, and Food Supply

The Failure of Federal Biotechnology Regulation

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THE FAILURE OF FEDERAL BIOTECHNOLOGY REGULATION

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ABSTRACT

The recent court case and state ballot measures regarding mandatory labels for Genetically Modified Organisms ("GMOs") suggest the need for a deeper conversation about the federal framework for regulating biotechnology. What is it about GMOs that consumers feel they have the "right to know?" Why has a generation of federal biotechnology regulation failed to satisfy consumer concerns? Are those concerns irrational, or is the regulatory structure inadequate? This Article argues that many consumer concerns underlying the labeling movement raise important scientific and extra-scientific questions that have been apparent since the advent of the technology in the 1980s. Moreover, these concerns persist because the Coordinated Framework for Regulation of Biotechnology has failed to respond to them effectively. The Coordinated Framework was based on statutes that pre-existed the technology and thus poorly fit the unique risks of genetic engineering. Today, genetic engineering is on the verge of a radical shift in technology, a shift that has already begun to burst the seams of those old statutes, leaving agencies with no regulatory authority at all over new products. This Article reviews the evidence behind persistent concerns about GMOs, considers the failures of the Coordinated Framework to address the most valid of those concerns, and canvasses policy questions that Congress must consider to more effectively tailor agency authority to address the risks and to enhance the potential of this rapidly-changing field of technology.

I. INTRODUCTION

It has become fashionable for the media to write off consumer concerns about GMOs as "science denial," akin to denying scientific evidence of climate change or evolution.[1] Nevertheless, those concerns

* Professor of Law, West Virginia University College of Law. This work was prepared with the support of the West Virginia University College of Law and the Arthur B. Hodges Summer Research Grant. The author also wishes to thank the 2016 World Champion Chicago Cubs without whom this Article would have been finished a lot sooner.

[1] *See, e.g.*, Fred Hiatt, *Science That is Hard to Swallow*, WASH. POST (Feb. 8, 2015), https://www.washingtonpost.com/opinions/fred-hiatt-genetically-modified-foods-

persist. Moreover, the controversy over labeling of genetically-engineered foods suggests the need for a deeper conversation about the federal framework for regulating biotechnology.[2] Why do consumers feel they have the "right to know" if a food is genetically modified, and what, exactly, do they want to know about those foods? Why has a generation of federal biotechnology regulation failed to satisfy these consumer concerns? Are these concerns simply irrational, or does their persistence suggest that federal regulation has missed the mark?

Instead of setting up a straw man by asking the simplistic question, "Are GMOs safe?," what is needed is a careful consideration of the most legitimate concerns raised about genetically-engineered products and a carefully nuanced approach to regulation that addresses those legitimate concerns. As United Kingdom journalist Mark Henderson stated: "The whole question of being pro- or anti-GMO is in many ways a bad one. The better question is what crop, with what modification, for what purpose, made by whom?"[3] This Article seeks to take consumer concerns seriously, to identify the most legitimate public concerns, and to explain why the current federal regulatory framework fails to adequately respond to those

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prove-hard-for-americans-to-stomach/2015/02/08/3ae7902c-ad60-11e4-9c91-e9d2f9fde644_story.html?utm_term=.6e20e47ce351 [https://perma.cc/JXB8-P2ZP]; *see also* Joel Achenbach, *Why Do Many Reasonable People Doubt Science?*, NAT'L GEOGRAPHIC (Mar. 2015), http://ngm.nationalgeographic.com/2015/03/science-doubters/achenbach-text [https://perma.cc/VG7S-Z8NM]; William Saletan, *Unhealthy Fixation: The War against Genetically Modified Organisms is Full of Fearmongering, Errors, and Frauds. Labeling Them Will Not Make You Safer*, 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/6BH8-3MGQ].

[2] In recent years, several states passed laws requiring that genetically-engineered ("GE") foods be labeled. *See, e.g.*, 2013 CONN. PUB. ACTS 9–10 (13-183); ME. REV. STAT. ANN. tit. 22 § 2591 (2013); VT. STAT. ANN. tit. 9 § 3043 (2016); *see also* Ross H. Pifer, *Mandatory Labeling Laws: What Do Recent State Enactments Portend for the Future of GMOs?*, 118 PENN. ST. L. REV. 789, 790 (2014). In 2015, a federal district court upheld the Vermont law against claims that it impermissibly mandated speech and restricted interstate commerce. Grocery Mfrs. Ass'n v. Sorrell, 102 F. Supp. 3d 583, 615 (D. Vt. 2015). Before the Vermont law could become operative, Congress passed legislation requiring the Department of Agriculture to develop a federal "disclosure standard" for genetically-engineered foods. National Bioengineered Food Disclosure Standard, Pub. L. 114-126, 130 Stat. 834 (July 29, 2016). The compromise legislation satisfied neither food manufacturers nor consumer's groups. Dan Charles, *Congress Just Passed a GMO Labeling Bill. Nobody's Super Happy about It.*, ALL THINGS CONSIDERED (July 14, 2016), http://www.npr.org/sections/thesalt/2016/07/14/486060866/congress-just-passed-a-gmo-labeling-bill-nobodys-super-happy-about-it [https://perma.cc/M25R-LQJF].

[3] *See The Geek Manifesto on GM Crops*, GEEK MANIFESTO (May 24, 2012), https://geekmanifesto.wordpress.com/2012/05/24/the-geek-manifesto-on-gm-crops/ [https://perma.cc/AJY3-5C45] (expressing the need for more poignant questions about how genetically-modified ("GM") crops are being utilized); *see generally* MARK HENDERSON, THE GEEK MANIFESTO 231–35 (2012) (discussing a variety of issues related to GM crops).

concerns. This diagnosis of the real problem with GMOs is intended to pave the way toward modifications of the current regulatory structure that respond rationally to the persistent concerns of the majority of U.S. consumers.

This Article concludes that, as research on human health impacts develop, consumer concerns raise legitimate questions about proven agro-environmental impacts, socio-economic harms, and the appropriate level of precaution. These questions remain reasonable even if, as GMO supporters assert, most genetically-engineered foods are safe for human consumption most of the time. These reasonable consumer concerns have persisted, in large part, because they were ignored by the Coordinated Framework for Regulation of Biotechnology, released by the Reagan Administration's Office of Science and Technology Policy in 1986 as the first attempt to coordinate federal oversight of the emerging technology.[4] The cracks in that foundation have begun to grow as some products now evade regulation under that framework.[5] As long as federal regulators continue to ignore these cracks and fissures, public dissatisfaction with GMO regulation will continue. Moreover, as genetic engineering continues to evolve and is set for a transformative breakthrough with the use of new technologies, biotechnology is set to outgrow the Coordinated Framework entirely, and discussion of a new regulatory structure is urgently needed.[6]

Part II of this Article identifies actual and legitimate consumer concerns about genetic engineering and concerns that arise from scientific, as well as economic, social, and legal factors.[7] Part III turns to the failures of the existing regulatory regime based on the Coordinated Framework, as well as risks that the Coordinated Framework does not purport to reach, such as trade losses and unique liability concerns relating to

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4 *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

5 *See infra* Part III.

6 *See* Memorandum from John P. Holdren, Assistant to the President for Science and Technology, to Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture (July 2, 2015), https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf [https://perma.cc/B38G-5F9W] [hereinafter Coordinated Framework Executive Memorandum]. Federal Regulators recognize this dilemma. *Id.* On July 2, 2015, the Executive Office of the President issued a memorandum directing the three primary agencies that regulate biotechnology products to update the Coordinated Framework, "develop a long-term strategy to ensure that the Federal [biotechnology] regulatory system" is prepared for the "future products of biotechnology," and commission an expert analysis of the future landscape of biotechnology products to support this effort. *Id.* at 4.

7 *See infra* Part II.

intellectual property rights.[8] This Article concludes that new legislation is necessary in the near terms and, in Part IV, canvasses four major policy issues that any new legislation must resolve.[9] Only a conscious and comprehensive scheme based on updated legislation can adequately regulate the risks of modern genetic engineering and simultaneously pave the way for technological developments and new products that could save lives and improve the environment.

II. PEELING OFF THE "SCIENCE DENIER" LABEL

Under the headline "Science that is Hard to Swallow," the *Washington Post* in 2015 featured an editorial about public opinion on GMOs that began, "Sophisticated readers know a science denier when they see one . . . ."[10] The author, Fred Hiatt, noted that in a recent survey, eighty-eight percent of scientists believed that genetically modified ("GM") foods were safe to eat, while only thirty-seven percent of the public thought so.[11] The survey noted that it was the largest opinion difference between scientists and the public on a range of scientific issues surveyed.[12] The author opined that the public's fears would be warranted only if plant breeding itself, originating with Gregor Mendel, is unsafe, then lambasted the public for obstructing technological progress that might feed the hungry.[13] Hiatt's editorial compared those who believed GM foods are unsafe to eat with those who disputed the safety and efficacy of vaccination, with those who denied that climate change has anthropogenic causes, and with those who disputed the theory of evolution.[14] The *Washington Post* is not alone in leveling this critique; others in the media have painted GM labeling proponents as anti-science.[15]

Is it true that consumer concerns about genetically-engineered products are scientifically invalid? Part II.A considers three different categories of common consumer concerns—safety for human

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8 *See infra* Part III.

9 *See infra* Part IV–V.

10 *See* Hiatt, *supra* note 1.

11 *See id.*; *see also* Cary Funk & Lee Rainie, *Public and Scientists' Views on Science and Society*, PEW RES. CTR. (Jan. 29, 2015), http://www.pewinternet.org/2015/01/29/public-and-scientists-views-on-science-and-society/ [https://perma.cc/3KYT-49SC].

12 *See* Funk & Rainie, *supra* note 11.

13 *See* Hiatt, *supra* note 1.

14 *See id.*

15 *See* Achenbach, *supra* note 1; Saletan, *supra* note 1.

consumption, environmental or agro-environmental harms, and socio-economic impacts—and identifies legitimate areas of concern.[16]

A. Limited Consensus on Health Effects of Consuming GE Foods

Are GE foods safe to consume? Numerous scientific and popular sources have claimed a scientific consensus that consumption of genetically-engineered ("GE") foods poses no risk to human health.[17] While most scientists and scientific bodies agree that most GE foods are safe to consume, claims that the safety debate is "over" tend to overstate the extent of scientific agreement.

First, the general conclusion: most scientific bodies agree that most of the GE foods tested to date are probably safe for human consumption. In its 2016 report on genetic engineering, the National Academy of Science's ("NAS") "overall finding" on health risks was that "the committee found no differences that implicate a higher risk to human health from GE foods than from their non-GE counterparts."[18] While media reports have mostly emphasized this finding, claiming that the NAS declared all GE foods to be "safe," they have also overstated their conclusions.[19] Similarly, other scientific bodies have released opinions that generally validate the safety of GE foods.[20]

Based on those opinions, fear-mongering about GE food consumption is unwarranted; studies so far have not convincingly shown that GE foods

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16 *See infra* Part II.A; *see, e.g.*, *5 Reasons to Be Concerned about GMOs*, GMO INSIDE.ORG, http://gmoinside.org/top-5-gmo-concerns/ [https://perma.cc/CCL9-DRA4]; *10 Reasons to Avoid GMOs*, INST. FOR RESPONSIBLE TECH. ("IRT"), http://responsibletechnology.org/10-reasons-to-avoid-gmos/ [https://perma.cc/2LME-JP7N].

