GENETICALLY MODIFIED (GM) CROPS AND AN AGROECOLOGICAL FUTURE: A PROPOSAL FOR SYSTEMIC REFORM OF UNITED STATES GM CROP REGULATION

Alice Carli†

† Alice Carli is a graduate of the UCLA School of Law, where she served as the Chief Managing Editor of the *Journal of Environmental Law and Policy* and graduated with a specialization in environmental law. Before attending law school, Alice co-founded a food-based education company. Her experiences in policy, law, public health, and food education drive her holistic approach to tackling the complexities inherent in agricultural regulation and food systems. She will be clerking for the Honorable Stanley Blumenfeld Jr., United States District Court, Central District of California, beginning in 2025.

ABSTRACT

As climate change increases stress on the United States' food system, researchers are looking to deploy genetically modified crops as a tool to build more resilient agricultural systems. Yet, innovators in plant biotechnology are increasingly faced with a regulatory system that falls short of addressing the critical environmental and economic challenges of genetically modified agriculture. The United States' Coordinated Framework for Regulation of Biotechnology, established in the 1980s, prioritizes commercialization but is fragmented and ill-equipped to manage biotechnology advancements or align GM crop regulation with sustainable agriculture practices.

This Article proposes a systemic overhaul of the United States' regulatory framework for genetically modified crops, outlining the principles and core reforms of a re-envisioned, unified regulatory approach. Using agroecology as a guiding framework, the Article emphasizes the potential for GM crops to align with sustainable agricultural practices, combat climate change, and enhance resilience in food systems.

I. INTRODUCTION

Humans have been altering plants through selective breeding for upwards of 10,000 years.[1] This process of genetic modification has significantly impacted the biodiversity of the planet, the development of human societies, and the domestication of crops.[2] Early methods of plant husbandry included seed selection, hybridization, and plant grafting.[3] After millennia of these breeding practices, scientists developed transgenic genetic engineering, which involves inserting DNA from one organism into an unrelated organism.[4] This discovery

1. U.S. AGENCY FOR INT'L DEV. ET AL., BRIEF #1: WHAT IS AGRICULTURAL BIOTECHNOLOGY? 1 (2004), http://absp2.cornell.edu/resources/briefs/documents/warp_briefs_eng_scr.pdf [https://perma.cc/9FT6-HS4L].

2. *See generally* Yves Vigouroux et al., *Biodiversity, Evolution and Adaptation of Cultivated Crops*, 334 COMPTES RENDUS BIOLOGIES 450 (2011); Julia Chacón-Labella et al., *Plant Domestication Disrupts Biodiversity Effects Across Major Crop Types*, 22 ECOLOGY LETTERS 1472 (2019).

3. Pam Ronald, *What Is Plant Genetics?*, EXPLORE BIOLOGY (May 2024), https://explorebiology.org/collections/genetics/what-is-plant-genetics [http://perma.cc/PL5Q-Z55A].

4. *See* Gabriel Rangel, *From Corgis to Corn: A Brief Look at the Long History of GMO Technology*, HARVARD: SCI. IN THE NEWS (Aug. 9, 2015), https://sitn.hms.harvard.edu/flash/2015/from-corgis-to-corn-a-brief-look-at-the-long-history-of-gmo-technology/ [https://perma.cc/PF9H-DPD8].

fundamentally shifted humans' ability to manipulate genetic matter and opened a Pandora's box of possibilities in agriculture and beyond.[5]

In agriculture, transgenic engineering fundamentally challenged our understanding of what food *is* and what it *should be*. More recently developed genetic engineering methods allow scientists to manipulate genetic matter with added precision and without introducing foreign DNA into the target organism.[6] But scientists, policymakers, farmers, and citizens alike struggle to agree on what role genetic engineering should play in our food system.[7]

The United States has the world's largest production of genetically modified (GM) crops by acreage.[8] It is estimated that upwards of 75% of processed foods on supermarket shelves in the United States contain genetically engineered (GE) ingredients.[9] Notwithstanding the ubiquity of GM foods in the American food system, the country has a fragmented regulatory system that is failing to address environmental, health, and economic equity issues.[10]

The Coordinated Framework for Regulation of Biotechnology (Coordinated Framework or Framework) was established in the 1980s to appease growing public concern about biotechnology[11] while allowing the genetic engineering industry to

5. *Id.*

6. *See* Michaela A. Boti et al., *Recent Advances in Genome-Engineering Strategies*, GENES, Jan. 2023, at 1, 1.

7. *See* Aaron M. Shew et al., *CRISPR versus GMOs: Public Acceptance and Valuation*, 19 GLOB. FOOD SEC. 71, 72 (2018).

8. M. Shahbandeh, *Acreage of Genetically Modified Crops Worldwide from 2015 to 2019, by Leading Country (in Million Hectares)*, STATISTA (May 22, 2024), https://www.statista.com/statistics/263294/acreage-of-genetically-modified-crops-by-country-since-2003/ [https://perma.cc/TNY5-UHA9].

9. Mark Reynolds & C. Eugene Emery Jr., *Sen. Donna Nesselbush: Three Quarters of Processed Foods Have Genetically Modified Organisms*, THE POYNTER INST.: POLITIFACT (Mar. 22, 2015), https://www.politifact.com/factchecks/2015/mar/22/donna-nesselbush/sen-donna-nesselbush-three-quarters-processed-food/ [https://perma.cc/ZK5G-7DKK].

10. *See* Rea Globus & Udi Qimron, *A Technological and Regulatory Outlook on CRISPR Crop Editing*, 119 J. CELLULAR BIOCHEMISTRY 1291, 1295 (2018); NAT'L ACADS. OF SCIS., ENG'G, & MED., GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS 333–34, 500 (2016) [hereinafter GENETICALLY ENGINEERED CROPS].

11. David T. Kingsbury, *The Regulatory 'Coordinated Framework' for Biotechnology*, 4 NATURE BIOTECH. 1071, 1071–73 (1986) (describing that the goal of the Biotechnology Science Coordinating Committee was "to explain to the American public that human health and the health of the environment are adequately protected").

proceed with minimal hindrance to innovation.[12] The result was a safety net without meaningful protection for farmers and the physical environment, and one not well adapted to future developments in biotechnology. The Coordinated Framework has succeeded in incentivizing considerable technological developments since its inception, but it does not provide adequate protection for communities and environments impacted by GM crop cultivation.

Since the late 1990s, a prominent faction of the American public has contested the regulatory policies governing biotechnology.[13] Despite these objections, there has not been any legislative reform to the regulation of genetically modified organisms (GMOs), nor have the responsible agencies substantially reinterpreted their existing statutory authority.[14] Meanwhile, the country faces mounting environmental and food systems challenges, exacerbated by climate change and intensive monoculture farming.[15] These include flooding, soil degradation, biodiversity collapse, and malnutrition.[16] Significant and holistic changes to American agriculture are needed to tackle these problems.

Agroecology is an integrated framework for agricultural systems that has increasingly been applied to develop sustainable agriculture and tackle the environmental challenges of monoculture farming and climate change.[17] It aims to

12. SHELDON KRIMSKY & ROGER WRUBEL, AGRICULTURAL BIOTECHNOLOGY AND THE ENVIRONMENT: SCIENCE, POLICY, AND SOCIAL ISSUES 251 (1996) (describing "the overall thrust of the regulatory response to biotechnology" as "a minimalist, cost-effective, priority-driven approach requiring a burden of proof that regulation is warranted").

13. *See, e.g.*, Jenny Splitter, *How a Decade of GMO Controversy Changed the Dialogue About Food,* FORBES (Jan. 10, 2020, 12:23 PM), https://www.forbes.com/sites/jennysplitter/2019/12/20/how-a-decade-of-gmo-controversy-changed-the-dialogue-about-food/ [https://perma.cc/6D2P-QY7B] (describing how the controversy around GMOs "really hit its peak in the United States" in the past 15 years).

14. *See generally* Alison Peck, *Does Regulation Chill Democratic Deliberation? The Case of GMOs*, 46 CREIGHTON L. REV. 101, 128, 131–32 (2013).

15. *See* FOOD & AGRIC. ORG. OF THE UNITED NATIONS, THE STATE OF FOOD AND AGRICULTURE: MAKING AGRIFOOD SYSTEMS MORE RESILIENT TO SHOCKS AND STRESSES xvi–xvii (2021) [hereinafter, THE STATE OF FOOD AND AGRICULTURE 2021], https://www.fao.org/3/cb4476en/cb4476en.pdf [https://perma.cc/T7QQ-TAD2].

16. *See id.*

17. *See, e.g.*, Shiney Varghese, *What Is Agroecology, and How Can It Provide Solutions to Crises that Plague our Food Systems and Create Food Democracies?*, INST. FOR AGRIC. & TRADE POL'Y (June 16, 2022), https://www.iatp.org/agroecology-takes-center-stage-global-agenda-transforming-agriculture-and-food-systems [https://perma.cc/4Y4Q-5C5A]; Chandra Shekhar Karki, *Agroecology – A Contribution to Food Security?*, UNITED NATIONS ENV'T PROGRAMME (Oct. 15, 2020), https://www.unep.org/news-and-stories/story/agroecology-contribution-food-security [https://perma.cc/AXN6-LJT2].

enhance agricultural productivity, sustainability, and resilience, while minimizing environmental harm by improving factors like soil health and biodiversity.[18] However, agroecological principles have long been considered at odds with genetic engineering, often due to deontological concerns about the naturalness of genetic engineering as it relates to deeply held ethical or cultural values.[19] Such objections to genetic engineering stem from the belief that genetic manipulation is "unnatural" and goes against core values about the relationship between humans and nature and the importance of traditional and culturally informed approaches to food production.[20]

In recent years, the question of whether agroecology and genetic engineering are compatible has drawn increasing interest. More observers propose that biotechnology can be a tool to address agroecology's central concerns and combat threats posed by climate change.[21] Given that GM crops are ubiquitous in the United States food system, aligning their regulation with emerging norms and understandings of sustainable agriculture can help break the existing political and social divisions around them.

If regulated effectively, GM crops have the potential to mitigate climate change and make United States agriculture more sustainable and climate resilient. When designed with climate-smart features, these crops can significantly enhance

18. *Agroecology Knowledge Hub*, FOOD & AGRIC. ORG. OF THE UNITED NATIONS (Oct. 26, 2024, 12:36 PM), https://www.fao.org/agroecology/overview/en/ [https://perma.cc/4P6T-39HB].

19. *See* Steve Gliessman, *Agroecology: Growing the Roots of Resistance*, 37 AGROECOLOGY & SUSTAINABLE FOOD SYS. 19, 20, 25 (2013).

20. *See* Blake Hurst, *Scientists Sit Out Genetic Engineering Debate*, AM. ENTER. INST. (Sept. 24, 2014), https://www.aei.org/articles/scientists-sit-out-genetic-engineering-debate/ [https://perma.cc/9DWX-R66G]; Dimitrios T. Karalis et al., *Genetically Modified Products, Perspectives and Challenges*, CUREUS, Mar. 18, 2020, at 3–4.

21. *See, e.g.*, Sylvie Bonny, *High-Tech Agriculture or Agroecology for Tomorrow's Agriculture?*, *in* HARV. COLL. REV. ENV'T & SOC'Y, ENGINEERING OUR FOOD 28, 29 (2017), https://hal.science/hal-01536016/file/Bonny_High-tech%20Agriculture%20or%20Agroecology%20for%20Tomorrow%20s%20Agriculture_%7BB43CD3E8-2709-4297-BA81-BE1B3FB2FCA7%7D.pdf [https://perma.cc/JWY8-4ATG]; L.A.P Lotz et al., *Genetically Modified Crops and Sustainable Agriculture: A Proposed Way Forward in the Societal Debate*, 70–71 NJAS: WAGENINGEN J. LIFE SCI. 95 (2014) [hereinafter Lotz et al., *Genetically Modified Crops and Sustainable Agriculture*].

nutrient or photosynthesis efficiency,[22] provide flood,[23] drought, and disease resistance, and even improve soil carbon sequestration.[24] Agroecology is thus a valuable framework for understanding how biotechnology, including GM crops, can be appropriately regulated to play a role in a sustainable and climate-friendly future.