17 *See, e.g.*, Alessandro Nicolia et al., *An Overview of the Last 10 Years of Genetically Engineered Crop Safety Research*, 34 CRIT. REV. BIOTECH. 77, 84 (2014); Michael White, *The Scientific Debate about GM Foods Is over: They're Safe*, PAC. STANDARD (Sept. 24, 2013), https://psmag.com/the-scientific-debate-about-gm-foods-is-over-they-re-safe-84697ee0b9a1#.hwl5dfcp6 [https://perma.cc/2UVP-47QY].

18 THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, MEDICINE, GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS 149 (2016), https://www.nap.edu/catalog/23395/genetically-engineered-crops-experiences-and-prospects [https://perma.cc/WT67-N7HL] [hereinafter NATIONAL ACADEMIES].

19 *See, e.g.*, Andrew Pollack, *Genetically Engineered Crops Are Safe, Analysis Finds*, N.Y. TIMES (May 17, 2016), http://www.nytimes.com/2016/05/18/business/genetically-engineered-crops-are-safe-analysis-finds.html?_r=0 [https://perma.cc/622B-WZQZ]; *see also* Kelly Servick, *Once Again, U.S. Expert Panel Says Genetically Engineered Crops Are Safe to Eat*, SCIENCE (May 17, 2016), http://www.sciencemag.org/news/2016/05/us-panel-releases-consensus-genetically-engineered-crops [https://perma.cc/3AA5-FV28].

20 *See, e.g.*, *Frequently Asked Questions on Genetically Modified Foods*, WORLD HEALTH ORG. ("WHO") (Oct. 11, 2016), http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/# [https://perma.cc/8HTD-FZD9] [hereinafter *Frequently Asked Questions*].

are harmful to human health. But, read in context, the statements of these health organizations are more qualified than any blanket assertion that all GE foods are safe.[21] The NAS report acknowledged the existence of scientific uncertainty, stating that "many of the favorable institutional statements about safety of foods from GE crops . . . contain caveats, for example, 'no overt consequences,' 'no effects on human health have been shown,' 'are not per se more risky,' and 'are not likely to present risks for human health.'"[22] The committee noted that its own finding was stated very carefully so as not to overstate the "safety" of GE foods or any other foods.[23] The report made a number of recommendations to help increase scientific certainty, such as identifying in studies what level of difference will be considered "biologically relevant;" conducting follow-up experimentation using trusted research protocols, personnel, and publication outlets where early published studies produced equivocal results; and providing public funding in the United States for such follow-up studies.[24] In a preface to the report, the chairman of the committee wrote, "We received impassioned requests to give the public a simple, general, authoritative answer about GE crops. Given the complexity of GE issues, we did not see that as appropriate."[25]

On many questions, the NAS report notes that data is limited. For instance, with regard to the question of whether foods from GE crops may affect gut microbes, the study concluded that the topic needs additional research to reach a reliable conclusion.[26] With regard to the impacts of increased use of glyphosate in connection with glyphosate-resistant GE plants, the report concluded that the potential harm of GE crops is inconclusive to the degree that more research is needed to reach a higher level of certainty on glyphosate's potential harm. With regard to questions concerning an increase in cancer incidences, allergies, or celiac disease, the report noted that data was limited but based its conclusions primarily on roughly equivalent increases between the United States and Canada, where GE foods are consumed, and the United Kingdom, where they are generally not consumed.[27] The report concluded that these comparisons in fact reflect a negative correlation between GE foods and incidences of cancer.[28] The report acknowledged, however, that these comparisons also demonstrate that there is "no relationship between

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21 *See generally* NATIONAL ACADEMIES, *supra* note 18, at 113.
22 *Id.*
23 *See id.* at 10.
24 *See id.* at 11.
25 *Id.*
26 *Id.*
27 *See* NATIONAL ACADEMIES, *supra* note 18, at 136, 144.
28 *See id.* at 137.

cancer and GE foods because there can be a delay in the onset of cancer that would obscure a trend, and one could hypothesize that something else has occurred with GE foods in the United States that has lowered cancer incidence and thus obscured a relationship."[29]

Other leading scientific organizations have also given their opinions in carefully worded language that is not often captured by media reports and have acknowledged the need for better safety assessments of new GE products. For example, the World Health Organization ("WHO") has stated that GM foods currently on the market are unlikely to present risks to human health, and no such impacts have been proven.[30] However, WHO also states that GE food safety cannot be proven or disproven across the board: "Different GM organisms include different genes inserted in different ways. This means that individual GM foods and their safety should be assessed on a case-by-case basis and that it is not possible to make general statements on the safety of all GM foods."[31] WHO acknowledges three main areas of concern for human health: allergic effects of transferred proteins; transfer of antibiotic-resistant to humans; or migration of genes from GM plants into conventional crops or wild relatives, which could have impacts on food production.[32] Similarly, the American Medical Association ("AMA") has stated that "[t]here is no evidence that unique hazards exist either in the use of rDNA techniques

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29 *Id.* at 137. In this earlier 2004 report, the National Academy of Science ("NAS") acknowledged that, at the time, "no adverse health effects attributed to genetic engineering have been documented in the human population." *Id.* This statement is something of a truism, however. Since no epidemiological studies on humans have been conducted, control groups are not possible because genetically-modified organisms ("GMO") foods are not currently labeled and most people do not know if they have consumed them. *See also Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, NAT'L ACADEMIES PRESS (2004), https://www.nap.edu/catalog/10977/safety-of-genetically-engineered-foods-approaches-to-assessing-unintended-health [https://perma.cc/P5P3-RBS2]. Moreover, the report concluded that "there remain sizeable gaps in our ability to identify compositional changes that result from genetic modification of organisms intended for food; to determine the biological relevance of such changes to human health; and to devise appropriate scientific methods to predict and assess unintended adverse effects on human health." *Id.* at 15. The report agreed that genetic engineering using genes from diverse species has greater risk of producing unexpected effects than conventional cross-breeding. *Id.* at 66. The report recommended both pre- and post-market assessment approaches to identify "unintended changes in the levels of nutrients, toxins, toxicants, allergens, or other compounds" in foods subject to genetic modification of any kind, including conventional cross-breeding and genetic engineering. *Id.* at 2.

30 *See Frequently Asked Questions*, *supra* note 20.

31 *Id.*

32 *Id.*

or in the movement of genes between unrelated organisms."[33] At the same time, however, the AMA also supports the implementation of safety assessments for GMO foods to detect unintended effects, toxicity, or allergenicity and to decrease use of antibiotic resistance markers in new genetically-engineered products.[34]

Some recent studies of scientific opinion on the safety of GM foods also concluded that the literature shows a low degree of scientific consensus regarding the safety of GM foods and the need for further research.[35] One study examined eight systematic reviews, twenty-six individual studies reporting adverse effects or uncertainties related to GM foods fed to animals, and the opinions of professional societies, like the NAS, the British Medical Association, and the Society of Toxicology.[36] Of the eight systematic reviews, the author reported two reviews that found evidence of serious health impacts on study animals and one study that concluded that GM plants are safe—though distinct from non-modified counterparts on non-health-related parameters.[37] The remaining five studies either reported some effects but did not draw conclusions about their health significance, concluded that little evidence had shown GM foods to be unsafe, but noted the limitations of the research to date, or focused primarily on the limitations of the research.[38] The author concluded that no one can read these reviews and conclude that the science has resolved the health effects of GMOs.[39]

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33 *H-480.958 Bioengineered (Genetically Engineered) Crops and Foods*, AM. MED. ASS'N (2013), https://www.cga.ct.gov/2013/KIDdata/Tmy/2013HB-06527-R000305-AMA%20Bioenginerred%20Crops%20and%20Foods-TMY.PDF [https://perma.cc/4Y77-6TV6].

34 *See id.*

35 *See* Sheldon Krimsky, *An Illusory Consensus Behind GMO Health Assessment*, SCI., TECH. & HUMAN VALUES (Aug. 7, 2015), http://emerald.tufts.edu/~skrimsky/PDF/Illusory%20consensus%20GMOs.PDF [https://perma.cc/2YVN-CXJY].

36 *See id.* at 12.

37 *See id.* at 12, 15; *see also* B.M. Maghari & A.M. Ardekani, *Genetically Modified Foods and Social Concerns*, 3 AVICENNA J. MED. BIOTECHNOLOGY 109, 114–15 (2011); *cf.* C. Snell et al., *Assessment of the Health Impact of GM Plant Diets in Long-Term and Multigenerational Animal Feeding Trials: A Literature Review*, 50 FOOD & CHEM. TOXICOLOGY 1134, 1146–47 (2012).

38 *See* A.S. Bawa & K.R. Anilakumar, *Genetically Modified Foods: Safety, Risks and Public Concerns – A Review*, 50 J. FOOD SCI. & TECH. 1035, 1044 (2013); Jose L. Domingo & Jordi Gine Bardonaba, *A Literature Review on the Safety Assessment of Genetically Modified Plants*, 37 ENV'T INT'L 734, 739–40 (2011) (summarizing the 2011 literature review, which chronicles a collection of research findings on studies on different species of animals); J.A. Magana-Gomez & A.M. Calderon de la Barca, *Risk Assessment of Genetically Modified Crops for Nutrition and Health*, 67 NUTRITION REV. 1, 14 (2008); W. Zhang & F. Shi, *Do Genetically Modified Crops Affect Animal Reproduction? A Review of the Ongoing Debates*, 5 ANIMAL 1048, 1056–57 (2011); *Scientific Opinion on Application, European Food Safety Authority (EFSA-GMO-UK-2009-76) for the Placing on the Market of Soybean MON87769*, 12 EFSAJ. 1, 34 (2014).

39 *See* Krimsky, *supra* note 35, at 12, 15. With regard to the twenty-six individual studies, Krimsky focused on the two that aroused the most controversy. *See* Stanley Ewen & Arpad

Other sources agree that scientific debate persists. In 2016, the NAS stated that "[t]he overall results of short-term and long-term animal studies with rodents and other animals and other data on GE-food nutrient and secondary compound composition convince[s] many . . . but not all involved researchers . . . that currently marketed GE foods are as safe as foods from conventionally bred crops."[40] Similarly, a 2015 joint statement signed by more than 300 scientific researchers and scholars stated that "the claim that [scientific consensus on GMO safety] does exist . . . is misleading and misrepresents or outright ignores the currently available scientific evidence and the broad diversity of scientific opinions among scientists on this issue."[41] The joint statement asserts that the available data on the safety of GMOs is inconclusive.[42] The authors took issue with "a climate of complacency" arising from overstated claims of consensus leading to carelessness in both safety assessment and regulation of GE products.[43] A European scientific organization has also

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Pusztai, *Effects of Diets Containing Genetically Modified Potatoes Expressing* Galanthus nivalis lectin *on Rat Small Intestine*, 354 LANCET 1353, 1354 (1999); Gilles-Eric Séralini et al., *Long Term Toxicity of a Roundup Herbicide and a Roundup-Tolerant Genetically Modified Maize*, 50 FOOD & CHEM. TOXICOLOGY 4221, 4229–30 (2012) (retracted 2014). The Ewen & Pusztai article reported that rats fed a diet of GM foods, compared to controls, grew less well, showed unusual changes in tissue, and had immune problems. *Retraction Notice to "Long term Toxicity of a Roundup Herbicide and a Roundup-Tolerant Genetically Modified Maize,"* 63 FOOD & CHEM. TOXICOLOGY 244 (2014). The Séralini article reported adverse effects in rats fed with GM maize alone—for Monsanto's herbicide glyphosate alone, and for GM maize with glyphosate residues—including "severe hormone-dependent mammary, hepatic and kidney disturbances." Séralini et al., *supra* note 39, at 4230. Krimsky considered the firestorm of controversy that followed both articles, including the unprecedented decision by the journal *Food and Chemical Toxicology* to retract Séralini's paper two years later, despite any evidence of fraud or intentional misrepresentation of data, on the grounds that the paper was "inconclusive." *See* Retraction Notice, *supra* note 39. Analysis of the scientific validity of these two studies is beyond the scope of this Article, since even serious limitations in current research on GM food safety may support arguments in favor of greater federal regulatory oversight of biotechnology. *Id.* Nevertheless, the amount of criticism generated against these two studies and the unusual decision of a journal to retract a single animal study because its results were "inconclusive," raises questions about whether reactions were unbiased. *Id.*

40 NATIONAL ACADEMIES, *supra* note 18, at 136 (emphasis added); *see also* Domingo & Bardonaba, *supra* note 38, at 739–40 (presenting results of studies conducted on different animal species); Angelika Hilbeck et al., *No Scientific Consensus on GMO Safety*, 27 ENVTL. SCI. EUROPE 4, 7 (2015) (finding lack of consensus after comprehensive review of animal feeding studies); Laura DeFrancesco, *How Safe Does Transgenic Food Need to Be?*, 31 NATURE BIOTECH. 794 (2013), http://www.nature.com/nbt/journal/v31/n9/full/nbt.2686.html?message-global=remove [https://perma.cc/7T83-GGRL] (discussing the dispute among researchers and regulators concerning food safety risk assessment standards).