This Article posits that GM crops are not fundamentally incompatible with agroecology and can play an important role in our food system. Using agroecology as a framework for regulating GM crops can provide a new way of thinking about food technology and help ensure that GM crop regulation aligns with evolving norms and values around sustainable food.

This Article joins a growing chorus of voices calling for an overhaul of the Coordinated Framework for Regulation of Biotechnology.[25] It contributes to the body of literature by addressing how the United States should replace the Coordinated Framework, using principles drawn from agroecology as a guide. It lays out a vision for gene editing to be reclaimed in the public interest through a new regulatory framework that aligns GM crops with the goals and methods of

---

22. Paul F. South et al., *Synthetic Glycolate Metabolism Pathways Stimulate Crop Growth and Productivity in the Field*, SCIENCE, Jan. 4, 2019, at 1, 1.

23. *See* Krishna Ramanujan, *Rice Survives Long-Term Floods Due to Newly Discovered Genetic Mechanism*, CORNELL COLL. OF AGRIC. & LIFE SCI. (July 12, 2018), https://cals.cornell.edu/news/rice-survives-long-term-floods-due-newly-discovered-genetic-mechanism [https://perma.cc/TDS9-WG65].

24. *See* Christy Clutter, *Unearthing the Soil Microbiome, Climate Change, Carbon Storage Nexus*, AM. SOC'Y FOR MICROBIOLOGY (May 13, 2021), https://asm.org/Articles/2021/May/Unearthing-the-Soil-Microbiome,-Climate-Change,-Ca [https://perma.cc/ZN9W-EQYE].

25. *See, e.g.*, Debra M. Strauss, *The Role of Courts, Agencies, and Congress in GMOs: A Multilateral Approach to Ensuring the Safety of the Food Supply*, 48 IDAHO L. REV. 267, 272 (2012) [hereinafter Strauss, *The Role of Courts*] ("The existing framework of power sharing between the USDA, EPA, and FDA yields an incomplete regulatory scheme."); Maria R. Lee-Muramoto, *Reforming the "Uncoordinated" Framework for Regulation of Biotechnology*, 17 DRAKE J. AGRIC. L. 311, 316–17 (2012); Heather Hosmer, *Outgrowing Agency Oversight: Genetically Modified Crops and the Regulatory Commons Theory*, 25 GEO. INT'L ENV'T L. REV. 647, 649 (2013); Gregory Jaffe, *Necessary Regulatory Changes to Improve the Federal Government's Oversight of GE Crops*, *in* HARV. COLL. REV. ENV'T & SOC'Y, ENGINEERING OUR FOOD 19, 19 (2017), https://www.cspinet.org/sites/default/files/attachment/HCRES_2017_Jaffe.pdf [https://perma.cc/5HY4-MBDU]; Jordan Emmert, Note, *A Case for United States Overhaul of Its Current Biotechnology Regulation Scheme Through the Implementation of Biotechnology-Specific Legislation to Clarify Existing Uncertainties Seen in the Collective Framework*, 2 INT'L COMP., POL'Y & ETHICS L. REV. 529, 533 (2019); Alison Peck, *Re-Framing Biotechnology Regulation*, 72 FOOD & DRUG L.J. 314, 314 (2017).

agroecology, minimizing their harms while harnessing GM technology as a tool to build a sustainable future for agriculture.

Part II begins by introducing the topic of genetic modification. Part III then recounts the history of the Coordinated Framework and discusses its limitations. Part IV posits that agroecological principles represent a shifting understanding of agriculture and food systems in response to declining agroecological health and the impending threat of climate change.

Using this emerging understanding of our food systems as a foundation, Part V proposes a comprehensive policy approach for GM crop regulation. The Article identifies four fundamental principles, drawn from the intersection of agroecology and the GM crop market, that should guide reform efforts. It then recommends the primary legislative changes needed to align GM crop regulation with agroecology. Finally, it explores best-practice policy tools that could further animate these fundamental principles within the proposed legislative framework.

II. Defining Genetic Modification

Genetic modification spans a long history of various biotechnologies, making it difficult to create functional categories for discussing and regulating GMOs.[26] Historically, traditional plant breeding involved techniques such as "selective breeding, hybridization, mutation breeding, and marker-assisted selection," which were all used to create lineages of plants with more desirable traits.[27] In the early twentieth century, plant breeders began using chemical and irradiating agents to induce crop mutations.[28] This was done with the hope that some resulting mutations would prove beneficial and could be selected and cultivated.[29] Thus, traditional plant breeding and induced mutations rely on spontaneous mutations arising from a plant's cellular replication process.[30]

---

26. Marcy E. Gallo & Amanda K. Sarata, Cong. Rsch. Serv., R44824, Advanced Gene Editing: CRISPR-Cas 9, at 11 (2018).

27. Eleni G. Bickell, Cong. Rsch. Serv., R46737, Agricultural Biotechnology: Overview, Regulation, and Selected Policy Issues 2 (2021) [hereinafter Bickell, Agricultural Biotechnology] (noting how "many conventional breeding practices rely on laboratory techniques and genetic analysis" as opposed to genetic engineering).

28. Tadesse Fikre Teferra, *Should We Still Worry About the Safety of GMO Foods? Why and Why Not? A Review*, 9 Food Sci. & Nutrition 5324, 5325 (2021).

29. *Id.*

30. *See* F.J. Novak & H. Brunner, *Plant Breeding: Induced Mutation Technology for Crop Improvement*, IAEA Bulletin, Dec. 1992, at 25, 25–26 (explaining that natural selection operates to bring about evolution through the variability created by spontaneous

A significant change occurred in the 1970s with the development of recombinant DNA technology.[31] This technology allows scientists to combine DNA from two or more sources to achieve desired trait outcomes.[32] GMOs with recombinant DNA from an individual of the same species are considered cisgenic, and GMOs with recombinant DNA from an individual of a different species are considered transgenic.[33] When using recombinant genetic engineering, scientists are generally unaware of where the recombinant DNA has been placed in the organism's genome.[34]

In the past 20 years, another significant development took place in the field of genetic engineering: the creation of high-precision genome editing tools.[35] These tools allow scientists to make specific changes to targeted portions of the genome by inserting, deleting, or modifying gene sequences and using epigenetic techniques that change when and how an organism expresses genes without changing the underlying genetic sequence.[36] The most common tool for genome editing is Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), which utilizes a bacterial protein to cut a DNA sequence in a particular location and make changes.[37]

Genome editing tools are generally not considered recombinant DNA technologies because no DNA from another organism is left in the target plant, and modifications can be made with heightened precision and reliability.[38] CRISPR allows the creation of plant traits that could, in theory, happen naturally through the plant's evolutionary processes, but without needing to wait for the mutation to

natural mutations and amplified by subsequent recombination of genes during sexual reproduction); Nancy A. Reichert, *History of Plant Genetic Mutations ± Human Influences*, 57 IN VITRO CELLULAR & DEVELOPMENTAL BIOLOGY-PLANT 554, 554 (2021) (describing how, since spontaneous mutation rates are low, plant breeders developed procedures to induce mutations via physical (primarily ionizing radiation) and chemical treatments).

31. *See* GALLO & SARATA, *supra* note 26, at 2.

32. *Recombinant DNA Technology*, NAT'L HUMAN GENOME RSCH. INST. (Oct. 26, 2024), https://www.genome.gov/genetics-glossary/Recombinant-DNA-Technology [https://perma.cc/T4PB-GECZ].

33. BICKELL, AGRICULTURAL BIOTECHNOLOGY, *supra* note 27, at 3.

34. *Id.*

35. GALLO & SARATA, *supra* note 26, at 1.

36. *Id.* at 2–3, 34.

37. *What Are Genome Editing and CRISPR-Cas9?*, MEDLINEPLUS, NAT'L LIBR. OF MED. (Oct. 26, 2024, 2:13 PM), https://medlineplus.gov/genetics/understanding/genomicresearch/genomeediting/ [https://perma.cc/2SEE-TN36].

38. *See id.*; GALLO & SARATA, *supra* note 26, at 2.

arise spontaneously.[39] However, CRISPR can theoretically create crop varieties with computationally designed DNA sequences that have no other biological source.[40] Also, "while CRISPR systems are more precise, they [do] not eliminate[] the potential for off-target effects."[41]

In the 20 years since the first commercial GM crop hit shelves in the United States,[42] four major transgenic crops have emerged in the domestic market: corn, soybeans, cotton, and canola.[43] As of 2017, 84% of all soybean acreage in the United States was comprised of transgenic GMOs, as well as 92% of corn acreage and 96% of cotton acreage.[44] GM crops currently on the market are often engineered to improve yield quantity or quality, be herbicide-tolerant, pesticide-tolerant, insect/pathogen-resistant, or have desirable aesthetic traits.[45]

Various concerns have been raised about the safety and efficacy of GM crops. These concerns can generally be divided into four categories: harm to human health, environmental harm, economic harm, and ethical issues.

No direct human safety hazards regarding GM foods as a category have been verified,[46] and meta-analyses of scientific research have concluded that GM foods are generally safe to eat.[47] However, potential risks to human health from exposure to GM crops include toxicity, allergenicity, nutritional changes, and any

---

39. *What Are Genome Editing and CRISPR-Cas9?*, *supra* note 37.

40. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 494.

41. ELENI G. BICKELL, CONG. RSCH. SERV., R47683, GENE-EDITED PLANTS: REGULATION AND ISSUES FOR CONGRESS 15 (2023) [hereinafter BICKELL, GENE-EDITED PLANTS].

42. *See Science and History of GMOs and Other Food Modification Processes*, U.S. FOOD & DRUG ADMIN. (Mar. 5, 2024), https://www.fda.gov/food/agricultural-biotechnology/science-and-history-gmos-and-other-food-modification-processes [https://perma.cc/3CVL-U5D5].

43. *GM Crops: A Story in Numbers*, 497 NATURE 22, 23 (2013).

44. NANCY MATHESON ET AL., NAT'L CTR. FOR APPROPRIATE TECH., GENETICALLY MODIFIED CROPS: TRANSGENICS AND CISGENICS 2 (2018), https://attra.ncat.org/wp-content/uploads/2022/07/gmocrops.pdf [https://perma.cc/Y53T-KRVM].

45. Globus & Qimron, *supra* note 10, at 1296.

46. Teferra, *supra* note 28, at 5326.

47. Alessandro Nicolia et al., *An Overview of the Last 10 Years of Genetically Engineered Crop Safety Research*, 34 CRITICAL REVS. IN BIOTECH. 77, 84–85 (2014); GENETICALLY ENGINEERED CROPS, *supra* note 10, at 172 (noting a study where the 130 research projects funded by the European Commission on the topic found no special risk from GM crops); David H. Freedman, *The Truth About Genetically Modified Food*, SCI. AM. (Sept. 1, 2013), https://www.scientificamerican.com/article/the-truth-about-genetically-modified-food/.

unintended effects of a specific modification.[48] The potential harms from GM crops to the environment include invasiveness,[49] gene drift,[50] secondary pollution, damage to other organisms, and general impacts on biodiversity and ecosystem health.[51] Lastly, the introduction of GM crops has precipitated a series of economic harms for farmers due to consolidation in the market for seeds and the creation of economic dependency cycles.[52]

This Article makes policy recommendations with the understanding that GM crops are highly prevalent in the United States.[53] It proceeds on the premise that GM crops are part of the United States' food system and can be regulated to reflect evolving perspectives about the future of sustainable agriculture. Thus, while genetic engineering has also been criticized as being "unnatural" or akin to "playing God,"[54] these ethical concerns are not the focus of this Article. They are complex societal and philosophical issues that are not easily addressed through

48. *Food, Genetically Modified*, WORLD HEALTH ORG. (May 1, 2014), https://www.who.int/news-room/questions-and-answers/item/food-genetically-modified [https://perma.cc/3BGG-Y3KK].