41 Hilbeck et al., *supra* note 40, at 2.

42 *See id.* at 1.

43 *See id.* at 2.

made statements denying a scientific consensus around the safety of GE foods.[44]

Are GMOs safe to consume? The simple answer to this question is—we do not know with certainty. So far, most studies and scientific organizations have not found evidence to indicate that GE foods are generally unsafe. But scientific evidence remains insufficient, ambiguous, or of questionable objectivity. Moreover, objective scientific groups emphasize that all GE foods are distinct and that it is not possible to make one-size-fits-all claims about their safety or lack of safety. Given the limited data available, the scarcity of financially independent or publicly-funded research, the variability from product to product, and the lack of scientific consensus, reasonable people may differ with regard to the appropriate level of precaution that should guide federal regulation and individual consumer decisions.

B. Scientific Evidence of Adverse Environmental and Agronomic Impacts

While proponents of GE food labeling usually cite concerns about health impacts, some consumers also seek to avoid purchasing products made with GE ingredients because of concerns about harm to the environment.[45] Consumers whose desire for labeling of GE ingredients derives at least in part from environmental concerns that in no sense deny science, but rather call attention to ecological and agronomic impacts that have so far remained fairly obscured in the debate over biotechnology development, regulation, and impacts.

Numerous sources have reported environmental benefits from the introduction of GE crops.[46] Benefits include substitution of the glyphosate for more-toxic herbicides, greater adoption of conservation tillage, and decreased use of pesticides.[47]

Those benefits, however, may soon be offset as farmers attempt to cope with the rise in glyphosate-resistant weeds, which have already caused major crop losses. Four years after commercialization of genetically-engineered seeds, the first glyphosate-resistant weed appeared in a Delaware soybean field.[48] In the first fourteen years of

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44 *See, e.g.*, *Statement: No Scientific Consensus on GMO Safety*, ENSSER (Oct. 21, 2013).

45 *See, e.g.*, *GMO Facts*, NON-GMO PROJECT (2016), http://www.nongmoproject.org/gmo-facts/ [https://perma.cc/HC3K-ZZMD].

46 *See, e.g.*, *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States*, NAT'L ACAD. OF SCI. (2010), http://www.nationalacademies.org/includes/genengcrops.pdf [https://perma.cc/P5P3-RBS2] [hereinafter NAS 2010 Report].

47 *See id.* at 1–2.

48 *See* William Neuman & Andrew Pollack, *Farmers Cope with Roundup-Resistant Weeds*, N.Y. TIMES (May 3, 2010), http://www.nytimes.com/2010/05/04/business/energy-

commercialization of glyphosate-resistant crops, ten glyphosate-resistant weed species had appeared in the United States; by comparison, only seven glyphosate-resistant species had appeared worldwide in the previous thirty-six years.[49] Four years later, in 2014, fourteen species of glyphosate-resistant crops had appeared in thirty-two U.S. states.[50] One of the most troublesome weeds, glyphosate-resistant Palmer amaranth, was reported in twenty-five U.S. states and in Brazil by 2015.[51] The two species of weeds that most widely appear in crops grown with Monsanto's glyphosate-resistant seeds are already resistant to other herbicides as well.[52]

The appearance of glyphosate-resistant weeds has sent production agriculture scrambling to outdated herbicides and more labor-intensive strategies to control weeds.[53] Some studies showed that despite more than doubling farmers' herbicide costs, herbicides were still insufficient to control glyphosate-resistant Palmer amaranth, which has affected U.S. cotton, maize, and soybean crops.[54] In 2010, the president of the Arkansas Association of Conservation Districts told the *New York Times*, "[Glyphosate-resistant weed growth] is the single largest threat to production agriculture that we have ever seen."[55] The chairman of the Georgia Cotton Commission was quoted as saying, "If we don't whip this thing, it's going to be like the boll weevil did to cotton . . . [i]t will take it away."[56]

Farmers have shown reluctance to stop using glyphosate-resistant crops when facing problems with controlling glyphosate-resistant weeds, preferring instead to increase the amount and frequency of glyphosate use, to use other herbicides in addition to glyphosate, or to increase their

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environment/04weed.html?ref=business&_r=0 [https://perma.cc/57X2-K2H3]; Mark J. VanGessel, *Glyphosate-Resistant Horseweed from Delaware*, 49 WEED SCI. 103, 103 (2001).

49 *See* NAS 2010 Report, *supra* note 46; *see also* Georgina Gustin, *Roundup's Potency Slips, Foils Farmers: Resistant Weeds Are Spreading North, Adding Costs, Workload*, ST. LOUIS POST-DISPATCH (July 25, 2010), http://www.stltoday.com/business/roundup-s-potency-slips-foils-farmers/article_b503aada-7f4e-5ded-86d4-8eb0703ef7bb.html [https://perma.cc/3KFU-FF6H]; *cf.* Neuman & Pollack, *supra* note 48.

50 *See Weeds Resistant to EPSP Synthase Inhibitors (G/9) by Species and Country*, INT'L SURVEY OF HERBICIDE RESISTANT WEEDS, http://www.weedscience.org/summary/MOA.aspx?MOAID=12 [https://perma.cc/NZ5E-ET2Y] [hereinafter Heap Table].

51 *See id.*

52 *See id.*

53 *See* Lynn M. Sosnoskie & A. Stanley Culpepper, *Glyphosate-Resistant Palmer Amaranth (Amaranthus palmeri) Increases Herbicide Use, Tillage, and Hand-Weeding in Georgia Cotton*, 62 WEED SCI. 393, 400 (2014).

54 *See id.*; *see also* Sarah M. Ward et al., *Palmer Amaranth (*Amaranthus palmeri*): A Review*, 27 WEED TECH. 12, 17 (2013).

55 Neuman & Pollack, *supra* note 48.

56 *Id.*

use of tillage.[57] In 2010, the NAS stated that "the environmental consequences of those practices, if they were widely adopted by producers of [herbicide-resistant] crops, would negate the environmental benefits previously achieved [through use of GE crops]."[58] Seed developers have more recently received approvals for new seed varieties with resistance to herbicides besides or in addition to glyphosate.[59] Nevertheless, the NAS concluded in 2016 that "[w]eed resistance to glyphosate is a problem" and that "integrated weed-management approaches beyond simply spraying mixtures of herbicides are needed."[60] The report observed that empirical evidence is currently insufficient to determine the most effective management strategy and that farmers will be unable to move away from intensive use of herbicides without more assistance from knowledgeable extension agents.[61]

While the impacts of glyphosate-resistance are among the primary environmental concerns from GE crops, scientists have observed other impacts that raise environmental concerns as well. These include: a shift to more toxic pesticides as weeds develop glyphosate resistance; transfer of GE traits to non-GE varieties of cultivated crops in neighboring fields, which can reduce food crop biodiversity; transfer of GE traits to weedy relatives, which may produce weed-management problems; and transfer of GE traits to wild strains, which can then outcompete wild strains and reduce genetic diversity available for crop improvement.[62] While the scope of these environmental impacts remains uncertain, some consumers' concerns about these risks reflect not a denial of science, but rather a high degree of sensitivity to the risk.

Moreover, new genetic engineering technologies raise the possibility of new unintended environmental consequences. For example, recent technological breakthroughs now permit scientists to proliferate genetic

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57 *See* NATIONAL RESEARCH COUNCIL ET AL., IMPACT OF GENETICALLY ENGINEERED CROPS ON FARM SUSTAINABILITY IN THE UNITED STATES 75 (2010) [hereinafter FARM SUSTAINABILITY].

58 *Id.* at 77.

59 *See 2,4-D- and Dicamba-Tolerant Crops – Some Facts to Consider,* PURDUE EXTENSION (Nov. 2012), https://www.extension.purdue.edu/extmedia/id/id-453-w.pdf [https://perma.cc/YD29-V4F3]; *see also Petitions for Determination of Nonregulated Status,* BIOTECHNOLOGY (Oct. 16, 2016), https://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml [https://perma.cc/8BRV-K63Q].

60 NATIONAL ACADEMY OF SCIENCE ET AL., GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS 90 (2016).

61 *See id.* at 89–90.

62 *See* FARM SUSTAINABILITY, *supra* note 57, at 107. In the United States, scientists have documented at least fifteen crop species that hybridize with weedy relatives. *Id.* Since only a few crops (sunflower, pecan, blueberry, and some squashes) were domesticated in the United States, the risk to conservation of genetic diversity is less acute here than in countries with more native species and landraces. *Id.*

modifications throughout entire species—or even eliminate a species entirely—in just a few generations.[63] Scientists hope these techniques, called gene drives, will lead to life-saving advances, such as the elimination of malaria-carrying mosquitos.[64] While this possibility holds great promise for biological control of risks such as mosquito-spread diseases, benefits of such controls must outweigh the harm, or the "fitness cost," to the target organism or its ecosystem.[65] Moreover, the risk of unintended and quickly irreversible consequences is substantial, as scientists estimate that gene drive modifications may become fixed in a population within tens of generations.[66] Since those effects would almost certainly cross borders, political and legal ramifications of ecological changes would be complex.[67]

C. Consumer Concerns outside the Realm of Science

Finally, some consumers wish to avoid purchasing GM foods because of economic or social concerns, about which science has nothing to say.[68] Many of these impacts are well documented and significant. Some have already resulted in multi-million dollar liability for seed developers, while the full extent of economic and social costs cannot yet be estimated.[69] A few of these concerns are discussed below.

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63 *See* Robert L. Unckless et al., *Modeling the Manipulation of Natural Populations by the Mutagenic Chain Reaction*, GENETICS INVESTIGATION (July 30, 2015), http://www.genetics.org/content/early/2015/07/30/genetics.115.177592 [https://perma.cc/4S8U-ZWVY].

64 *See* NATIONAL ACADEMY OF SCIENCE ET AL., GENE DRIVES ON THE HORIZON: ADVANCING SCIENCE, NAVIGATING UNCERTAINTY, AND ALIGNING RESEARCH WITH PUB. VALUES 1 (2016).

65 *See* Unckless et al., *supra* note 63 ("[T]he speed of the process presents reason for considerable caution before considering a field release of such a construct . . . .").

66 *See* Samantha Mathewson, *Gene Editing Technology Could Have Serious Consequences, Researchers Say*, NATURE WORLD NEWS (Oct. 6, 2015), http://www.natureworldnews.com/articles/17271/20151006/gene-editing-technology-serious-consequences-researchers.htm [https://perma.cc/Z7YA-BC7M] (quoting lead study author saying "[t]hat's one of the things that is scary, if you imagine that one of these alleles gets into a population that you don't want it in").