49. Rosie Hails & Tracey Timms-Wilson, *Genetically Modified Organisms as Invasive Species?*, *in* BIOLOGICAL INVASIONS 293, 293 (Wolfgang Nentwig ed., 2007) (explaining how invasiveness refers to the possibility that GM crops could spread aggressively and disrupt the local ecosystem, potentially displacing native species and altering habitats).

50. Anthony J. Conner et al., *The Release of Genetically Modified Crops into the Environment*, 33 PLANT J. 19, 36 (2003) (detailing how gene drift refers to the unintentional movement of genes from GM crops to wild or non-GM plants); Suzanne I. Warwick et al., *Gene Flow, Invasiveness, and Ecological Impact of Genetically Modified Crops*, 1168 ANNALS N.Y. ACAD. SCI. 72, 75 (2009) (describing how gene drift can occur through processes like wind pollination, where pollen from GM crops fertilize neighboring wild plants, leading to the unintended spread of GM traits).

51. Aristidis M. Tsatsakis et al., *Environmental Impacts of Genetically Modified Plants: A Review*, 156 ENV'T RSCH. 818, 818 (2017) (listing potential secondary impacts to include crop invasiveness and herbicide tolerance).

52. *See infra* note 217 and accompanying text.

53. *See* MATHESON ET AL., *supra* note 44, at 2.

54. Stefaan Blancke, *Why People Oppose GMOs Even Though Science Says They Are Safe*, SCI. AM. (Aug. 18, 2015), https://www.scientificamerican.com/article/why-people-oppose-gmos-even-though-science-says-they-are-safe/; *see also* Manreet Sohi et al., *Analyzing Public Sentiment Toward GMOs via Social Media Between 2019–2021*, GM CROPS & FOOD, Mar. 22, 2023, at 1, 3 (detailing "disgust" as a primary emotional reaction to GMOs). The sentiment that GMOs are unnatural is further exemplified by a series of lawsuits against food manufacturers who have labeled their products "natural" while using GM ingredients. *See, e.g.*, Cox v. Gruma Corp., No. 12-CV-6502, 2013 WL 3828800, at *1–2 (N.D. Cal. July 11, 2013) (alleging "all natural" claims on chips made from GMO corn are false and misleading).

regulatory reform, short of banning GMOs altogether.[55] This Article focuses instead on how regulatory reform can continue to ensure human safety while more adequately addressing environmental and economic harms.

III. EXISTING REGULATION OF GM CROPS

The rapid developments in genetic engineering have made it challenging for the public to understand the science of GMOs and for policymakers to decide how GM crops should be regulated.[56] Countries have taken diverging approaches to regulating agricultural biotechnology, with the United States strongly favoring the commercialization of GM crops.[57] These differing policy approaches can broadly be categorized as "process-based," where crops are regulated depending on the method of genetic modification used, and "process-agnostic," where crops are regulated based on their traits and qualities, regardless of how they were modified.[58]

In the United States, biotechnology is governed by the Coordinated Framework for Regulation of Biotechnology.[59] This regulatory system has largely remained the same since it was established in 1986.[60] It has a stated goal of taking

55. Labeling laws help to address some of these concerns by empowering consumer choice. In 2016, Congress passed a law to establish guidelines for the labeling of GM food in the hopes of giving consumers more information, and thus choice, about what they eat. *BE Disclosure*, AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC. (Oct. 26, 2024, 2:06 PM), https://www.ams.usda.gov/rules-regulations/be [https://perma.cc/5MDE-AGCA]. The new standards will become mandatory in 2025, with numerous ways companies can comply with disclosure requirements. *Id.*

56. *See* Alan McHughen, *A Critical Assessment of Regulatory Triggers for Products of Biotechnology: Product vs. Process*, 7 GM CROPS & FOOD 125, 130–31 (2016).

57. *See* Crystal Turnbull et al., *Global Regulation of Genetically Modified Crops Amid the Gene Edited Crop Boom – A Review*, FRONTIERS PLANT SCI., Feb. 24, 2021, at 1, 5 (surveying the varied global regulatory landscape for agricultural biotechnology and describing the United States as "the global leader in the development and commercialization of GM crops, holding close to 30% of the global market share"); Jingang Liang et al., *The Evolution of China's Regulation of Agricultural Biotechnology*, 3 ABIOTECH 237, 238 (2022) (comparing the United States' use of the permissive "reliability science principle" with the European Union's use of the precautionary principle in choosing whether to restrict GM technology).

58. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 455–56, 483; see Klaus Ammann, *Genomic Misconception: A Fresh Look at the Biosafety of Transgenic and Conventional Crops. A Plea for a Process Agnostic Regulation*, 31 NEW BIOTECH. 1, 2 (2014).

59. BICKELL, GENE-EDITED PLANTS, *supra* note 41, at 3.

60. *Id.*

a process-agnostic approach to GM crop regulation.[61] Yet, as discussed below, the modification process generally determines whether a plant is subject to federal regulation.[62]

A. The Coordinated Framework for Regulation of Biotechnology

The Coordinated Framework for Regulation of Biotechnology was established in 1986 in response to rapid advancements in biotechnology and the growing need for a regulatory approach that could address the safety, environmental, and ethical concerns associated with GMOs.[63] At its inception, the Coordinated Framework represented a compromise between increasing public concern about the safety of genetic engineering and the government's desire to permit the industry to develop relatively unobstructed.[64]

The Framework delegated oversight of biotechnology to three federal agencies based on the conclusion that GM products are not categorically distinct from existing products but instead "are on a continuum" with them.[65] Fundamental to the Framework is the assumption that unless proven otherwise through sound scientific risk assessments, the products of genetic engineering pose no novel threat to the environment or human health.[66] This approach aligned with the interests of the agricultural and pharmaceutical industries, which exercised considerable influence on the development of the Framework, seeking to ease the

61. GALLO & SARATA, *supra* note 26, at 10.

62. *See generally* Fred Gould et al., *Toward Product-Based Regulation of Crops*, 377 SCIENCE 1051, 1051 (2022).

63. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986); David L. Stepp, The History of FDA Regulation of Biotechnology in the Twentieth Century 53 (Winter 1999) (unpublished third year paper, Harvard Law School), https://dash.harvard.edu/handle/1/8965554 [https://perma.cc/R5V5-4LQJ] (discussing how the Supreme Court decision in *Diamon v. Chakrabarty*, 447 U.S. 303 (1980), which held that genetically engineered bacteria was patentable subject matter, raised intense religious and ethical objections to the ownership of life and created a public sense of unease regarding the direction and implications of biotechnological research).

64. Request for Information, 87 Fed. Reg. 77900, 77901 (Dec. 20, 2022).

65. Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 734, 738 (2003).

66. *See* Allison H. Scott, Comment, *Genetically Modified Crop Regulation: The Fraying of America's Patchwork Farm Lands*, 26 VILL. ENV'T L.J. 145, 152–55 (2015); GENETICALLY ENGINEERED CROPS, *supra* note 10, 469–70.

way for minimally restrictive regulation.[67] Specifically, industry members wanted GMOs to be regulated no more stringently than similar products developed through conventional methods.[68]

No one statute or federal agency governs biotechnology regulation.[69] Instead, existing agencies were tasked with regulating GMOs under existing statutory authority.[70] Generally, the FDA oversees GM foods, food additives, and medications for humans and animals, pursuant to several legislative mandates.[71] The EPA oversees microbial pesticides and other GE microbes designed for widespread commercial and environmental use.[72] The USDA regulates GMOs in plants and animals.[73]

The FDA regulates the safety of GM crops that humans or animals consume under the Federal Food, Drug, and Cosmetic Act (FFDCA).[74] The FFDCA charges the FDA with regulating any foods that contain substances that may be harmful to health or that contain unsafe food additives.[75] Transgenic proteins fall within this category of food additives, but they can avoid pre-market approval if they are generally recognized as safe (GRAS) based on science or prior regulatory experience.[76]

---

67. Kurt Eichenwald, *Redesigning Nature: Hard Lessons Learned; Biotechnology Food: From the Lab to a Debacle*, N.Y. TIMES (Jan. 25, 2001), https://www.nytimes.com/2001/01/25/business/redesigning-nature-hard-lessons-learned-biotechnology-food-lab-debacle.html (detailing the efforts of Monsanto and other industry players in driving the development of biotechnology regulation favorable to the industry).

68. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23302–03 (summarizing public comments to the Office of Science and Technology Policy regarding the Coordinated Framework, which focused on whether new gene editing *techniques* would pose a greater risk than traditional manipulations of genetic material).

69. PEW INITIATIVE ON FOOD & BIOTECH., GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS 1 (2001), https://www.pewtrusts.org/~/media/legacy/uploadedfiles/wwwpewtrustsorg/reports/food_and_biotechnology/hhsbiotech0901pdf [https://perma.cc/9DVG-8FB8].

70. *See id.*

71. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23304.

72. *Id.* at 23304–05.

73. *Id.*

74. BICKELL, AGRICULTURAL BIOTECHNOLOGY, *supra* note 27, at 26.

75. *Id.*; 21 U.S.C. § 342(a)(1).

76. BICKELL, AGRICULTURAL BIOTECHNOLOGY, *supra* note 27, at 26–27; 21 U.S.C. § 321(s).

The FDA considers most GM crops as "substantially equivalent" to non-GM crops and therefore, GRAS.[77] If a plant expresses products (e.g., proteins, carbohydrates, fats) that "differ[] significantly in structure, function or composition from substances currently found in food" and is potentially harmful to human health, the FDA reserves the authority to require pre-market approval.[78] The FDA also operates a voluntary program that allows developers to submit safety assessment data to the FDA and receive a consultation to resolve any safety issues.[79]

The EPA regulates biopesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[80] The agency's regulatory role is relatively narrow under FIFRA, which allows it to regulate the "distribution, sale, or use" of pesticides to the "extent necessary to prevent unreasonable adverse effects on the environment."[81] This authority is limited to regulating the pesticide, not the crop itself.[82] FIFRA only grants the EPA authority to regulate a crop genetically engineered to carry a gene for a pesticide, or a plant-incorporated protectant (PIP), defined as a substance produced by plants for protection against pests.[83]

The EPA operates through a registration and permitting process.[84] It requires experimental use permits when an applicant wishes to field test an experimental PIP.[85] The EPA has also "exercised its authority under FIFRA to require post-approval monitoring and pest-resistance-management programs" for crops within its jurisdiction.[86] This allows for the imposition of restrictions intended to reduce the potential for unwanted gene flow.[87] In 2023, the EPA announced changes to its

77. PEW INITIATIVE ON FOOD & BIOTECH., *supra* note 69, at 20, 21.

78. *Id.*

79. *Programs on Food from New Plant Varieties*, U.S. FOOD & DRUG ADMIN. (Dec. 16, 2024), https://www.fda.gov/food/food-new-plant-varieties/consultation-programs-food-new-plant-varieties [https://perma.cc/3WX6-G2HJ].

80. BICKELL, AGRICULTURAL BIOTECHNOLOGY, *supra* note 27, at 28; 7 U.S.C. § 136a(a).

81. 7 U.S.C. § 136a(a).

82. Lee-Muramoto, *supra* note 25, at 322.

83. 40 C.F.R. §§ 174.1, 174.3 (2024).

84. BICKELL, AGRICULTURAL BIOTECHNOLOGY, *supra* note 27, at 28; 40 C.F.R. § 172.3(a).

85. *Pesticide Registration Manual: Chapter 12 — Applying for an Experimental Use Permit*, U.S. ENV'T PROT. AGENCY (June 4, 2024), https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit [https://perma.cc/9HWT-DZG7].

86. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 507.

87. *Id.*

regulations to exempt certain plants from registration, including those with genetic modifications that reduce or eliminate gene activity and PIPs in which a gene has been inserted or modified to match a gene found in a sexually compatible plant.[88]

The USDA governs GM crops under the authority of the Plant Protection Act (PPA).[89] Within the USDA, this authority primarily belongs to the Animal and Plant Health Inspection Service (APHIS), which regulates crops known or suspected to be plant-pests or pose a plant-pest risk.[90] The definition of plant-pest is wide-ranging, encompassing any organism that can "directly or indirectly injure, cause damage to, or cause disease in any plant" and includes "[a]ny living stage of a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen."[91] Plant-pest risk refers to "[t]he potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from . . . a [plant-pest.]"[92]

APHIS regulates GM crops through a permitting process or a determination of non-regulated status.[93] Many GM crops are produced using bacteria or viruses that APHIS classifies as plant-pests and, therefore, are by default considered a regulated article.[94] GM crops tested and shown not to pose a risk may be eligible for non-regulated status.[95] Safety is proven using published and unpublished scientific studies and data from field tests, as provided by the developer.[96] Non-regulated status decisions are subject to public comment periods.[97] The APHIS regulation process is narrowly focused on plant-pest risk and does not typically require rigorous environmental or health review.[98] Once granted non-regulated

88. *EPA Finalizes Rule to Accelerate Use of Plant-Incorporated Biotechnologies to Protect Against Pests*, U.S. ENV'T PROT. AGENCY (May 6, 2024), https://www.epa.gov/pesticides/epa-finalizes-rule-accelerate-use-plant-incorporated-biotechnologies-protect-against [https://perma.cc/59JE-XWSL].

89. BICKELL, AGRICULTURAL BIOTECHNOLOGY, *supra* note 27, at 24.

90. *Id.*

91. 7 C.F.R. § 340.3 (2024).

92. *Id.*

93. Kevin P. Braig, *The Legal Basics of Genetically Modified Organisms and Organic Food Regulation*, *in* TRENDS IN AGRICULTURE: GMOS AND ORGANICS: LEADING LAWYERS ON LABELING, PRODUCTION, AND COPYRIGHT RESTRICTIONS 1, 12 (2016).

94. BICKELL, AGRICULTURAL BIOTECHNOLOGY, *supra* note 27, at 24–25.

95. Braig, *supra* note 93, at 12.

96. *Id.*

97. *Id.*

98. Rita Barnett-Rose, *Judicially Modified Democracy: Court and State Pre-Emption of Local GMO Regulation in Hawaii and Beyond*, 26 DUKE ENV'T L. & POL'Y F. 71, 86–87 (2015).

status, the GM crop is no longer subject to APHIS oversight, including post-market monitoring.[99]

In 2020, APHIS adopted the SECURE rule (Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient), which exempted specific categories of GM plants from regulation where they could have otherwise been developed through conventional breeding.[100] The rule allowed certain gene-edited products, such as those achieved through single-base pair substitutions, to completely circumnavigate regulation and enter the market without any health and safety assessment.[101] In 2024, the rule was vacated by the United States District Court for the Northern District of California.[102] As a result, APHIS has reverted to its pre-2020 regulatory framework, though the agency may still appeal the ruling.[103]

When the Framework was established, it relied upon a disassociation, rather than a harmonization, of the responsible agencies, stating: "To the extent possible, responsibility for a product use will lie with a single agency," and, "Where regulatory oversight or review for a particular product is to be performed by more than one agency, the policy establishes a lead agency, and consolidated or coordinated reviews."[104] This disassociated structure was balanced by two

---

99. *Id*. at 86.

100. ELENI G. BICKELL, CONG. RSCH. SERV., IF11573, USDA'S SECURE RULE TO REGULATE AGRICULTURAL BIOTECHNOLOGY 1 (2023) [hereinafter BICKELL, USDA'S SECURE RULE].

101. *See* Jamie Auslander et al., *SECURE Rule Amends USDA Regulation of Genetically Engineered Organisms*, BEVERIDGE & DIAMOND (May 19, 2020), https://www.bdlaw.com/publications/secure-rule-amends-usda-regulation-of-genetically-engineered-organisms/ [https://perma.cc/JX7J-LNUA] (explaining how the rule replaces APHIS's previous approach of presuming regulatory oversight of virtually all new GE organisms involving a plant-pest and instead allows developers to self-determine that their plant falls within an exemption, including for genetic modifications involving single-base pair substitutions).

102. Nat'l Fam. Farm Coal. v. Vilsack, No. 21-cv-05695, 2024 WL 4951257, at *5, *10, *15 (N.D. Cal Dec. 2, 2024) (holding APHIS's rulemaking was arbitrary and capricious because it did not state why the agency ran counter to its previously stated intent to expand its oversight of GM plants by using its noxious-weed authority, in addition to its plant-pest authority).

103. *See APHIS Restarts Permitting and Am I Regulated Processes for Products of Biotechnology*, ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC. (Jan. 17, 2025, 8:28 PM), https://www.aphis.usda.gov/news/program-update/aphis-restarts-permitting-am-i-regulated-processes-products-biotechnology [https://perma.cc/7KVP-8ZYR].

104. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23303 (June 26, 1986).

coordinating groups, one of which was ultimately terminated amidst criticism that it was dominated by industry interests.[105]

In 2022, the Biden Administration issued an Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy.[106] The Order articulates a priority of a coordinated, whole-government approach to biotechnology regulation.[107] It emphasizes the need to innovate in health, climate change, food security, and supply chain resilience.[108] The Order set out a policy of boosting climate-smart incentives for agriculture and assessing how biotechnology can be used to innovate and improve sustainability in food and agriculture.[109]

This Executive Order suggests growing political interest in aligning biotechnology regulation with climate-resilient and sustainable agriculture.[110] However, the FDA, EPA, and USDA have limited statutory authority, leaving them unable to meaningfully realign the GM crop market.

B. States and Municipalities

Within this patchy federal framework, states have attempted to regulate GM crops.[111] Numerous states have enacted legislation requiring additional permitting from GM cultivators before planting in their state.[112] Others have passed some form of food or seed labeling law.[113] However, states and localities are often preempted from participating in GMO regulation.[114]

Due to an express preemption provision in the PPA, states are prohibited from regulating the movement of any articles regulated under the PPA in interstate

105. Linda Maher, *The Environment and the Domestic Regulatory Framework for Biotechnology*, 8 J. ENV'T L. & LITIG. 133, 139–40 (1993).

106. Exec. Order No. 14081, 88 Fed. Reg. 25711 (Apr. 27, 2023).

107. *Id.* at 25712–13.

108. *Id.* at 25712.

109. *See id.*

110. *See* Jill Furgurson et al., *Seizing the Policy Moment in Crop Biotech Regulation: An Interdisciplinary Response to the Executive Order on Biotechnology*, FRONTIERS BIOENG'G & BIOTECH., Aug. 7, 2023, at 1, 1 ("The release of the Biden Administration's Executive Order on Biotechnology and Biomanufacturing signals that a policy window is open for significantly revising and evolving the existing regulatory framework for agricultural biotechnology products.").

111. Scott, *supra* note 66, at 155–56.

112. Barnett-Rose, *supra* note 98, at 90.

113. *Id.*

114. *Id.*

commerce.[115] The Ninth Circuit in *Hawai'i Papaya Industry Ass'n v. County of Hawaii* and *Atay v. County of Maui* later interpreted the provision expansively to preempt even wholly intrastate plant-pest regulation.[116] County or local ordinances are further preempted by state law when states have enacted legislation regarding GM crops.[117] Also, local governments that receive their authority through enabling legislation are restricted to regulating areas specified within that legislation, which often does not include biotechnology regulation.[118]

The impact of preemption in the GM space has been to dampen local democratic activity, privilege private corporations, and privatize control over the lived environment.[119] However, the difficulty of containing GM crops within state lines, and the fact that GM crops are part of a national and international market, will continue to render state regulation impractical unless the role of states in this regulatory framework is clarified at the federal level.[120]

C. Limitations of the Coordinated Framework

Since its creation, the Coordinated Framework has struggled to deliver on its promise of a regulatory process that "adequately considers health and environmental safety consequences of the products and processes of the new biotechnology as they move from the research laboratory to the marketplace."[121] The Framework has permitted a large GM crop market to develop in the United States, but it is widely considered unable to keep pace with innovation.[122]

The early years of the Framework were marked by controversies reflecting a lack of coordination between the agencies.[123] It has since been heavily criticized

115. 7 U.S.C. § 7756.

116. Hawai'i Papaya Indus. Ass'n v. Cnty. of Haw., 666 F. App'x. 631, 633 (9th Cir. 2016); Atay v. Cnty. of Maui, 842 F.3d 688, 701–02 (9th Cir. 2016).

117. Barnett-Rose, *supra* note 98, at 95.

118. *See id.* at 95–96.

119. *See id.* at 122, 127. For example, in 2013-2014, three local counties in Hawaii attempted to restrict the growth of GMOs, including disclosure requirements, buffer zones, additional safety testing, and field-testing restrictions. *Id.* at 72. All three were struck down based on federal and state preemption. *Id.* at 73.

120. *See Atay*, 842 F.3d at 701–02.

121. *See* Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50856, 50857 (Dec. 31, 1984).

122. Rohit Sinha, Note, *A Crispr Framework for Emerging Biotechnology Applications: A Proposal to Separate Science from Politics*, 18 J. HEALTH & BIOMED. L. 142, 159–60 (2022).

123. *See* Stepp, *supra* note 63, at 59–63 (discussing a series of controversies in the early years of the Coordinated Framework).

on many fronts, and numerous commentators have called for it to be replaced.[124] Many legal articles written on the Framework "agree[] it is confusing, unacceptably slow, and inadequate to address future technologies."[125] A 2017 National Academies of Sciences, Engineering, and Medicine report, *Preparing for Future Products of Biotechnology*, describes that, "This complexity can cause uncertainty and a lack of predictability for developers of future biotechnology products and creates the potential for loss of public confidence in oversight of future biotechnology products."[126]

First and foremost, the Framework creates overlapping responsibilities and gaping loopholes. The lack of a single statute and lead agency has been described as incoherent, piecemeal, and haphazard.[127] Certain genetic engineering methods blur the lines of existing regulatory scopes or are regulated in duplicative and inefficient ways. Even plants with a single GE trait fall under the purview of multiple agencies.[128] For example, plants with pest-resistant traits are subject to APHIS regulation for importation, interstate movement, and field testing, while the EPA regulates the pesticidal substance.[129] Finally, new techniques such as gene

124. *See, e.g.*, Strauss, *The Role of Courts*, *supra* note 25, at 272 ("The existing framework of power sharing between the USDA, EPA, and FDA yields an incomplete regulatory scheme."); Lee-Muramoto, *supra* note 25, at 3; Hosmer, *supra* note 25, at 649; Jaffe, *supra* note 25, at 19.

125. Sarah Luther, *From Un-Coordinated to Efficient: A Proposal for Regulating GE Products in a Way That Meets the Needs of Consumers, Producers, and Innovators*, 20 VT. J. ENV'T L. 32, 46 (2019); *see, e.g.*, Michael P. McEvilly, Note, *Lack of Transparency in the Premarket Approval Process for Aquadvantage Salmon*, 11 DUKE L. & TECH. REV. 413, 415–16 (2012); Michael Bennett Homer, Note, *Frankenfish . . . It's What's for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology*, 45 COLUM. J.L. & SOC. PROBS. 83, 101 (2011); Lars Noah, *Whatever Happened to the "Frankenfish"?: The FDA's Foot-Dragging on Transgenic Salmon*, 65 ME. L. REV. 605, 606 (2013); Lee-Muramoto, *supra* note 25, at 313–14; Dorothy W. Bisbee, Note, *Preparing for a Blue Revolution: Regulating the Environmental Release of Transgenic Fish*, 12 VA. ENV'T L.J. 625, 656 (1993); Holly Beth Frompovicz, Comment, *A Growing Controversy: Genetic Engineering in Agriculture*, 17 VILL. ENV'T L.J. 265, 277–78 (2006); Jaffe, *supra* note 25, at 20.

126. NAT'L ACADS. OF SCIS., ENG'G, & MED., PREPARING FOR FUTURE PRODUCTS OF BIOTECHNOLOGY 6 (2017).

127. *See* John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 823 (2001).

128. U.S. FOOD & DRUG ADMIN., HOW GMOS ARE REGULATED IN THE UNITED STATES (2022), https://www.fda.gov/media/135278/download [https://perma.cc/QS23-DLWB].