67 *See* Kevin M. Esvelt et al., *Concerning RNA-Guided Gene Drives for the Alteration of Wild Populations*, ELIFE (July 17, 2014), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4117217/ [https://perma.cc/8F7Q-K672].

68 *See, e.g.*, *GMO Facts: Frequently Asked Questions*, NON GMO PROJECT (Oct. 16, 2016), http://www.nongmoproject.org/learn-more/ [https://perma.cc/TZ3C-A4EH].

69 *See infra* Part C.1.

1. Uncertainty for Farmers about Liability for Adventitious Presence of GM Seed

GE traits in crops in one farmer's field can be transferred by wind or insects to cross-pollinate with non-GE crops in a different farmer's field.[70] This raises the possibility of intellectual property violations, since GE seed may legally be grown only under licensing agreements between the seed developer and the farmer.[71] This raises several complicated and unsettled legal issues for the farmer on whose land the non-licensed seed is found. First, can the seed developer sue the farmer for violating its patent? If the use is intentional, the answer is yes, but if the adventitious presence occurred because of unintentional cross-pollination, then the answer is no.[72] Proving a farmer's intent (or lack thereof), however, can be complicated and costly.

Second, where GE seed has adventitiously appeared in non-GE fields, who should bear the losses incurred when the non-GE farmer loses sales to buyers that want only non-GE crops? This debate has been referred to as the "fence in/fence out" dilemma, and tort law principles have not resolved who should bear the burden of keeping GE and non-GE crops separate in the fields (and losses when such strategies fail).[73] A federal task force considered the possibility of establishing some type of compensation mechanism to compensate farmers for such losses, but its final report failed to make a definitive recommendation.[74]

2. Harm to Farmers and Damage to U.S. Trade Relations from Loss of Foreign Markets

Neither the Coordinated Framework nor any other federal law instructs the United States Department of Agriculture ("USDA") or any

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70 *See* FARM SUSTAINABILITY, *supra* note 57, at 104.

71 *See 2008 Monsanto Technology/Stewardship Agreement*, GROWER LICENSING, MONSANTO (Oct. 16, 2016), http://www.monsanto.com/sitecollectiondocuments/tug_sample.pdf [https://perma.cc/XN67-HY9A].

72 *See generally* Benjamin M. Cole et al., *Food for Thought: Genetically Modified Seeds as De Facto Standard – Essential Patents*, 85 U. COLO. L. REV. 314, 326–27 (2014).

73 *See* Thomas P. Redick, *Coexistence of Biotech and Non-GMO or Organic Crops*, 19 DRAKE J. AGRIC. L. 39, 49–50 (2014).

74 *See* UNITED STATES DEPARTMENT OF AGRICULTURE, ENHANCING COEXISTENCE: A REPORT OF THE AC21 TO THE SECRETARY OF AGRICULTURE 9 (Nov. 19, 2012) (reporting that "[m]embers of the AC21 are not in agreement about the extent to which a systemic problem exists and whether there is enough data to warrant a compensation mechanism to address it"). The task force recommended that the United States Department of Agriculture ("USDA") gather data to evaluate the scope of the problem and, if it found that a compensation mechanism was warranted, to model the mechanism after federal crop insurance programs. *Id.* at 14–15.

other agency to coordinate with regulators in other major markets to coordinate approval. Since regulators in different countries will approve traits at different times—and in some countries, regulators may decline to approve some traits at all—farmers engaging in international sales of GE crops must be certain that their harvests do not contain traits not approved for sale in the destination country.[75] Where shipments contain GE traits—whether intentionally or adventitiously—that have not been approved in the destination country, buyers in that country may seek damages for losses related to those unapproved shipments, refuse to buy future shipments from GE producers in the country of origin, and decline to buy from non-GE producers in the country of origin because of concerns over adventitious presence of the unapproved trait.[76]

Asynchronous approvals have led to catastrophic harms to farmers of both GE and non-GE seed. In a pending lawsuit against Syngenta, for example, plaintiffs seek to recover billions of dollars arising out of market losses related to asynchronous approvals between the United States and China.[77] Two Syngenta corn products genetically engineered with pesticide resistance were deregulated by the Animal and Plant Health Inspection Service ("APHIS") in 2010 and 2013.[78] In the following years, corn with those traits contaminated fields of other corn farmers in the United States through cross-pollination and eventually infiltrated the general domestic corn supply.[79] In November 2013, China, which had not yet approved the traits, began rejecting all corn from the United States

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[75] *See* Laura Rance, *Gap Between Innovation, Approval Leaves Farmers Outside Looking In*, WINNIPEG FREE PRESS (May 28, 2016), http://www.winnipegfreepress.com/business/gap-between-innovation-approval-leaves-farmers-outside-looking-in-381191781.html [https://perma.cc/W7SX-L8A3].

[76] *See id.* (providing steps that buyers can take when shipments containing GE traits arrive).

[77] *See* Ray Scherer, *Lawsuits Seek Loss Recovery for Corn Farmers*, ST. JOSEPH NEW-PRESS (Apr. 18, 2016), http://www.newspressnow.com/news/local_news/lawsuits-seek-loss-recovery-for-corn-farmers/article_6d7f3b69-d496-529a-9dd6-7aa7df45f139.html [https://perma.cc/9AAE-AQDH]; *see also* Scott+Scott, LLP, *Scott+Scott, Attorneys at Law, LLP Files Class Action on Behalf of Corn Farmers Harmed by Drop in U.S. Corn Prices – SYT*, GLOBENEWSWIRE (Jan. 15, 2015), https://globenewswire.com/news-release/2015/01/15/697835/10115808/en/Scott-Scott-Attorneys-at-Law-LLP-Files-Class-Action-on-Behalf-of-Corn-Farmers-Harmed-by-Drop-in-U-S-Corn-Prices-SYT.html [https://perma.cc/GPQ5-YPGS].

[78] *See generally Regulation, Testing, and Deregulation of MIR162*, SYNGENTACORNCASE (Oct. 18, 2016), http://www.syngentacorncase.com/about-the-case/case-updates-documents/class-action/factual-allegations/regulation-testing-and-deregulation-of-mir162/ [https://perma.cc/R4T6-YTXM]; *see also Determination of Nonregulated Status of Event 5307 Corn*, USDA APHIS, (Oct. 18, 2016), https://www.aphis.usda.gov/brs/aphisdocs/10_33601p_det.pdf [https://perma.cc/6C7A-BW9L].

[79] *See* Mem. Order at 51–52, *In re* Syngenta AG MIR 162 Corn Litig., 131 F. Supp. 3d 1177 (D. Kan. 2015).

containing the GE traits.[80] In the lawsuit, the plaintiffs alleged that Syngenta misled the public about the timing and likelihood of China approving the pesticide-resistance traits.[81] Plaintiffs claim for damages may total more than a billion dollars because they alleged that the decline in corn prices due to the loss of the Chinese market harmed plaintiffs who had not grown the GE corn as well as those that had.[82]

APHIS currently does not appear to coordinate approvals with regulators in major export markets.[83] In response to proposed rulemaking, commenters have pushed APHIS to consider coordination of approvals with other major markets.[84] For example, in February 2016, APHIS announced its intent to prepare a Programmatic Environmental Impact Statement under the National Environmental Policy Act ("NEPA") for potential changes to its regulation of biotechnology products.[85] APHIS's preferred action alternative would likely have excluded some products from APHIS permitting process.[86] The grain and oilseeds industry association urged APHIS to ensure that any regulatory changes are "comparable and compatible, to the maximum extent possible, with regulatory approaches used by competent government authorities in important U.S. export markets so as to minimize or avoid the risk of

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80 *See* Ricardo Lopez, *China Rejects Shipments of Genetically Modified Corn*, L.A. TIMES (Dec. 27, 2013), http://www.latimes.com/business/la-fi-mo-china-rejects-shipment-of-gmo-corn-20131227-story.html [https://perma.cc/DE3E-WT9R]; *see also* Christina Sarich, *Biotech Outraged after China Rejects Several Billion Tons of GMO Corn*, NATURAL SOC'Y (Jan. 8, 2015), http://naturalsociety.com/biotech-outraged-china-rejects-several-billion-tons-gmo-corn/ [https://perma.cc/BE9X-EXK5].

81 *See In re* Syngenta AG MIR162 Corn Litigation, 65 F. Supp. 3d 1401 (D. Kan. 2014).

82 Mem. Order, *supra* note 79, at 3–4.

83 *See, e.g.*, Corn Refiners Association et al., *Joint Statement to APHIS on Part 340 EIS Notice Biotech Regs 4-21-16* (Apr. 21, 2016), http://www.regulations.gov/document?D=APHIS-2014-0054-0106 [https://perma.cc/HYZ7-DX75]. The authors of the letter state that their "organizations also are extremely alarmed about what appears to this point to be a lack of outreach by APHIS or on its behalf by other USDA agencies (e.g., the Foreign Agricultural Service) concerning changes being contemplated to Part 340." *Id.* at 3.

84 *See id.* at 4 ("[I]ncreasing lack of coherence in various nations' regulatory systems regarding safety reviews and approval of new biotech-enhanced events . . . have indeed prevented or reduced access of U.S. crops to foreign markets and resulted in very significant downward pressure on prices paid to farmers and reduced the economic value of U.S. agricultural production . . . .").

85 *See* Environmental Impact Statement; Introduction of the Products of Biotechnology, 81 Fed. Reg. 6225 (Feb. 5, 2016).

86 *See* Department of Agriculture, *Environmental Impact Statement; Introduction of the Products of Biotechnology,* ANIMAL & PLANT HEALTH INSPECTION SERV. (Feb. 1, 2016), https://www.aphis.usda.gov/newsroom/federal_register/brs_regs.pdf [https://perma.cc/JTV8-F6BQ] (inviting public input on "potential justifiable exceptions or exemptions that would exclude certain 'products of biotechnology' from APHIS").

market and trade disruptions."[87] It is unclear whether the Coordinated Framework and the Plant Protection Act ("PPA") give APHIS authority to consider economic, rather than agronomic and environmental, impacts of its regulations.[88]

3. Lack of Market Incentives to Develop and Transfer Intellectual Property Rights to Life-Saving Technologies

GM seed has been promoted as a way to dramatically decrease world hunger and malnutrition.[89] Numerous applications of genetic engineering currently in the research and development pipeline might be beneficial to farmers and consumers in developing countries. In a 2012 Food and Agricultural Organization ("FAO") conference on the biotechnology pipeline in developing countries, participants identified a late blight resistant potato in Bangladesh, a golden mosaic virus resistant common bean in Brazil, a fungal resistant wheat in China, and many others.[90] The most often-discussed example, known as "Golden Rice," is genetically engineered to produce beta carotene, a good source of vitamin A, to reduce the incidence of blindness and other diseases in children whose diets rely heavily on rice.[91]

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87 Corn Refiners Ass'n et al., *Joint Statement to APHIS on Notice of Intent to Prepare Environmental Impact Statement under 7 CFR Part 340*, at 2 (Apr. 21, 2016), https://www.agri-pulse.com/ext/resources/pdfs/j/o/i/1/6/Joint-Statement-to-APHIS-on-Part-340-EIS-Notice-Biotech-Regs-4-21-16.pdf [https://perma.cc/Q63A-6BN5]. APHIS declined media requests to comment on the issue. Philip Brasher, *Grain Trade Alarmed by USDA Biotech Plans*, AGRI-PULSE COMMC'N INC. (Apr. 27, 2016), http://www.agri-pulse.com/Grain-trade-alarmed-by-USDA-biotech-plans-04272016.asp [https://perma.cc/3WR9-JPVL].