129. *See* BICKELL, GENE-EDITED PLANTS, *supra* note 41, at 4–5.

drives[130] are causing regulatory consternation, with the National Academies of Sciences, Engineering, and Medicine concluding that they could fall under the purview of all three agencies in the Framework.[131]

Additionally, some new genetic engineering methods lie outside the jurisdiction of any specific agency.[132] Some methods do not align with agency definitions and standards despite clearly belonging to an agency's domain, presenting issues that exceed the regulatory capabilities of those agencies.[133] For example, the EPA characterizes "genetically engineered" organisms as those that have received DNA from a different taxonomic genus.[134] However, advancements in genomic knowledge and genetic engineering technologies allow for significant alterations within an organism through the "deletion, duplication, or even rearrangement of genetic sequences within a given species or genus."[135] These modifications currently exist in a regulatory void.[136]

Additionally, the EPA describes "genetically engineered" as an organism created by the intentional transfer of DNA.[137] Yet, the technique of directed evolution, made possible through novel DNA sequencing technologies, leads to changes that do not meet that definition and thus also reside in a regulatory loophole.[138]

Meanwhile, the SECURE rule brought many GM crops out of APHIS oversight.[139] This was criticized for lacking a basis in scientific risk assessment.[140] The rule operated as though a change in one DNA base pair, or a deletion of any size that could occur through conventional breeding, is safe simply because it could

130. "Gene drives are being developed to suppress invasive species and control vector borne diseases by driving genetic alternations through wild populations of sexually reproducing plants and animals." KENNETH OYE ET AL., MASS. INST. OF TECH., ON REVISION OF THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 2 (2016), https://poet.mit.edu/sites/default/files/images/ON%20REVISIONOFCF2016-03-22-FINAL.pdf [https://perma.cc/5JLU-C5J5].

131. NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES ON THE HORIZON 155 (2016).

132. *See* OYE ET AL., *supra* note 130, at 2.

133. *Id.*

134. *Id.* at 5.

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.*

139. *See* BICKELL, USDA'S SECURE RULE, *supra* note 100, at 1.

140. *See* Gould et al., *supra* note 62, at 1051.

be achieved through traditional plant breeding.[141] Yet, for example, a small change could prevent the production of an enzyme that catalyzes a crucial step in a metabolic pathway.[142] This could result in a desired new trait but also an unintended metabolic impact with potentially harmful consequences.[143] The flawed assumption that mutations that can be achieved through conventional breeding are low risk is partly why a judge recently vacated the rule.[144]

While the SECURE rule is no longer in force, it was emblematic of APHIS's new approach to risk assessment.[145] Despite the risk of unintended consequences from modifications, developers were not required to perform comprehensive sequencing if the intended modifications fell into one of the SECURE rule's exceptions.[146] The detection of such unintended alterations could necessitate regulatory oversight of the product. Yet, the SECURE rule left the job of identifying unintended modifications to the developers.[147]

Meanwhile, the FDA's review process "is not mandatory, and when it is completed, the FDA does not state its opinion about the safety of foods and ingredients made from the GE crop in question."[148] The process instead centers on a safety assessment and data review done in consultation with the developer.[149] The final documentation of this review focuses only on whether any unresolved safety or regulatory questions exist and "reminds the developer that they remain legally obligated to ensure the safety of the food products they bring to market."[150] With this process, the FDA has been criticized for a general lack of expertise in dealing with agricultural, ecological, and environmental concerns, while

141. *See* BICKELL, USDA'S SECURE RULE, *supra* note 100, at 1.

142. *See* Leslie A. Pray, *DNA Replication and Causes of Mutation*, NATURE EDUC. (2008), https://www.nature.com/scitable/topicpage/dna-replication-and-causes-of-mutation-409/ [https://perma.cc/67LK-2RAV]; Eugenia M.A. Enfissi et al., *New Plant Breeding Techniques and Their Regulatory Implications: An Opportunity to Advance Metabolomics Approaches*, J. PLANT PHYSIOLOGY, Mar.–Apr. 2021, at 1, 3.

143. *See* Pray, *supra* note 142.

144. Nat'l Fam. Farm Coal. v. Vilsack, No. 21-cv-05695, 2024 WL 4951257, at *12 (N.D. Cal Dec. 2, 2024).

145. *Id.* at *15.

146. *See* BICKELL, USDA'S SECURE RULE, *supra* note 100, at 1–2.

147. *Id.* at 1.

148. Jaffe, *supra* note 25, at 20.

149. *Id.*

150. *Programs on Food from New Plant Varieties*, *supra* note 79.

simultaneously eschewing its duty to develop robust regulations by providing a voluntary, instead of mandatory, consultation option.[151]

Neither the EPA nor APHIS address conflicts arising from the coexistence of GE and non-GE crops throughout the regulatory approval process.[152] Additionally, "APHIS has taken the position that it lacks the legal authority to require post-market conditions or monitoring," including monitoring for resistance or other unexpected effects.[153] The overlapping but incomplete jurisdiction of the agencies means that proponents of new GM crops are forced to navigate a confusing maze of agencies and statutes described as a "bureaucratic maze" and "alphabet soup" of initiatives.[154]

The APHIS process, and the Coordinated Framework more generally, are also notoriously un-participatory and opaque. There is no public involvement in allocating permits, and petitions for deregulated status are restricted to a narrow comment period.[155] Opportunities for public engagement in the agency decision-making process are limited, and much of the information submitted in support of approval remains protected as confidential business information.[156] This lack of public access to health and safety data creates distrust within some stakeholder groups.[157] The Framework also lacks robust statutory authority, which limits regulators' ability to consider and balance various factors when making permitting decisions.[158]

Unsurprisingly, it is difficult for the agencies to accurately discern congressional intent when regulating products that did not exist when their authorizing statutes were written.[159] A 2017 National Academies of Sciences,

151. Saby Ghoshray, *Food Safety and Security in the Monsanto Era: Peering Through the Lens of a Rights Paradigm Against an Onslaught of Corporate Domination*, 65 ME. L. REV. 491, 497 (2013).

152. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 474.

153. *Id.* at 507.

154. Henry I. Miller & John J. Cohrssen, *A Biotech Bureaucratic Bonanza*, CITY J. (Oct. 13, 2022), https://www.city-journal.org/article/a-biotech-bureaucratic-bonanza [https://perma.cc/X529-WGE3]; Ghoshray, *supra* note 151, at 498; Kunich, *supra* note 127, at 823.

155. Maywa Montenegro de Wit, *Democratizing CRISPR? Stories, Practices, and Politics of Science and Governance on the Agricultural Gene Editing Frontier*, ELEMENTA SCI. ANTHROPOCENE, Feb. 25, 2020, at 1, 18 [hereinafter Montenegro de Wit, *Democratizing CRISPR?*].

156. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 505.

157. *Id.*

158. *Id.* at 467, 471, 473.

159. Emmert, *supra* note 25, at 550.

Engineering, and Medicine study concluded that the FDA, USDA, and EPA lack the expertise and resources to effectively address the rise in biotechnology products.[160] Again, this is no surprise considering that the three agencies are attempting to fit new, evolving, and sophisticated issues into old statutes that were not written with biotechnology in mind.[161]

Because of this lack of statutory guidance, approval decisions generally do not address socioeconomic effects.[162] Biotechnology regulation under the Framework has primarily been viewed as a technical process.[163] The system is not designed to distinguish between genetic engineering that addresses societal needs versus that which is cosmetic, duplicative, or raises the prospect of harmful impacts beyond the scope of the reviewing agency's jurisdiction.[164] The result is minimal consideration of ecological impacts and the respective social utility of a product.[165]

The National Environmental Policy Act (NEPA) requires agencies to assess their decisions' "ecological . . . aesthetic, historic, cultural, economic, social, or health" effects.[166] However, NEPA does not provide legal authority to make or alter decisions based on those factors.[167] Therefore, even if APHIS conducts an environmental assessment when deregulating a crop, "it legally is required to deregulate [it] if it is not a [plant-pest], regardless of the outcome of the NEPA analysis."[168]

This culminates in a striking "lack of 'independent, accurate, and credible risk assessment' prior to GM crop approval."[169] Patent holders can use licensing restrictions to prevent access to their food products for independent safety testing.[170] Meanwhile, manufacturers are not required to submit independent safety

160. PREPARING FOR FUTURE PRODUCTS OF BIOTECHNOLOGY, *supra* note 126, at 133.

161. Ghoshray, *supra* note 151, at 498.

162. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 493.

163. *See* Jonas J. Monast, *Editing Nature: Reconceptualizing Biotechnology Governance*, 59 B.C. L. REV. 2377, 2411 (2018).

164. *Id.*

165. *Id.* at 2402, 2411.

166. 40 C.F.R. §§ 1500.3, 1508.1(i)(4) (2024).

167. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 473; 42 C.F.R. § 137.287 (2024) (describing NEPA as "a procedural law" that requires federal agencies to merely review and document the environmental impact of their actions).

168. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 473.

169. Scott, *supra* note 66, at 166.

170. Jeanette M. Roorda, Note, *Patents, Hidden Novelty, and Food Safety*, 68 FLA. L. REV. 657, 662 (2016).

studies as part of their permitting review and FDA consultations.[171] This fact appears to have benefitted crop developers, as evidenced by the fact that from 1992 to 2018, "the agency approved 130 of the 162 petitions for deregulation," and "[t]he other 32 were voluntarily withdrawn."[172]

Finally, although, in theory, the Framework is intended to be a process-agnostic approach to regulation, APHIS and the EPA both consider the development process when deciding which plants to regulate.[173] For example, consider the EPA system for regulating PIPs.[174] On the surface, it appears as if the EPA is regulating crops based on their pesticidal properties.[175] In practice, regulation is triggered by whether those pesticidal qualities were created or enhanced through a transgenic process, while crops produced through conventional breeding are exempt from this oversight.[176]

Similarly, the SECURE rule exempted specific categories of GM plants from regulation where they could have otherwise been developed through conventional breeding.[177] The regulation permitted specific gene-edited products to bypass regulatory scrutiny entirely and go to market without undergoing health and safety evaluations.[178] This focus on the modification method rather than the end product limited the publicly available information about many GM plants.[179]

IV. Agroecology: A Lens for Re-Envisioning GM Crop Regulation

Numerous challenges currently plague the United States' agricultural system and are poised to increase as climate change impacts weather patterns and threatens food security across the globe.[180] Current American agricultural practices are

171. *Id.* at 680–81.

172. Montenegro de Wit, *Democratizing CRISPR?*, *supra* note 155, at 18.

173. Genetically Engineered Crops, *supra* note 10, at 492.

174. John A. Erwin & Robert Glennon, *Feeding the World: How Changes in Biotech Regulation Can Jump-Start the Second Green Revolution and Diversify the Agricultural Industry*, 44 William & Mary Env't L. & Pol'y R. 327, 358 (2020).

175. *Id.*

176. *Id.*

177. Bickell, USDA's SECURE Rule, *supra* note 100, at 1.

178. *See id.*

179. *See* Doria R. Gordon et al., *Responsible Governance of Gene Editing in Agriculture and the Environment*, 39 Nat. Biotech. 1055, 1056–57 (2021).

180. *See* Tom Philpott, *Unless We Change Course, the US Agricultural System Could Collapse*, The Guardian (Aug. 26, 2020), https://www.theguardian.com/commentisfree/2020/aug/26/us-farming-agriculture-food-supply-danger [https://perma.cc/EK68-P4AR].

widely believed to be unsustainable and a significant driver of climate change.[181] Industrial monoculture farming contributes to biodiversity loss,[182] air and water pollution,[183] soil erosion,[184] soil nutrient depletion,[185] the degradation of vital ecological processes, and more.[186] Meanwhile, animal husbandry, fertilizer use, fuel combustion, deforestation, farm waste management, and soil carbon disruption release greenhouse gases into the atmosphere.[187]

In turn, climate change poses a significant threat to our food systems. A 2021 report by the United Nations Food and Agriculture Organization (FAO) found that high levels of pollution and greenhouse gas emissions are severely degrading land and environmental services.[188] Other stressors like extreme weather and desertification will negatively impact farm yields and crop health.[189] Changes in rainfall patterns are expected to lead to decreased land suitability and increased water run-off, soil erosion, biodiversity loss, and crop damage.[190] These harms,

181. *Id.*; *How Does Agriculture Contribute to Climate Change?*, WORLD FUTURE COUNCIL (Oct. 21, 2012), https://www.worldfuturecouncil.org/how-does-agriculture-contribute-to-climate-change/ [https://perma.cc/R2TA-2FFT].

182. Douglas A. Landis et al., *Increasing Corn for Biofuel Production Reduces Biocontrol Services in Agricultural Landscapes*, 105 PNAS 20552, 20552 (2008).

183. *See Nonpoint Source: Agriculture*, U.S. ENV'T PROT. AGENCY (Dec. 20, 2023), https://www.epa.gov/nps/nonpoint-source-agriculture#Q2 [https://perma.cc/E4RE-RVDT].

184. David R. Montgomery, *Soil Erosion and Agricultural Sustainability*, 104 PNAS 13268, 13268 (2007).

185. W. S. Jang et al., *The Hidden Costs of Land Degradation in US Maize Agriculture*, EARTH'S FUTURE, Feb. 2021, at 1, 10.

186. Leo Horrigan et al., *How Sustainable Agriculture Can Address the Environmental and Human Health Harms of Industrial Agriculture*, 110 ENV'T HEALTH PERSP. 445, 445 (2002).

187. Emily Joiner & Michael A. Toman, *Agricultural Greenhouse Gas Emissions 101*, RES. FOR THE FUTURE (Sept. 8, 2023), https://www.rff.org/publications/explainers/agricultural-greenhouse-gas-emissions-101/ [https://perma.cc/M9RU-6KJC]; Pete Smith et al., *Agriculture, Forestry and Other Land Use (AFOLU)*, *in* CLIMATE CHANGE 2014: MITIGATION OF CLIMATE CHANGE 811, 818 (Ottmar Edenhofer et al. eds., 2014).

188. THE STATE OF FOOD AND AGRICULTURE 2021, *supra* note 15, at 5.

189. *See id.* at 12.

190. *See* Prasanna Gowda et al., *Agriculture and Rural Communities*, *in* U.S. GLOB. CHANGE RSCH. PROGRAM, FOURTH NATIONAL CLIMATE ASSESSMENT, VOLUME II: IMPACTS, RISKS, AND ADAPTATION IN THE UNITED STATES 391, 393, 399 (2018).

among others, will create the risk of food insecurity[191] and place severe economic strain on farmers.[192]

Agroecology has been put forth as an approach that could reverse the harms of industrial monoculture farming and lessen the climate impacts of agriculture.[193] The FAO defines agroecology as a holistic and integrated approach to designing and managing sustainable agriculture and food systems.[194] This approach promotes biodiversity, nutrient cycling, soil regeneration, and water conservation, often incorporating traditional and local knowledge to create more sustainable and equitable food systems.[195] It involves diversified farming systems that foster complex species interactions to enhance biodiversity and support beneficial ecosystem services (e.g., nutrient cycling and weed, disease, and pest management) without synthetic inputs.[196] Practices include multispecies crop rotation, cover cropping, no-till farming, agroforestry, integrated livestock and crop production, and organic fertilizer and compost usage.[197]

Integrating agroecological practices is highly farm-specific, and system-wide adoption would require cross-sector interventions, including research, education, information sharing, institutional support, and public and private

191. *See* Tim Wheeler & Joachim Von Braun, *Climate Change Impacts on Global Food Security*, 341 SCIENCE 508, 508 (2013).

192. *See, e.g.*, *The Economic Impact of Climate Change on Northwest Farms*, CLIMATE HUBS, U.S. DEP'T OF AGRIC. (Oct. 26, 2024, 1:52 PM), https://www.climatehubs.usda.gov/hubs/northwest/topic/economic-impact-climate-change-northwest-farms [https://perma.cc/Y5L5-S7AW]; LIDA R. WEINSTOCK, CONG. RSCH. SERV., R47063, HOW CLIMATE CHANGE MAY AFFECT THE U.S. ECONOMY 10 (2022).

193. *See* Colin Anderson et al., *Agroecology – A Promising Alternative to the Biodiversity Crisis in Agriculture and Industrial Food Systems*, RESILIENCE (Jan. 10, 2023), https://www.resilience.org/stories/2023-01-10/agroecology-a-promising-alternative-to-the-biodiversity-crisis-in-agriculture-and-industrial-food-systems/ [https://perma.cc/L6FW-TUW5]; Shefali Sharma & Karen Hansen-Kuhn, *Agroecology: Key to Agricultural Resilience and Ecosystem Recovery*, INST. FOR AGRIC. & TRADE POL'Y (Jun. 16, 2019), https://www.iatp.org/agroecology-key-agricultural-resilience-and-ecosystem-recovery [https://perma.cc/XT37-WFFH]; Raj Patel, *Agroecology Is the Solution to World Hunger*, SCI. AM. (Sept. 22, 2021), https://www.scientificamerican.com/article/agroecology-is-the-solution-to-world-hunger/.

194. *Agroecology Knowledge Hub*, *supra* note 18.

195. Claire Kremen et al., *Diversified Farming Systems: An Agroecological, Systems-Based Alternative to Modern Industrial Agriculture*, ECOLOGY & SOC'Y, Dec. 2012, at 1, 1–2.

196. *Id.*

197. Alexander Wezel et al., *Agroecological Practices for Sustainable Agriculture. A Review*, 34 AGRONOMY FOR SUSTAINABLE DEV. 1, 4–6 (2014) (thoroughly explaining a variety of agroecological practices).

investments.[198] Yet, studies have repeatedly shown that integrated agroecological practices can match industrial monoculture yields while creating co-benefits and reducing externalities.[199] These co-benefits include increased soil sequestration, improved soil health, and heightened resistance to pests, diseases, droughts, and floods.[200]

There are growing calls for adopting agroecological practices[201] and GM crops as tools to mitigate and adapt to climate change,[202] respectively. Yet, biotechnology and agroecology are often considered in opposition, and their respective proponents are frequently in conflict.[203] Agroecology challenges industrial technology by promoting principles that enhance biological interactions, recycle ecosystem services, and prioritize knowledge-intensive practices, reducing

198. *See* Thomas C. Wanger, *Integrating Agroecological Production in a Robust Post-2020 Global Biodiversity Framework*, 4 NATURE ECOLOGY & EVOLUTION 1150, 1151 (2020).

199. *See, e.g.*, Adam S. Davis, *Increasing Cropping System Diversity Balances Productivity*, *Profitability and Environmental Health*, PLOS ONE, Oct. 2012, at 1, 1–2 (explaining that diverse crop rotation systems in the United States Corn Belt have been shown to produce 4–9% higher yields while significantly reducing fertilizer, herbicide, and fossil fuel use); Colin Skinner et al., *Greenhouse Gas Fluxes from Agricultural Soils Under Organic and Non-Organic Management—A Global Meta-Analysis*, 468–69 SCI. TOTAL ENV'T 553, 561 (2014); Lauren C. Ponisio et al., *Diversification Practices Reduce Organic to Conventional Yield Gap*, PROC. ROYAL SOC'Y B: BIOLOGICAL SCI., Jan. 2015, at 1, 4; RODALE INST., FARMING SYSTEMS TRIAL 40-YEAR REPORT 18 (2022), https://rodaleinstitute.org/wp-content/uploads/FST_40YearReport_RodaleInstitute-1.pdf [https://perma.cc/KQ7D-T6U4].

200. RODALE INST., *supra* note 199, at 7, 12.

201. *See, e.g.*, Miguel A. Altieri et al., *Agroecology and the Design of Climate Change-Resilient Farming Systems*, 35 AGRONOMY FOR SUSTAINABLE DEV. 869 (2015); Kyle M. Dittmer et al., *Agroecology Can Promote Climate Change Adaptation Outcomes Without Compromising Yield in Smallholder Systems*, 72 ENV'T MGMT. 333 (2023); *Agroecology Case Studies*, OAKLAND INST. (Oct. 26, 2024, 12:36 PM), https://www.oaklandinstitute.org/agroecology-case-studies [https://perma.cc/PCW3-S5NR].

202. *See, e.g.*, Mughair Abdul Aziz et al., *Genetically Engineered Crops for Sustainably Enhanced Food Production Systems*, FRONTIERS PLANT SCI., Nov. 8, 2022, at 1; Shahbaz Khan et al., *Development of Drought-Tolerant Transgenic Wheat: Achievements and Limitations*, INT'L J. MOLECULAR SCI., July 8, 2019, at 1; Angelika Mustroph, *Improving Flooding Tolerance of Crop Plants*, AGRONOMY, Sept. 2018, at 1; Joanna K. Sax, *Genetically Engineered Food, Food Security, and Climate Change*, 6 BUS. ENTREPRENEURSHIP & TAX L. Rev. 1 (2022).

203. *See, e.g.*, Bonny, *supra* note 21, at 28; Gliessman, *supra* note 19, at 19; Maywa Montenegro de Wit, *Can Agroecology and CRISPR Mix? The Politics of Complementarity and Moving Toward Technology Sovereignty*, 38 AGRIC. & HUM. VALUES 733, 735 (2021) [hereinafter Montenegro de Wit, *Can Agroecology and CRISPR Mix?*]; Eric Holt-Giménez & Miguel A. Altieri, *Agroecology, Food Sovereignty and the New Green Revolution*, 37 J. SUSTAIN. AGRIC. 90 (2013).

reliance on external farm inputs.[204] Advocates of agroecology emphasize the conservation of resources and the implementation of eco-efficient and integrated farming systems with few artificial inputs.[205] Meanwhile, agricultural input industries, including the agrochemical and seed industries, consider industrial agriculture the best way to use inputs, manage costs, and maximize productivity efficiently.[206] Agricultural technologies have often been developed to enhance measures such as yield and profit, which has exacerbated the negative externalities that agroecology seeks to address.[207]

Genetic modification can be seen as a "continuation of the trend" towards the industrialization of agriculture,[208] suggesting that genetic engineering is incompatible with agroecological principles.[209] The current selection of transgenic crops on the market is perceived as supporting a system predisposed to industrialized, large-scale cultivations, which creates more dependency on chemical inputs.[210]

However, this perception is not a consequence of the process of genetic engineering itself, but of how these GM varieties have been designed and governed.[211] For example, several GM crops have been designed to permit the increased use of a single pesticide or herbicide by making crops resistant to that chemical, allowing for more effective weed or pest control.[212] But continued, excess use of a single pesticide or herbicide can precipitate the development of

204. Montenegro de Wit, *Can Agroecology and CRISPR Mix?*, *supra* note 203, at 735.

205. *Id.* at 734–35.

206. Bonny, *supra* note 21, at 28, 29.

207. *See* Summer Sullivan, *Ag-Tech, Agroecology, and the Politics of Alternative Farming Futures: The Challenges of Bringing Together Diverse Agricultural Epistemologies*, 40 AGRIC. & HUM. VALUES 913, 913–14 (2023) [hereinafter Sullivan, *Ag-Tech*].

208. Paul C. Struik, *Response to Lotz et al.: Genetically Modified Crops and Sustainable Agriculture: A Proposed Way Forward in the Societal Debate*, 70–71 NJAS: WAGENINGEN J. LIFE SCI. 101, 102 (2014).

209. Lambertus A.P. Lotz et al., *Genetic Engineering at the Heart of Agroecology*, 49 OUTLOOK ON AGRIC. 21, 23, 26 (2020) [hereinafter Lotz et al., *Genetic Engineering*].

210. *Id.* at 24.