88 *See* Corn Refiners Ass'n, *supra* note 87, at 2–3.

89 J. Madeleine Nash, *Grains of Hope*, TIME (July 23, 2000), http://content.time.com/time/magazine/article/0,9171,50576,00.html [https://perma.cc/5T56-SWRH] (exemplifying the hope that GMO foods may provide a viable solution to malnutrition and world hunger).

90 *See* John Ruane, *An FAO E-mail Conference on GMOs in the Pipeline in Developing Countries: The Moderator's Summary*, FOOD & AGRIC. ORG. OF THE U.N. ("FAO") (2013), http://www.fao.org/docrep/017/ap998e/ap998e.pdf [https://perma.cc/PP9P-K9XP]; *see also Crop Biotech Update*, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS ("ISAAA") (June 22, 2016), http://www.isaaa.org/kc/cropbiotechupdate/newsletter/default.asp?/Date=6/22/2016 [https://perma.cc/P8TB-ZKGQ].

91 Golden Rice has been widely discussed in the academic literature on genetic engineering and has been subject to considerable controversy. *See* Peter Beyer et al., *Golden Rice: Introducing the Beta-Carotene Biosynthesis Pathway into Rice Endosperm by Genetic Engineering to Defeat Vitamin A Deficiency*, 132 J. NUTRITION 506S (2002); *see also* John Christensen, *SCIENTIST AT WORK: Ingo Potrykus; Golden Rice in a Grenade-Proof Greenhouse*, N.Y. TIMES (Nov. 21, 2000), http://www.nytimes.com/2000/11/21/science/scientist-at-work-ingo-potrykus-golden-rice-in-a-grenade-proof-greenhouse.html?pagewanted=all&_r=0 [https://perma.cc/3GGV-PR3A]. The Golden Rice controversy is largely outside the scope of this work, and the author does not intend to imply any position for or against the viability of the Golden Rice technology to deliver nutritional benefits. Golden Rice is

To date, however, nearly all commercialized GM seed varieties have been engineered with traits that benefit farmers in developed, not developing, countries.[92] The reasons are not science-driven, but market-driven: private sector seed development corporations, like Monsanto, have sufficient resources to develop new traits that might benefit developing-country farmers, but have economic incentives to focus on technologies that will be attractive to farmers in developed-country markets.[93] For example, after a professor of plant genomics at UC-Davis pioneered a genetically-altered rice that resists *Xanthomonas*, Asia's worst rice blight, Monsanto and Pioneer originally sought to license the gene.[94] As the university was negotiating the terms of the deal, however, Monsanto and Pioneer lost interest, and the technology has not yet been brought to market.[95] The developers of Golden Rice required the assistance of the Rockefeller Foundation to negotiate licenses to the seventy protected intellectual and technical property rights belonging to thirty-two different companies and universities that were used in developing the transgenic rice.[96] Transfer of the technology to researchers in developing countries to infuse the technology into locally-viable rice varieties added an additional layer of complexity.[97]

According to the FAO, genetic engineering for developing country agriculture is being led by the public sector, the private sector, and some public-private partnerships, with strong leadership by the public sector in countries including Brazil, China, India, and Iran.[98] As noted by a former Syngenta executive in the FAO conference, the private sector is likely to continue to focus on larger, more commercial crops, although a trend has

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mentioned only to highlight the challenges expressed by the developers in obtaining intellectual property rights and transferring those rights for public benefit.

92 *See Petitions for Determination of Nonregulated Status*, USDA APHIS (Oct. 2016), https://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml [https://perma.cc/6GAA-TGQS].

93 *See* A. Max Jarvie, *Productivity and Diversity in Research and Agriculture: Improving the IPR Landscape for Food Security*, 40 WM. & MARY ENVT'L L. & POL'Y REV. 849, 868–69 (2016).

94 *See* Frederick Kaufman, *Genetically Monetized Food*, SLATE (Dec. 20, 2012), http://www.slate.com/articles/life/food/2012/12/plant_patent_law_why_overhauling_it_will_do_more_to_help_the_food_movement.html [https://perma.cc/E6M7-FJZE].

95 *See id*.

96 *See* C.S. Prakash & Gregory Conko, *Relevance of Genetically Modified Crops to Developing Countries,* 34 CUMB. L. REV. 437, 442 (2003); *see also* Ann Weilbaecher, *Diseases Endemic in Developing Countries: How to Incentivize Innovation,* 18 ANNALS HEALTH L. 281, 295 (2009).

97 *See* Prakash & Conko, *supra* note 96, at 442–43.

98 *See* Chantal Phol Nielsen & Kym Anderson, *Genetically Modified Foods, Trade, and Developing Countries: Is Golden Rice Special?,* AGBIOWORLD (Oct. 2016), http://www.agbioworld.org/biotech-info/topics/goldenrice/specialgoldrice.html [https://perma.cc/8QPN-6XLM].

begun for the private sector to address subsistence crops to some degree.[99] Until the public and private sector can overcome these market barriers to greater research and development in genetic engineering for developing-country agriculture, claims of lifesaving impacts of genetic engineering may reasonably fail to convince many developed-country consumers of the life-saving value of GE crops.

III. THE FAILURE OF THE COORDINATED FRAMEWORK

On July 2, 2015, President Obama created an inter-agency task force among the USDA, Food and Drug Administration ("FDA"), and Environmental Protection Agency ("EPA") to update the Coordinated Framework and develop a strategy to prepare for changes in biotechnology.[100] From the President's charge, it is not clear whether the work of the task force will be limited to adjusting federal regulatory authority based on current statutes (Plant Protection Act, Federal Food, Drug, and Cosmetic Act, and Federal Insecticide, Fungicide, and Rodenticide Act ("PPA," "FDCA," and "FIFRA" respectively)), or whether the task force is also authorized to request passing new legislation to expand or change federal agency statutory authority.[101] The memorandum identifies the one-year objectives of the task force as the "development of an updated [Coordinated Framework] to clarify the roles and responsibilities of the agencies that regulate the products of biotechnology," as well as the formulation of a long-term risk assessment strategy and the commissioning of an independent analysis of future biotechnology products.[102]

To what extent can and will the federal agencies reinterpret the scope of their existing authority under the relevant statutes in a way that addresses persistent consumer concerns? Are those statutes sufficiently broad to allow the agencies to exercise jurisdiction in a way that meaningfully responds to such concerns? This Part addresses failures of

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99 *See All Messages from the FAO 2012 E-mail Conference on "GMOs in the Pipeline: Looking to the Next Five Years in the Crop, Forestry, Livestock, Aquaculture and Agro-Industry Sectors in Developing Countries*," FAO (Nov. 29, 2012), http://www.fao.org/fileadmin/user_upload/biotech/docs/conf18msgs.pdf [https://perma.cc/PP9P-K9XP] (providing an e-mail from the participant stating that "[m]ajor R&D based companies are bound to focus on the larger and more commercial crops as that is where they will get the best returns and they have financial obligations to their shareholders"). According to the participant, forces driving the trend include advances in plant genomics; diversification of private sector research from corn, soybeans, and cotton into rice and wheat; increasing prominence of corporate social responsibility; and increasing the market potential of developing countries. *Id*.

100 *See* Coordinated Framework Exec. Mem., *supra* note 4.

101 *See id*. at 3.

102 *Id.* at 3.

the Coordinated Framework to address consumer concerns—failures arising both from agency interpretation of existing authority and from lack of agency authority to regulate current and emerging products or ancillary impacts of those products.

A. Statutory Bases for Agency Jurisdiction under the Coordinated Framework

In the Coordinated Framework, the White House Office of Science and Technology Policy ("OSTP") divided regulatory authority for agricultural biotechnology among three federal agencies: the USDA, which regulates the testing and commercialization of new agricultural biotech products; the FDA, which regulates the introduction and marketing of foods created through the use of genetic engineering; and the EPA, which regulates genetically-altered microorganisms and pesticide properties of genetically-engineered plant varieties.[103] Each of these agencies regulates under statutes that pre-date commercial agricultural biotechnology. The Coordinated Framework located the FDA's authority primarily in the FDCA, a 1938 act that includes authorization for the FDA to ensure food safety through regulation of food additives and misbranding.[104] The USDA's authority was identified as stemming primarily from a law that dates back to the Federal Plant Pest Act of 1957, reorganized in the PPA, which gave the USDA jurisdiction over bacteria and viruses.[105] The Coordinated Framework identified the EPA's authority as deriving from the relatively modern pesticide and toxics control laws of the 1970s, including FIFRA and the Toxic Substances Control Act ("TSCA").[106]

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[103] *See* Neil A. Belson, *U.S. Regulation of Agricultural Biotechnology: An Overview*, 3 AGBIOFORUM 15, 15 (2000) (describing the three federal agencies that have regulatory authority for agricultural biotechnology).

[104] *See* 21 U.S.C. § 321(s) (2012) (defining the term "food additive"); § 321(n) (explaining what "misbranding" means); § 371 (providing the authority to promulgate regulations); § 372 (describing the process for examinations and investigations); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2012) (introducing the definitions of the Federal Food, Drug, and Cosmetic Act).

[105] Plant Pest Regulations; Update of Current Provisions, 66 Fed. Reg. 51340 (proposed Oct. 9, 2001) (to be codified at 7 C.F.R. pt. 330) (giving a brief explanation of how the Federal Plant Pest Act ("PPA") has evolved over the years).

[106] *See* Chris A. Wozniak et al., *Regulation of Genetically Engineered Microorganisms under FIFRA, FFDCA, and TSCA,* EPA (Oct. 2016), https://www.epa.gov/sites/production/files/2015-09/documents/ch4-wozniak-etal-fifra-ffdca-tsca-112012_0.pdf [https://perma.cc/5RN8-F2J4] (expressing that FIFRA and TSCA are toxic control laws that give the EPA regulatory authority of biotechnology products).

B. Insufficient Statutory Authority for USDA

The first generation of biotechnology typically used *Agrobacterium* as a vector to insert the DNA of one species into the cells of a different species.[107] Thus, the Office of Science and Technology Policy could argue that the USDA's authority over plant pests also gave it authority over agricultural products created using these bacterial vector insertions of DNA (even though the viruses, once inserted, were not active and did not pose the types of threats that motivated the PPA).[108] As long as developers used bacterial or viral vectors to deliver DNA to target organisms, however, the PPA arguably provided an adequate jurisdictional hook. But biotechnology developers now have tools other than viruses at their disposal to make genetic modifications to target organism DNA. These tools include a "gene gun" that shoots DNA into cells without the use of any bacterial or viral vector and genome-editing technologies that allow scientists to directly edit or delete DNA rather than inserting anything. Biotechnology now, in 2016, stands on the verge of a technological revolution that will allow scientists to edit genes easily and with minimal cost.

That technological revolution is based on changes in the mechanisms scientists use to accomplish genetic changes in an organism. When the Coordinated Framework was released in 1986, all GE plants had been produced by using *Agrobacterium tumefaciens* as the vector to deliver the DNA to the species of interest.[109] The administration's decision in the Coordinated Framework to locate the FDA, USDA, and EPA statutory authority in the FDCA, PPA, and FIFRA was based on the assumption that bacteria would continue to be the mechanism for accomplishing the

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[107] *See* Lan-Ying Lee & Stanton B. Gelvin, *T-DNA Binary Vectors and Systems*, 146 PHYSIOLOGY 325, 325 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2245830/pdf/pp1460325.pdf [https://perma.cc/L797-ZANB].

[108] *See* Alex Camacho et al., *Genetically Engineered Crops that Fly under the US Regulatory Radar*, 32 NATURE BIOTECH. 1087, 1088–89 (2014), http://www.nature.com/nbt/journal/v32/n11/pdf/nbt.3057.pdf [https://perma.cc/69GQ-WY7E]. In the PPA, Congress found that "the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds is necessary for the protection of the agriculture, environment, and economy of the United States." 7 U.S.C. § 7701 (2012). A "plant pest" is defined as:

> any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease to any plant or plant product: (A) A protozoan, (B) A nonhuman animal, (C) A parasitic plant, (D) A bacterium, (E) A fungus, (F) A virus or viroid, (G) An infectious agent or other pathogen, (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.

§ 7702.

[109] *See* NATIONAL ACADEMIES, *supra* note 18.

genetic modifications.[110] Tellingly, however, the Coordinated Framework was out of date nearly as soon as it was written; within months, scientists began to publicize successful inventions of genetically engineered plants through a process called particle bombardment, or the "gene gun" that did not rely on bacteria to transfer genetic material.[111] Using a gene gun, scientists can coat microparticles with RNA or DNA and accelerate or shoot the particles to pierce cell walls of the plant.[112] The resultant organism expresses the inserted genetic codes.[113] Since no plant pest is involved, APHIS's jurisdiction under the PPA is not triggered.[114] Another type of product already in use are null segregants, in which a transgenic parental line and a nontransgenic elite line are crossed to produce nontransgenic progeny: the final product does not include the material used to transfer the new DNA, and thus does not trigger APHIS jurisdiction.[115]

Even more critical, new technologies or technologies now on the horizon that do not rely on plant pests will make direct genome editing fast, easy, and cheap.[116] Genome editing, an important class of new technologies, uses nucleases directed to a specific site on the DNA strand to delete, add, or change targeted DNA sequences in an organism.[117] Developers have used several different classes of these nucleases, most of

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110 *See* Coordinated Framework for Regulation of Biotechnology, *supra* note 4.

111 *See* T.M. Klein et al., *High-Velocity Microprojectiles for Delivering Nucleic Acids into Living Cells*, 327 NATURE 70, 70 (1987).

112 *See id.* at 71.

113 *See What Is Genetic Engineering and How Does It Work?*, AG BIOSAFETY (2005), http://agbiosafety.unl.edu/basic_genetics.shtml [https://perma.cc/NS7F-89XS].

114 *See, e.g.*, Michael C. Gregoire, *Confirmation of Regulatory Status/Kentucky Bluegrass (Poa pratensis L.)* (July 1, 2011), https://www.aphis.usda.gov/brs/aphisdocs/scotts_kbg_resp.pdf [https://perma.cc/PZ97-ZDML] (introducing a letter from Michael C. Gregoire, the Deputy Administrator for APHIS, to Dr. Richard Shank, the Senior Vice President for Scotts Miracle-Gro Company). In his letter, Gregoire concluded with the following:

> Because no plant pests, unclassified organisms, or organisms whose classification is unknown were used to genetically engineer this variety of GE Kentucky bluegrass, APHIS has no reason to believe it is a plant pest and therefore does not consider the Kentucky bluegrass described in the letter dated September 13, 2010 to be regulated under 7 CFR part 340 and is not subject to the plant pest provisions of the PPA.

Id.

115 *See* Camacho, *supra* note 108, at 1088.

116 *See* Amy Maxmen, *Easy DNA Editing Will Remake the World*, WIRED (Aug. 2015), https://www.wired.com/2015/07/crispr-dna-editing-2/ [https://perma.cc/H773-6NH3].

117 *See* NATIONAL ACADEMIES, *supra* note 18, at 241; *see also* Nicholas J. Baltes & Daniel F. Voytas, *Enabling Plant Synthetic Biology through Genome Engineering*, 33 TRENDS IN BIOTECH. 120, 125 (2015), http://www.ask-force.org/web/Genomics/Baltes-Enabling-plant-synthetic-biology-genome-editing-2015.pdf [https://perma.cc/Z5KV-B8QP].

which are best known by their space age-sounding acronyms: ZFNs, TALENs, and CRISPR.[118]

CRISPR, the most promising of these techniques, accomplishes genetic mutations using two molecules—the Cas9 nuclease, which cuts both strands of DNA at a specific location to allow the mutation, and the guide RNA, a sequence of about twenty base pairs that guides Cas9 to the target location of the genome modification.[119] The breaks in DNA are repaired by the cell, leading to deletions, insertions, or rearrangements using the template RNA sequence.[120] The CRISPR/Cas9 system, which was based on the discovery of a similar natural system in some bacteria to resist viruses, is simple and cheap to use because it only requires scientists to synthesize the short, twenty-nucleotide RNA sequence.[121]

Applications for genome editing using site-specific nucleases, especially CRISPR/Cas9, are promising for both human and animal welfare.[122] In agriculture, for example, researchers are working to introduce into dairy cattle a genetic variant that causes into some beef cattle to lack horns.[123] Farmers often de-horn dairy cattle, which are kept

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118 *See* Thorben Sprink et al., *Plant Genome Editing by Novel Tools: TALEN and Other Sequence Specific Nucleases*, 32 CURRENT OPINION IN BIOTECH. 47, 47 (2015), http://ac.els-cdn.com/S0958166914001979/1-s2.0-S0958166914001979-main.pdf?_tid=bf163418-8fc5-11e6-a6dc-00000aab0f6c&acdnat=1476199195_da7d604f14efe49d0d890c8c3e5353bd [https://perma.cc/VHH8-P5UN]; NATIONAL ACADEMIES, *supra* note 18, at 242.

119 *See* Baltes & Voytas, *supra* note 117, at 124; *see also What Is CRISPR-Cas9?*, YOUR GENOME (*last updated* June 07, 2016), http://www.yourgenome.org/facts/what-is-crispr-cas9 [https://perma.cc/DSP6-GKXF]; Khaoula Belhaj et al., *Editing Plant Genomes with CRISPR/Cas9 System for Plant Genome Editing and Beyond*, 31 BIOTECH. ADVANCES 41, 41 (2015), http://www.sciencedirect.com/science/article/pii/S0734975014001931 [https://perma.cc/4Y8G-ZJEP]; Luisa Bortesi & Rainer Fischer, *The CRISPR/Cas9 System for Plant Genome Editing and Beyond*, 33 BIOTECH. ADVANCES 41, 41 (2015); S. Antony Ceasar et al., *Insert, Remove or Replace: A Highly Advanced Genome Editing System Using CRISPR/Cas9*, BIOCHIMICA ET BIOPHYSICA ACTA (BBA)—MOLECULAR CELL RES. (June 24, 2016), http://www.sciencedirect.com/science/article/pii/S0167488916301781 [https://perma.cc/K3P9-X5PE]; NATIONAL ACADEMIES, *supra* note 18, at 244.

120 *See* Bortesi & Fischer, *supra* note 119, at 41.

121 *See* Martin Jinek et al., *A Programmable Dual-RNA–Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCIENCE 816 (Aug. 17, 2012); *see also* Ruud Jansen et al., *Identification of Genes That Are Associated with DNA Repeats in Prokaryotes*, 43 MOLECULAR MICROBIOLOGY 1565, 1565 (2002), http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2958.2002.02839.x/full [https://perma.cc/5A95-MWVX]; Belhaj et al., *supra* note 119, at 76.

122 *See* Dana Carroll & R. Alta Charo, *The Societal Opportunities and Challenges of Genome Editing*, 16 GENOME BIOLOGY 242, 242 (2015).

123 *See* Wenfang Tan et al., *Efficient Nonmeiotic Allele Introgression in Livestock Using Custom Endonucleases*, 110 PROCEEDINGS OF NAT'L ACADEMY SCI. 16526, 16527 (2013), http://www.pnas.org/content/110/41/16526.full.pdf [https://perma.cc/7QDF-HLTC]; Wenfang Tan et al., *Precision Editing of Large Animal Genomes*, 80 ADVANCES IN GENETICS 37, 70–72 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3683964/pdf/nihms471281.pdf [https://perma.cc/NM47-4AW6].

in close quarters, for safety reasons, but physical de-horning methods are invasive, painful, and expensive.[124] Introducing the trait through traditional cross-breeding would result in loss of favorable traits for dairy production, but genome editing could introduce the variant into existing dairy herds without interfering with other, more desirable traits.[125] In medicine, genome editing is being used to explore the possibility of knocking out the gene for CCR5, the functional co-receptor in T-cells used by the HIV-1 virus.[126] People who naturally lack the CCR5 gene may become infected with the virus but do not become sick because their T-cells are resistant to being killed.[127] Knocking out the CCR5 gene in bone marrow stem cells might provide long-term HIV-resistant T-cells to the recipient.[128]

The challenge of these technologies for USDA jurisdiction is that they do not rely on bacterial or viral vectors to accomplish the desired genetic modification. Without some form of plant pest present in the new product, APHIS has no grounds to exercise jurisdiction under the PPA. Since no general statute gives APHIS jurisdiction over any form of biotechnology as such (a more adaptable type of process-based approach to regulation), nor over any new plant variety presenting novel risks (a product-based approach to regulation), the APHIS cannot regulate or will not be able to regulate most new plant varieties created using biolistics, site-directed nucleases like ZFNs, TALENs, and CRISPR, and any other new methods that do not incorporate plant pests into the product organism.

This gap in APHIS oversight already exists and is expected to explode in the near future as CRISPR technology advances. Between 2011 and 2015, developers submitted letters of inquiry to APHIS regarding novel products, seeking to know whether the products would be regulated.[129] Of the forty-nine products for which letters of inquiry were submitted to APHIS, only four were determined by APHIS to involve plant pests that

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124 *See* Bruno Graf & Markus Senn, *Behavioral and Physiological Responses of Calves to Dehorning by Heat Cauterization with and without Local Anesthesia*, 62 APPLIED ANIMAL BEHAV. SCI. 153 153–54 (1999) http://www.sciencedirect.com/science/article/pii/S0168159198002184 [https://perma.cc/L2P8-KR7T].

125 *See* Carroll & Charo, *supra* note 122, at 242–43.

126 *See* Pablo Tebas et al., *Gene Editing of CCR5 in Autologous CD4 T Cells of Persons Infected with HIV*, 370 NEW ENGLAND J. MED. 901, 901 (2014), http://www.natap.org/2014/HIV/nejmoa1300662.pdf [https://perma.cc/6V64-JMX6].

127 *See* Carroll & Charo, *supra* note 122, at 245.

128 *See id.*

129 *See, e.g.*, APHIS, *Am I Regulated under 7 CFR Part 340?*, APHIS (June 8, 2016), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated [https://perma.cc/J5F6-2SA6].

would give APHIS jurisdiction.[130] APHIS has indicated lack of regulatory jurisdiction over products created using biolistics (18), meganuclease deletions or substitutions (3), ZFNs (2), and TALENs (5).[131] Smaller laboratories and public institutions may already be deploying these technologies as a strategy for avoiding federal regulation.[132] Because CRISPR is simple and inexpensive, the technology may soon give rise to an explosion of new genetically engineered organisms from even very small research laboratories.[133]

The failure to capture new genome-editing technologies in federal regulatory authority may have safety consequences. Although these technologies offer important advancements over transgenic modifications because of their specificity and ability to limit off-target effects, techniques like CRISPR are not without risk that off-target effects will occur.[134] Without regulatory oversight, unintended consequences may occur and introduce risks that are not known until after commercialization and widespread release of the organism.