211. *Id.*

212. Graham Brookes, *Genetically Modified (GM) Crop Use 1996–2020: Environmental Impacts Associated with Pesticide Use Change*, 13 GM CROPS & FOOD 262, 270 (2022); JORGE FERNANDEZ-CORNEJO ET AL., ECON. RSCH. SERV., U.S. DEP'T OF AGRIC., GENETICALLY ENGINEERED CROPS IN THE UNITED STATES iv (2014), https://ers.usda.gov/sites/default/files/_laserfiche/publications/45179/43668_err162.pdf?v=99345 [https://perma.cc/JBW2-CXHW].

pesticide-resistant insects and herbicide-resistant "superweeds."[213] The increase in resistant weeds "has created a chemical arms race in which farmers must use more toxic combinations of herbicides to control the weed population."[214]

Meanwhile, on the governance side, intellectual property (IP) protections granted to GM crops have significantly strengthened the market power of seed conglomerates.[215] The resulting market consolidation has prohibited independent scientific scrutiny of GM crop safety by allowing a few companies to stifle nearly all research through restrictive user agreements.[216] It has also led to a decrease in farmers' market power and the creation of debt cycles.[217] Effective governance can address GM crop design and market power issues. It will thus play a vital role if the United States attempts to promote agroecology and GM crops as synergistic elements in transforming our food systems.

Scholars investigating the intersection of agroecology and genetic engineering have argued that biotechnologies must be designed for sustainable use, "linked with good agricultural, economic, environmental, and socio-political practices," and be accessible and affordable.[218] Deploying GM crops consistent with agroecological principles would involve integrating GM technology in ways

---

213. Scott, *supra* note 66, at 149–150; Brookes, *supra* note 212, at 270, 275; FERNANDEZ-CORNEJO ET AL., *supra* note 212, at iv.

214. Scott, *supra* note 66, at 150.

215. *See* discussion *infra* Section V.B.4.; *see also* Justin Brickey, *A Delicate Balance: Limiting Consolidation in Agricultural Seed Markets Without Stifling Innovation*, 4 BUS. ENTREPRENEURSHIP & TAX L. REV. 289, 298–99 (2020).

216. Sci. Am., *Do Seed Companies Control GM Crop Research?*, THE CORNUCOPIA INST. (Sept. 9, 2013), https://www.cornucopia.org/2013/09/seed-companies-control-gm-crop-research/ [https://perma.cc/364F-YAFG]; Bruce Stutz, *Companies Put Restrictions on Research into GM Crops*, YALEENV'T360 (May 13, 2010), https://e360.yale.edu/features/companies_put_restrictions_on_research_into_gm_crops [https://perma.cc/D9EK-FYLE].

217. Keith Fuglie & James M. MacDonald, *Expanded Intellectual Property Protections for Crop Seeds Increase Innovation and Market Power for Companies*, ECON. RSCH. SERV., U.S. DEP'T OF AGRIC.: AMBER WAVES (Aug. 28, 2023), https://www.ers.usda.gov/amber-waves/2023/august/expanded-intellectual-property-protections-for-crop-seeds-increase-innovation-and-market-power-for-companies/ [https://perma.cc/92WJ-95S2]. These impacts have been particularly severe in parts of the developing world. *'Bitter Seeds' Documentary Reveals Tragic Toll of GMOs in India*, IUCN (Aug. 15, 2012), https://www.iucn.org/content/bitter-seeds-documentary-reveals-tragic-toll-gmos-india [https://perma.cc/3ZG4-3MJQ]. In India, rates of suicide among farmers have skyrocketed. *Id.* This has been attributed to the debt cycles created when farmers employ GM crops, only to realize that those seeds require a prohibitively expensive regimen of pesticides that is difficult to administer without irrigation systems. *Id.*

218. Bonny, *supra* note 21, at 29.

that enhance biodiversity, improve soil health, reduce synthetic inputs, support more diversified farming, and allow for meaningful stakeholder engagement, transparency, and accountability.[219] For example, drought-resistant GM crops could be integrated into systems where water conservation is a priority, or insect-resistant GM crops could reduce the need for chemical pesticides, thereby promoting biodiversity.

GM crops designed within an agroecological frame must utilize fewer chemical inputs, such as pesticides and fertilizers.[220] They must also be designed to enhance nutrient use efficiency, resist pests and diseases through natural mechanisms, or be compatible with crop rotation, intercropping, and other traditional agroecological practices.[221] Additionally, agroecology demands a new emphasis on economic diversification and horizontal knowledge sharing between and among farmers and scientists.[222] This requires redistributing power within the food system and creating intentional independent research and knowledge-sharing infrastructures.[223]

Numerous successful attempts have been made to deploy climate-smart GM crops in a manner compatible with agroecological principles. For example, a Hawaiian scientist transgenically modified the Hawaiian Rainbow Papaya and saved the fruit from impending extinction by a ringspot virus.[224] Meanwhile, the International Rice Research Institute in the Philippines is the largest rice gene bank in the world and safeguards over 100,000 varieties of rice.[225] As flooding in the region worsened due to changing climate patterns, the Institute developed rice that could handle more than two weeks of flooding with almost no yield loss.[226] Similarly, another rice variety developed called SUSIBA2 contains a gene from the barley plant that reduces the crop's methane emissions by 10% without impacting yields.[227]

---

219. *Id.* at 28–29.

220. *See id.* at 29.

221. *See id.* at 29–30.

222. Sarah K. Jones et al., *Research Strategies to Catalyze Agroecological Transitions in Low- and Middle-Income Countries*, 17 SUSTAINABILITY SCI. 2557, 2570 (2022).

223. *See id.* at 2570–73.

224. Teferra, *supra* note 28, at 5326.

225. *International Rice Genebank*, INT'L RICE RSCH. INST. (Dec. 5, 2024, 10:59 AM), https://www.irri.org/international-rice-genebank [https://perma.cc/SLS2-VUQT].

226. *Scuba Rice: Stemming the Tide in Flood-Prone South Asia*, RICE TODAY (Apr. 14, 2009), https://ricetoday.irri.org/scuba-rice/ [https://perma.cc/24RW-ASH8].

227. J. Su et al., *Expression of Barley SUSIBA2 Transcription Factor Yields High-Starch Low-Methane Rice*, 523 NATURE 602, 602 (2015).

Several recent advances provide a further glimpse into what agroecology-aligned GM crops could look like. CRISPR technology has improved crop stress tolerance, disease resistance, and nutrient uptake.[228] Living Carbon is developing plants with increased soil carbon uptake to restore ecosystems, enhance biodiversity, and store carbon from the atmosphere.[229] Other active areas of research and development include:

- Crops that more efficiently use nitrogen.[230]
- Rice with enhanced expression of a hormone that promotes stem elongation, allowing it to survive deep water conditions due to flooding.[231]
- Rice with fewer stomata (the small openings used for gas exchange), which can reduce plant water usage by 60%.[232]
- Introducing the drought-resistant gene found in upland rice into higher quality lowland rice to merge the desirable traits of both crops.[233]
- Optimizing photosynthesis to make plants more water efficient or less carbon dioxide intensive.[234]

228. For example, the CRISPR-Cas system was used to engineer *Solanum lycopersicum* and *Nicotiana benthamiana* plants to develop resistance against tomato yellow leaf curl virus. Manal Tashkandi et al., *Engineering Resistance Against Tomato Yellow Leaf Curl Virus Via the CRISPR/Cas9 System in Tomato*, PLANT SIGNALING & BEHAV., Oct. 5, 2018, at 1, 1.

229. *Living Carbon's Mission is to Responsibly Rebalance the Planet's Carbon Cycle Using the Power of Plants*, LIVING CARBON (Oct. 26, 2024, 1:20 PM), https://www.livingcarbon.com/about [https://perma.cc/H3RJ-AHVH].

230. Mengjiao Li et al., *Genetically Modified Crops Are Superior in Their Nitrogen Use Efficiency- A Meta-Analysis of Three Major Cereals*, SCI. REPS., May 22, 2020, at 1, 2.

231. Ramanujan, *supra* note 23.

232. Robert S. Caine et al., *Rice with Reduced Stomatal Density Conserves Water and Has Improved Drought Tolerance Under Future Climate Conditions*, 221 NEW PHYTOLOGIST 371, 371 (2018).

233. Jay Sullivan, *The Future of Eating: How Genetically Modified Food Will Withstand Climate Change*, NAT. HIST. MUSEUM (Apr. 22, 2021), https://www.nhm.ac.uk/discover/the-future-of-eating-gm-crops.html [https://perma.cc/ZE8Y-3V2E].

234. Mansoureh Nazari et al., *Enhancing Photosynthesis and Plant Productivity Through Genetic Modification*, CELLS, Aug. 2024, at 1, 10, 17.

- Engineering roots to be sturdier, more extensive, and deeper by using a molecule found in avocado and cantaloupe skins, such that the roots can better resist decomposition and minimize carbon escape from the soil.[235]
- Using genetic engineering to adjust the communication and interplay between roots and microbial communities, which helps to stabilize carbon in the soil.[236]
- Using GE plants to detoxify pollutants or absorb and accumulate pollutants from contaminated soil.[237]

As these examples show, GM crops can be designed to be compatible with the aims of agroecology, suggesting that the two are not in inherent conflict. There is increasing recognition in scientific literature that agroecology and genetic engineering can complement each other.[238] As the next Part discusses, using agroecology as a framework for designing a new system of biotechnology regulation offers a transformative opportunity to change how GM crops are regulated in a way that better aligns with changing norms in agriculture and food.

V. Regulating GM Crops for a Better Food System

As this Article has suggested, gene editing technology has the potential to significantly and positively contribute to making American agriculture more sustainable and climate resilient. Yet, the existing regulatory framework for biotechnology has largely been at odds with such aims. The Biden Administration has identified the need to use gene editing for sustainable agriculture, spurring additional calls to overhaul the Coordinated Framework.[239] The European Union (EU), which has historically let very few GM crops onto the market, is now

235. *Stopping Climate Change: A Moral Imperative*, SALK INST. FOR BIOLOGICAL STUD. (Oct. 26, 2024, 1:53 PM), https://www.salk.edu/science/power-of-plants/ [https://perma.cc/954C-Y7YN].

236. *Id.*

237. *See Biotechnology FAQs*, U.S. DEP'T OF AGRIC. (Oct. 26, 2024, 12:41 PM), https://www.usda.gov/topics/biotechnology/biotechnology-frequently-asked-questions-faqs [https://perma.cc/K97Q-DXWT].

238. Lotz et al., *Genetic Engineering*, *supra* note 209, at 26.

239. *See* Press Release, The White House, Fact Sheet: President Biden to Launch a Nat'l Biotech. & Biomfg. Initiative (Sept. 12, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/12/fact-sheet-president-biden-to-launch-a-national-biotechnology-and-biomanufacturing-initiative/ [https://perma.cc/GK3G-XUHN].

considering significant changes to its biotechnology regulation to help farmers contend with changing weather patterns due to climate change.[240]

The new EU proposal would exempt plants from regulation where the genetic modifications could, in theory, have occurred from natural mutation or conventional breeding.[241] The proposal would also introduce measures to incentivize plant products that "could contribute to a sustainable agri-food system."[242] EU officials emphasized that these exempted gene editing techniques are vital to maintaining crop yields as farmers contend with drought and floods and could also help reduce the use of chemical inputs.[243] These changes in the EU signal a recognition of the promise of gene editing technology and provide an opportunity for convergence of international standards towards using GM crops in agroecologically aligned ways.[244]

A. Public Interest Principles to Guide Reform

Any legislative intervention that uses agroecological practices to guide reform of the GM crop market must identify a new set of core principles that will govern GM crop regulation. These principles should reflect public interest priorities and support an environmentally and economically sustainable agricultural system. This Article identifies four such Public Interest Principles, developed through the lens of agroecology.

First, a robust regulatory framework for biosafety and risk assessments should be in place to ensure that GM crops do not pose risks to human health or the environment. The regulatory framework should balance profit measures, such as crop yields, with human and ecological health measures, including soil health, pollution from synthetic inputs, and biodiversity.[245] This framework should also facilitate the responsible commercialization of GM crops.[246] Regulators should

240. Andy Bounds, *EU Plans to Relax GMO Restrictions to Help Farmers Adapt to Climate Change*, FIN. TIMES (June 22, 2023), https://www.ft.com/content/5c799bc0-8196-466e-b969-4082e917dbe6.

241. *Id.*

242. *Id.*

243. *Id.*

244. To that end, the regulatory framework proposed here would also better align United States biotechnology governance with the United Nations Sustainable Development Goals, particularly as they relate to responsible consumption and production, life on land, and good health and well-being. *See The 17 Goals*, UNITED NATIONS DEP'T OF ECON. & SOC. AFFS. (Oct. 26, 2024, 1:50 PM), https://sdgs.un.org/goals [https://perma.cc/68CP-RABK].