At the same time, other new genetic engineering technologies raise the possibility of too much regulation. These new products of genetic engineering may not raise the same level of risk, or generate the same level of public concern, as traditional transgenic products, but might nevertheless be subject to the same level of oversight under the PPA if accomplished using bacterial vectors. For example, J.R. Simplot has developed a variety of potato using a technique known as intragenesis.[135] In intragenesis, developers package various plant DNAs from varieties of the target crop or its sexually compatible relatives, combine them into a gene delivery cassette, and insert them into the target organism.[136] Unlike transgenic organisms, which combines DNA from non-sexually-compatible species, these intragenic organisms could be made through

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130 *See* NAS 2010 Report, *supra* note 46, at 330 (Table 9-3); *see also* Camacho et al., *supra* note 108, at 1090.

131 *See* NAS 2010 Report, *supra* note 46, at 330 (Table 9-3).

132 *See* Camacho et al., *supra* note 108, at 1087.

133 *See* Maxmen, *supra* note 116.

134 *See* Heidi Ledford, *Enzyme Tweak Boosts Precision of CRISPR Genome Edits*, NATURE (Jan. 6, 2016), http://www.nature.com/news/enzyme-tweak-boosts-precision-of-crispr-genome-edits-1.19114 [https://perma.cc/FKF6-VP8P]; *see also* Benjamin P. Kleinstiver et al., *High-Fidelity CRISPR–Cas9 Nucleases with No Detectable Genome-Wide Off-Target Effects*, 528 NATURE 490, 490 (2016), http://www.nature.com/nature/journal/v529/n7587/pdf/nature16526.pdf [https://perma.cc/M892-LLUR].

135 *See* I.B. Holme et al., *Intragenesis and Cisgenesis as Alternatives to Transgenic Crop Development*, 11 PLANT BIOTECH. 395, 398 (2013) (noting that J.R. Simplot has developed intragenic potatoes).

136 *See* NAS 2010 Report, *supra* note 46, at 37 (stating that varieties of crop DNA are combined and inserted into the cell in intragenesis).

conventional breeding, just less efficiently.[137] While intragenic organisms may use Agrobacterium-mediated transformation and thus trigger APHIS's jurisdiction under the PPA, the use of cisgenesis has triggered debate about whether these organisms pose the same level of risk as transgenic organisms and whether they should be regulated the same.[138]

C. Insufficient Statutory Authority for the FDA

Like the USDA's authority under the PPA, the Reagan Administration's decision to locate the FDA's statutory authority in the FDCA was also based on the assumption that genetic engineering involved transgenic organisms.[139] The FDA's jurisdiction over GMO foods derives from the FDCA, which allows the FDA to regulate "food additives."[140] Since the first genetically-engineered foods involved the insertion of new DNA into a plant's genome using bacterial vectors, that generation of GMO foods arguably fell within the statutory definition of a food additive: "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[141]

If the FDA had chosen to require new GE foods to go through pre-market safety review as food additives, regulatory oversight and public participation would be significant. Under full pre-market safety review for food additives, food producers are required to submit a petition to the FDA demonstrating safety of the food, accompanied by supporting data generated by scientifically accepted methods.[142] The FDA may also require the petitioner to submit samples of the additive for testing, and provide descriptions of production methods and facilities.[143] The FDA is required to make an independent determination within ninety days as to

137 *See id.* (comparing the sexual compatibility of transgenic and intragenic organisms).

138 *See* Henk J. Schouten et al., *Cisgenic Plants Are Similar to Traditionally Bred Plants: International Regulations for Genetically Modified Organisms Should Be Altered to Exempt Cisgenesis*, 7 EMBO REP. 750, 750 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1525145/pdf/7400769.pdf [https://perma.cc/3RJ8-RWGT]; *but see* Eva Sirinathsinghji, *Cisgenesis Is Still Genetic Modification with All the Attendant Risks*, INST. OF SCI. IN SOC'Y (Aug. 14, 2013), http://www.i-sis.org.uk/Cisgenesis_is_still_Genetic_Engineering_with_all_attendant_risks.php [https://perma.cc/KWZ4-MZRG].

139 Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986; *see also* FDA, Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23,309–23,312 (June 26, 1986).

140 *See* 21 U.S.C. § 348 (2012).

141 § 321(s).

142 *See* § 348(b)(2).

143 *See* § 348(b)(3)–(4).

the safety of the food before the food can be marketed.[144] The regulation to approve the additive proposed by the petitioner must be published within thirty days of filing; although the FDCA does not mandate pre-order notice and comment, the FDA as a practical matter receives or invites public comment on the proposed regulation.[145] Orders issued by the FDA may be stayed pending a challenge by any person adversely affected and are subject to judicial review.[146]

In a 1992 policy statement, however, the FDA announced a presumption that all GE foods are safe and thus exempt from food additive pre-market safety review process.[147] A "food additive," as defined in the statute, includes substances described above only "if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use . . . ."[148] According to the FDA, all foods derived from genetic engineering fall into this generally recognized as safe ("GRAS") exemption from the pre-market safety review process.[149] The FDA reasoned, that "transferred genetic material [nucleic acids] . . . are present in the cells of every living organism . . . and do not raise a safety concern as a component of food. In regulatory terms, such material is presumed to be GRAS."[150]

As a result of this presumption, all foods produced using GE are exempt from the pre-market safety review process for food additives unless the intended expression of the genetic material differs significantly from substances already found in food.[151] Subsequent litigation showed that this presumption was questioned even by scientists within the FDA at the time it was announced.[152] The FDA's GRAS presumption and its

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144 § 348(c)(1)–(3). The statute states that no "regulation shall issue if a fair evaluation of the data before the Secretary . . . (A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe." *Id.*

145 § 348(b)(5). *See also* Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 BOSTON UNIV. L. REV. 329, 371 (1998).

146 *See* § 348(e)–(g).

147 Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992) [hereinafter *FDA Statement of Policy*].

148 § 321(s).

149 *See FDA Statement of Policy*, *supra* note 147, at 22,990.

150 *Id.*

151 *See id.*

152 *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 177 n.7 (D.C. Cir. 2012); *see also* Edwin J. Mathews, *Memorandum from Dr. Edwin J. Mathews to the Toxicology Section of the Biotechnology Working Group. Subject: "Analysis of the Major Plant Toxicants,"* (Oct. 28, 1991), http://biointegrity.org/FDAdocs/02/OEM1V.GIF [https://perma.cc/358S-ARTU]; Louis J. Pribyl, *Comments from Dr. Louis J. Pribyl re: the "Biotechnology Draft Document, 2/27/92"*

consequences also raise democratic concerns: without pre-market safety review, no public record of the FDA food safety approvals is created, and the public is deprived of any opportunity to review or comment on those decisions. Given the scientific uncertainty about the health effects of consuming GMOs, this lack of transparency has led to considerable consumer distrust of the FDA's determinations. The FDA encourages a voluntary, non-public consultation process, which, as a matter of practice, all developers have utilized before bringing a new GMO food to market.[153]

Moreover, it is unclear whether foods produced with new genetic engineering technologies will even fall within the FDCA definition of "food additive," which applies only to substances that "becom[e] a component or otherwise affect[] the characteristics of any food."[154] In its 1992 policy statement, the FDA stated, "[i]n the case of foods derived from new plant varieties, it is *the transferred genetic material* and the intended expression product or products that could be subject to food additive regulation, if such material or expression products are not GRAS."[155] But new GE techniques do not necessarily involve transferring any material into the plant products at all: genome editing techniques like CRISPR, for example, directly edit the genome of the target organism without inserting any new material.[156]

The "food additive" definition is deliberately broad, encompassing not only substances that become final components of the food but also substances used in production, manufacturing, and other phases of the food supply chain, if those substances are intended to affect the characteristics of the food.[157] Nevertheless, the definition hinges on the existence of a "substance."[158] Under longstanding federal biotechnology policy, however, a genetic engineering *process* is differentiated from the genetic engineering *product*.[159] As long as the FDA adheres to this policy

(Mar. 6, 1992), http://biointegrity.org/FDAdocs/04/OPCOM1V.GIF [https://perma.cc/P4TH-JFZM].

153 *See FDA Statement of Policy*, *supra* note 147, at 22, 984–91; Consultation Procedures under FDA's 1992 Statement of Policy—Foods Derived from New Plant Varieties, FDA (June 1996, revised Oct. 1997), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/ucm096126.htm [https://perma.cc/Q5Q9-566B]; *see also* Premarket Notice Concerning Bioengineered Foods, Fed. Reg. 4,706 (Jan. 18, 2001); *cf.* Proposed Rule, Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4,711.

154 21 U.S.C. § 321(s) (2012).

155 *FDA Statement of Policy*, *supra* note 147, at 22,990.

156 *See supra* note 124 and accompanying text.

157 *See* § 321(s).

158 *See id.*

159 *See* Exercise of Federal Oversight within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6,753, 6,755 (Feb. 27, 1992) ("No conceptual distinction exists between genetic modification of plants and

choice, it will be difficult to stretch the definition of "food additive" to accommodate foods produced through genetic engineering processes that do not involve the addition of any "substance" even in the production phase. Without the jurisdictional hook of food additive review under the FDCA, it is unclear whether the FDA will have any jurisdiction over new genetically-engineered foods, even the current voluntary pre-market consultation process. Even the FDA's authority to remove unsafe products from the market is based on its jurisdiction over "adulterated foods," which are defined as "substances" that render the food injurious to health.[160] The definition also excludes any substance that is "not an added substance . . . if the quantity of such substance in such food does not ordinarily render it injurious to health."[161] GE foods with no "added substance" may evade the FDA's recall authority even in the event of a verified health hazard.

D. Unduly Limited Role for EPA

Despite the risks to the agricultural and the broader environment from the use of genetically-engineered crops, the Coordinated Framework designates relatively little EPA oversight. The EPA regulates substances that are genetically engineered to control pests under FIFRA.[162] Like other pesticides, most genetically-engineered pesticidal substances (called plant-incorporated protectants, or PIPs) must be safety-tested and registered with the EPA before they may be distributed commercially.[163] The EPA also regulates genetically-engineered microorganisms under TSCA.[164] Under TSCA, any organization using a chemical substance that may present an unreasonable risk to health or the environment must submit a premanufacture notification to the EPA.[165]

Despite potential environmental risks such as GE species crossing with wild relatives and the development of herbicide-resistant "superweeds," the EPA does not have authority to control the environmental impacts of most of these products. With the EPA's limited statutory jurisdiction, most federal monitoring of environmental impacts

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microorganism by classical methods or by molecular techniques that modify DNA and transfer genes.").

160 § 342(a)(1).

161 *Id.*

162 7 U.S.C. § 136–136y (2012); *see also* 40 C.F.R. § 725.1(a) (2016).

163 *See* § 136a(a); *see also* § 136a(c)(5).

164 *See* 15 U.S.C. § 2601–95(d) (2012).

165 *See* § 2605(a) (regulating "chemical substance or mixture[s]" that "present[s] or which will cause it to present an unreasonable risk of injury to health or the environment"); *see also* § 2604 (citing the premanufacture notification requirement).

occurs pursuant to the National Environmental Policy Act ("NEPA").[166] Under NEPA, a federal agency is required to prepare an Environmental Impact Statement ("EIS") any time the agency undertakes a major federal action "significantly affecting the quality of the human environment."[167] With the FDA's GRAS presumption for genetically-engineered foods under the FDCA and the limited scope of authority of the EPA under FIFRA and TSCA, the most significant federal action taken with respect to genetically-engineered products is most often a decision by the USDA to grant a developer's petition for deregulation under the PPA.[168] During the NEPA review, APHIS will consider a broad range of environmental impacts, including the potential of GE crops to contaminate non-GE crops; potential of herbicide-tolerant crops to generate herbicide-resistant weeds; and potential effects of GE traits on wild relatives.[169]

While the NEPA analysis by APHIS offers an occasion for environmental monitoring, the protection available under NEPA is limited. For one thing, an agency need not undertake to complete an EIS if, on the basis of a shorter Environmental Assessment ("EA"), the agency determines that the proposed action will not have a significant impact on the environment.[170] Moreover, even if an EIS is prepared, NEPA does not prescribe any environmental norms by which impacts should be judged nor mandate any particular outcome concerning significant environmental impacts. NEPA is a purely process-based statute, requiring only that the agency conduct the analysis, consider action alternatives, and explain its chosen outcome on the basis of the evidence in the EIS.[171] In fact, APHIS rarely conducts a full EIS before granting a petition for nonregulated status. Until issuing an EIS ordered by federal courts to prepare an EIS in connection with genetically-engineered alfalfa and sugar beets, APHIS had granted more than ninety petitions for

166 *See* 42 U.S.C. §§ 4321–70(h) (2012).

167 § 4332.

168 *See* 7 U.S.C. § 7711(c)(2) (2012); *see also* 7 C.F.R. § 340.6 (2016).

169 *See, e.g.*, Rebecca L. Stankiewicz Gabel, *Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status*, APHIS (Dec. 2010), https://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf [https://perma.cc/A4VG-UM4J].

170 *See* 40 C.F.R. § 1508.9 (2016); *see also* § 1508.13.

171 *See* Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989) (stating that if "the adverse environmental effects of the proposed action are adequately identified and evaluated, the agency is not constrained by NEPA from deciding that other values outweigh the environmental costs").

deregulation based on EAs.[172] Of 123 products deregulated since 1995, APHIS has performed an EIS in only six cases.[173]

E. Lack of Attention to Socioeconomic Impacts

Federal biotechnology regulation mostly does not address socioeconomic impacts that are of concern to consumers. Under a few statutes, agencies are allowed to consider socioeconomic impacts in making decisions; for example, FIFRA requires the EPA to consider "the economic, social, and environmental costs and benefits of the use of any pesticide" in determining whether the pesticide will have "unreasonable adverse effect on the environment," and the NEPA analysis requires that agencies consider the "ecological, aesthetic, cultural, economic, social, or health" impacts of any major federal action.[174] But even those examples of regulatory oversight of socioeconomic impacts are highly limited: FIFRA applies only to plants with pesticidal properties, and NEPA does not mandate any particular outcome based on the analysis of impacts.[175]

This lack of attention to socioeconomic impacts is not inevitable; other countries mandate consideration of social and economic impacts in their regulatory systems for GE crops and foods. The European Union, for example, requires labeling as a gesture to public concerns and has developed general guidance for managing coexistence between producers of genetically-engineered and conventional crops.[176] Brazil protects non-

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172 *See* Geertson Seed Farms v. Johanns, No. C 06-01075CRB, 2007 WL 776146, at *2–3 (N.D. Cal. Mar. 12, 2007); *see also* Ctr. for Food Safety v. Vilsack, 734 F. Supp. 2d 948, 955 (N.D. Cal. 2010); Andrew Pollack, *Judge Revokes Approval of Modified Sugar Beets*, N.Y. TIMES (Aug. 14, 2010), http://www.nytimes.com/2010/08/14/business/14sugar.html?_r=0 [https://perma.cc/YKC8-ZLJP].

173 *See Determination of Nonregulated Status of Event 5307 Corn*, *supra* note 59. Apart from those ordered by the courts, the petitions for which APHIS has prepared a full EIS involved products engineered to withstand more toxic herbicides, such as Dicamba and 2,4-D, which offer growers alternatives to glyphosate use. *Id.* The EIS prepared a statement for Monsanto Dicamba and Glufosinate-tolerant cotton and Dicamba and Glufosinate-resistant corn. *Id.* For DOW, the EIS prepared glyphosate and glufosinate-tolerant soybean; 2,4-D and glufosinate-tolerant soybean; and 2,4-D and Glufosinate-tolerant cotton deregulated based on EA. *Id.*

174 7 U.S.C. § 136(bb) (2012); *see also* 40 C.F.R. § 1508.8 (2016).

175 *See* § 136(bb); *see also* 42 U.S.C. § 4372(d)(4) (2012).

176 *See* Commission Regulation 1829/03, 2003 O.J. (268) 16; Commission Regulation 1830/03, 2003 O.J. (268) 23; *see also Commission Improves Rules on Labelling and Tracing of GMOs in Europe to Enable Freedom of Choice and Ensure Environmental Safety* (July 25, 2001), https://research.cip.cgiar.org/confluence/download/attachments/3450/F2.pdf [https://perma.cc/N6U9-A5DQ]; *Report from the Commission to the Council and the European Parliament on the Coexistence of Genetically Modified Crops with Conventional and Organic Farming* (Apr. 2, 2009), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0153:FIN:en:PDF [https://perma.cc/N6U9-A5DQ].

GE growers through mandatory isolation distances, exclusion zones, and other coexistence rules for certain crops.[177] Brazilian law also protects non-GE farmers by allocating strict liability for contamination to anyone responsible for damage to the environment or third parties from GE.[178] Brazil also mandates the labeling of GE foods and food products.[179]

Federal agencies can, in some instances, address socioeconomic impacts of genetically engineered crops or foods through their more general authority. For example, a committee appointed by the USDA to consider coexistence measures recommended that more data be collected to better understand the extent of any economic losses to farmers from contamination.[180] If action should be needed, the committee recommended an insurance scheme modeled on federal crop insurance.[181] In 2009, the Department of Justice ("DOJ") opened an investigation of the consolidation of the seed market and the practices of the major seed developers, but the investigation was closed without action three years later.[182] The Obama Administration's "Feed the Future" program includes an initiative led by the United States Agency for International Development ("USAID") and the USDA "to strengthen international public goods research in ways that generate technologies and knowledge that support agricultural productivity in both the United States and developing countries," and progress reports on the program highlight a couple of genetic engineering initiatives.[183]

IV. POLICY CONSIDERATIONS FOR NEW BIOTECHNOLOGY LEGISLATION

With the necessity of new legislation comes the freedom to re-imagine that legislation to create a better, more nuanced, and more balanced approach to regulation. Instead of sweeping persistent consumer

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177 *See* Resolução Normativa, CTNBio No. 4 (Aug. 16, 2007) (corn); Resolução Normativa, CTNBio No. 10 (Oct. 2, 2013).

178 *See* Art. 20, Lei No. 11,105 (Mar. 24, 2005).

179 *See* Art. 6(III), Lei No. 8,078 (Sept. 11, 1990); *see also* Decreto 4680/03 (Apr. 24, 2003).

180 *See* USDA ENHANCING COEXISTENCE, *supra* note 74, at 9–15.

181 *See id.* at 14–15.

182 *See* Ian Berry & David Kesmodel, *U.S. Closes Antitrust Investigation Into Seed Industry, Monsanto*, WALL ST. J. (Nov. 16, 2012), http://www.wsj.com/articles/SB10001424127887324735104578123631878019070 [https://perma.cc/ZH42-HNCS]; Peter Whoriskey, *Monsanto's Dominance Draws Antitrust Inquiry*, WASH. POST (Nov. 29, 2009), http://www.washingtonpost.com/wp-dyn/content/article/2009/11/28/AR2009112802471.html [https://perma.cc/ZE46-AZHA].

183 *See* Feed the Future: Global Food Security Research Strategy 6 (May 2011), https://www.feedthefuture.gov/sites/default/files/resource/files/FTF_research_strategy.pdf [https://perma.cc/2S49-UAQX]; *see also id.* at 40–41; 2015 Feed the Future Progress Report 15–16 (2015), https://www.feedthefuture.gov/sites/default/files/resource/files/Feed_the_Future_Results_Summary_Progress_2015.pdf [https://perma.cc/F6LT-WQG9].

objections under the rug, that legislation may be crafted to acknowledge areas of scientific uncertainty, to support, rather than thwart, further safety research, and to reach ancillary socioeconomic questions relating to GMOs and their impacts on the farm, in the market, and around the world where the federal government may provide key leadership. That new legislation must address several important policy questions. The questions canvassed below will be examined in detail in future work.[184]

A. Framing of Risk Assessment

An updated legislative and regulatory framework should re-consider the appropriate mechanism for determining whether a GE plant variety or GE-derived food will be subject to regulatory oversight and at what level. A preliminary question to that determination is whether the regulatory mechanism should apply to all new plant varieties and animal breeds, or merely those derived using genetic engineering, and if the latter, what techniques should qualify as "genetic engineering" for regulatory purposes.

B. Allocation of Regulatory Authority

As long as the statutory authorization for agency oversight must be revised (and it must, as new technology outgrows the PPA and the FDCA), the allocation of regulatory authority among the various agencies can be reconsidered. APHIS, the FDA, and the EPA have acquired over a quarter-century of experience at biotechnology regulation, but in some ways that oversight has been a poor fit for respective agency mandates. New legislation could consider various options: keep the allocation as it is (field tests with APHIS, food safety and new animal breed approvals with the FDA, and plant pesticides and microorganisms with the EPA); reallocate authority among the current agencies (such as giving greater environmental oversight responsibility to the EPA); consolidation of authority in a single agency such as the FDA; or even creation of a new agency that would handle all aspects of biotechnology oversight and federally-funded research and monitoring.

C. Source of Statutory Authority for Agency Oversight

Can legislative authority for biotechnology regulation be accomplished by amending the PPA, FDCA, FIFRA, or TSCA? Or should Congress reject the determination made by the Office of Science and

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184 *See* Alison Peck, *Re-Imagining Federal Biotechnology Regulation*, FOOD & DRUG L.J. (forthcoming 2017).

Technology Policy in the 1980s that biotechnology regulation could be accomplished under statutes that predated the technology? While continuation of authority under the existing statutes seems more consistent with a risk-based rather than a process-based model, attempts to place jurisdiction under statutes that regulate "plant pests" or "food additives" seem increasingly anathema to modern genetic engineering techniques. A third option might include a combination of amendments, both substantial and minor, to existing statutes, along with the creation of a new federal body with coordinating and review responsibilities through new legislation.[185]

D. Addressing Socioeconomic Impacts

New legislation also offers an opportunity to address socioeconomic impacts more comprehensively. Express mandates to monitor and control these impacts might be placed in the agencies that oversee new products, or in other existing agencies like DOJ or the Federal Trade Commission where appropriate. Initiatives that should be considered and debated include coordination of approvals of new GE plant or animal varieties or GE-derived foods between the United States and foreign regulators; liability insurance schemes or other liability allocation mechanisms for farmers injured by contamination with GE varieties; publicly funded research for new GE plant and animal varieties of particular benefit to farmers in developing countries and beneficial terms for transfer of such technology; and, of course, federal labeling rules.

V. CONCLUSION

The Coordinated Framework need not be maintained out of loyalty or lethargy. That framework arose from an urgent desire to approve the first GMO products from U.S. developers in the early days of the technology, and was based on the type of technology used at the time. That framework failed to address many legitimate concerns shared by many consumers, including scientific uncertainty as to safety for human health, increasing adverse agronomic and environmental impacts, and lack of attention to socioeconomic effects of GMOs in the field and in the marketplace. Moreover, market conditions and technology have evolved since 1986 and so must federal oversight. Since regulation under the PPA, FDCA, and FIFRA does not give agencies adequate authority to deal with

[185] This hybrid approach was attempted by Congress in early efforts to pass new legislation governing biotechnology. *See* Biotechnology Science Coordination Act, H.R. 4452, 99th Cong. (1985), S. 1967, 99th Cong. (1985); Omnibus Biotechnology Act, H.R. 5232, 101st Cong. (1990).

many of these concerns and changes, it is critical that Congress pass new legislation in the near term. New legislation provides an opportunity to include the public's voice in the conversation and to address the most persistently-raised policy concerns in a way that recognizes adverse impacts and scientific uncertainty and takes public concerns seriously.