245. Aziz et al., *supra* note 202, at 2.

246. *Id.*

ensure that GM crops are designed and managed to minimize potential negative impacts on the environment and maximize positive ecological interactions among different elements of agroecosystems like plants, animals, trees, soil, and water.[247] This includes preventing gene flow to non-GM crops and wild relatives, conserving soil health, and avoiding practices that lead to declining biodiversity.[248]

Second, GM crop regulation must fundamentally restructure the distribution of power between farming communities and corporations involved in the plant biotechnology space. This requires considering the socioeconomic context of the farming communities and ensuring that the adoption of GM crops does not lead to increased dependency on proprietary seeds or create barriers to seed saving and sharing, which are essential aspects of farming systems.[249]

Third, the framework must re-open the doors to independent research, engagement, and scrutiny of GM crops. Transparency in the development and deployment of GM crops, with the active engagement of all stakeholders, is necessary to build trust and ensure that the use of GM crops aligns with the values and needs of the communities where they are grown.[250]

Finally, the system must invest in education and research infrastructure that can support the role of GM crops in a broader transition to agroecological practices. Supporting public-sector biotechnology research can lead to the development of GM crops that address the specific needs of smallholder farmers and are not solely driven by commercial interests. This can help ensure that the benefits of GM crops are accessible to a broader range of farmers, including those in developing countries.[251]

B. Regulatory Policy Proposals

The remainder of this Article outlines a proposal for a new structure of federal and state biotechnology regulation aligned with the four above Public

247. *Principles of Agroecology*, A EUR. ASS'N FOR AGROECOLOGY (Oct. 26, 2024, 12:28 PM), https://www.agroecology-europe.org/our-approach/principles/ [https://perma.cc/KM2M-QZU7].

248. Aziz et al., *supra* note 202, at 7–8.

249. David A. Quist et al., *Hungry for Innovation: Pathways for GM Crops to Agroecology*, *in* EUR. ENV'T AGENCY, LATE LESSONS FROM EARLY WARNINGS: SCIENCE, PRECAUTION, INNOVATION 458, 464, 467 (2013).

250. *See* GENETICALLY ENGINEERED CROPS, *supra* note 10, at 504–05.

251. *See* Joshua R. Muhumuza, *Pitting Agroecology Against Biotechnology Is Fundamental Error*, ALL. FOR SCI. (June 3, 2022), https://allianceforscience.org/blog/2022/06/pitting-agroecology-against-biotechnology-is-fundamental-error/ [https://perma.cc/5M9N-FR3Z].

Interest Principles. It first identifies the high-level, necessary components of the system structure and then explores best practices to further each Principle.

Above all, the Coordinated Framework should be replaced by creating a centralized federal regulatory authority. The change could most effectively be accomplished through a comprehensive legislative package. The legislation should: 1) explicitly delegate authority to a single federal agency with statutory language framing the agency's authority within the Public Interest Principles; 2) adopt a process-agnostic approach to regulation; 3) reserve, rather than preempt, regulatory authority for the states; and 4) modify the intellectual property rights available for GM crops. This would have the effect of streamlining oversight, expanding the role of the states, and addressing the core failings of the existing framework. These four statutory modifications are the backbone for the structural reform proposed in this Article.

1. Delegate Authority to a Single Federal Agency

First and foremost, Congress should delegate primary regulatory authority over GM crops to the USDA and APHIS. The USDA should be granted rulemaking and adjudicatory authority, with the core responsibilities of assessing crop safety, issuing permits for field testing and commercialization, and making rules to further the Public Interest Principles.

Public commenters have repeatedly recommended creating a single entry point for GE products to identify and streamline the need for complex risk assessments.[252] Delegating authority to the USDA would create a single entry point into federal biotechnology regulation, which has the potential to focus the regulatory process.[253] The USDA's mandate should "require a mandatory, pre-market approval process that is transparent and allows for public participation."[254]

The USDA, through APHIS, is well suited for this task because it already exercises the most oversight over GM crops. First, the USDA oversees the initial introduction and field testing of GM crops.[255] In contrast, the FDA and EPA's roles

252. *See* EXEC. OFF. OF THE PRESIDENT, MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 54 (2017) [hereinafter MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS], https://www.epa.gov/sites/default/files/2017-01/documents/2017_coordinated_framework_update.pdf [https://perma.cc/6FP7-9C6G].

253. Erwin & Glennon, *supra* note 174, at 380–82.

254. *See* Jaffe, *supra* note 25, at 20.

255. BICKELL, AGRICULTURAL BIOTECHNOLOGY, *supra* note 27, at 24.

kick in later in the lifecycle, focusing on food safety and environmental impacts, respectively.[256] Second, the USDA manages a more extensive set of regulations directly related to GM crops than the FDA and EPA, which are more narrowly focused on food safety and environmental protection.[257] The USDA's regulations cover a broader range of activities, including import, interstate movement, and environmental release.[258] Finally, the USDA reviews significantly more applications related to GM crops than the FDA and EPA. In 2023 alone, APHIS issued 15 Regulatory Status Review decisions and 784 authorizations for field testing or movement of GM organisms across 45 states.[259] By contrast, the FDA completed 180 consultations as of 2020, 25 years into the consultation program.[260] Thus, it is likely that the USDA holds the most institutional knowledge on critical issues and has an existing bureaucracy geared toward reviewing crop-specific safety research and issuing permits.

If the USDA were given singular authority for permitting GM crops, an interagency advisory body or task force should be established to retain input from the EPA, FDA, and other agencies with relevant expertise. The task force should create opportunities for public input on policy and include expert stakeholder representatives.

This type of interagency body facilitates collaboration among regulators, provides a platform for stakeholders to provide input into regulatory policy, and ensures that existing policies offer comprehensive assessments of regulated products. It would also draw on the expertise of diverse members to develop best practices and standards for GM crop development, testing, and cultivation.[261] Finally, the task force would be well-positioned to engage in forward-thinking policy development by responding to new scientific findings or emerging issues

256. *Id.* at 26, 28.

257. *See id.* at 24.

258. *Id.*

259. ANIMAL & PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., KEEPING U.S. AGRICULTURE HEALTHY FOR AMERICA AND THE WORLD: 2023 IMPACT REPORT 15 (2023), https://www.aphis.usda.gov/sites/default/files/aphis-impact-report-2023.pdf [https://perma.cc/7XNN-SDTM].

260. *Understanding New Plant Varieties*, U.S. FOOD & DRUG ADMIN. (May 12, 2023), https://www.fda.gov/food/food-new-plant-varieties/understanding-new-plant-varieties [https://perma.cc/CEA2-ZZXP].

261. *See* Sinha, *supra* note 122, at 161–62 (calling for a safety commission, insulated from presidential oversight to address gaps in the Coordinated Framework).

related to GM crops. Legislators should look to the National Organic Standards Board, created by the Organic Foods Production Act, as a model.[262]

Such a body would require coordination between the agencies to capture the Coordinated Framework's original plan.[263] It would also build on the existing use of executive working groups that have been established to help coordinate the work of the Framework agencies.[264] Overall, this model could bring a balanced, informed, and transparent approach to federal biotechnology policy, aligning a broader range of interests and concerns.

Centralizing authority over GM crop regulation in a single agency would also increase transparency and clarity for all stakeholders. Under the Framework, data is siloed across its three agencies, which often work independently and share limited data online.[265] The lack of transparency in decision-making and the absence of a centralized data system leaves consumers and others struggling to piece together a complete picture of the product.[266] Thus, scholars have called for a shared database to centralize information reported by the three agencies.[267] Delegation of authority to a single agency would go even further to address the underlying fragmentation of the system and avoid further entrenchment in an incoherent regulatory scheme.

2. Adopt a Process-Agnostic Approach to Regulation

Second, the federal regulatory system should adopt a process-agnostic approach to regulating new GM plant varieties. This would return the United States to the original intent of the Framework.[268]

A process-based approach focuses on the method of genetic modification.[269] It typically subjects transgenic crops to higher levels of scrutiny while exempting

262. *See National Organic Standards Board (NOSB)*, AGRIC. MKTG. SERV., U.S. DEP'T OF AGRIC. (Oct. 26, 2024, 1:30 PM), https://www.ams.usda.gov/rules-regulations/organic/nosb [https://perma.cc/Y836-43A4].

263. Erwin & Glennon, *supra* note 174, at 381.

264. Carlene Dooley, *Regulatory Silos: Assessing the United States' Regulation of Biotechnology in the Age of Gene Drives*, 30 GEO. ENV'T. L. REV. 547, 560 (2018).

265. Furgurson et al., *supra* note 110, at 2.

266. *Id.*

267. *Id.*

268. Erwin & Glennon, *supra* note 174, at 378–79.

269. Giovanni Tagliabue, *Product, Not Process! Explaining a Basic Concept in Agricultural Biotechnologies and Food Safety*, LIFE SCIS. SOC'Y & POL'Y, Mar. 3, 2017, at 1, 4.

cisgenic GM crops from some or all regulatory oversight.[270] This is premised on the belief that cisgenic modifications, which are retroactively indistinguishable from those arising through evolution, should not be subject to additional scrutiny compared to spontaneous evolutionary mutations.[271] Gene editing techniques have received less scrutiny under this approach when gene editing does not require the use of recombinant DNA and when the products of gene editing could otherwise be produced through conventional breeding.[272]

Canada has adopted a process-agnostic approach, in which crops are regulated based on their novel traits and mutations, rather than by the type of genetic modification process that created them.[273] This is based on the conclusion that GM crops are not categorically different from their parent crops and that it is inappropriate to draw a differentiating line along the "continuous spectrum of minor differences" between a native plant and any altered varieties.[274] Thus, the focus is on ensuring that all novel plant varieties are safe for humans and the environment, regardless of how they are produced.[275] Biotechnology scientists worldwide support a process-agnostic approach[276] because of a long-standing understanding that the process of genetic modification is generally unrelated to

270. MATHESON ET AL., *supra* note 44, at 3.

271. Henk J. Schouten et al., *Cisgenic Plants are Similar to Traditionally Bred Plants*, 7 EMBO REPS. 750, 752 (2006).

272. BICKELL, GENE-EDITED PLANTS, *supra* note 41, at 11.

273. John Davison & Klaus Ammann, *New GMO Regulations for Old: Determining a New Future for EU Crop Biotechnology*, 8 GM CROPS & FOOD 13, 15–16 (2017). However, transgenic origin of the donor DNA is an important criterion. *Draft Guidance for Determining Whether a Plant is Subject to Part V of the Seeds Regulations*, CAN. FOOD INSPECTION AGENCY (Sept. 16, 2021), https://inspection.canada.ca/about-cfia/transparency/consultations-and-engagement/share-your-thoughts/draft-guidance/eng/1619540046303/1619540212691 [https://perma.cc/Z98H-M2U2].

274. Davison & Ammann, *supra* note 273, at 15–16.

275. Tagliabue, *supra* note 269, at 2.

276. *See* Gary E Marchant & Yvonne A Stevens, *A New Window of Opportunity to Reject Process-Based Biotechnology Regulation*, 6 GM CROPS & FOOD 233 (2015).

risk.[277] Given this understanding, oversight is necessary primarily when novel traits are introduced into plants and ecosystems.[278]

The presence and impact of a novel trait can be best detected through an end-product assessment. The interaction of a GM crop with the human body or the environment is highly case-specific based on the type of crop and the exact modification; "many unintended changes are likely to be benign."[279] Additionally, gene flow in an environment is not exclusive to GM crops because ecosystems are not genetically defined, static entities.[280] DNA and gene pools undergo continuous and extensive changes in nature and through conventional breeding, which is why modern crops bear little resemblance to their ancient wild progenitors.[281] Therefore, using the process by which a plant was modified to determine how it should be regulated is not well suited to identifying and mitigating the potential harms of cultivating that plant.[282]

Regulations under a process-agnostic approach would be based on the risk of the plant's traits and how these traits might interact in its proposed environment, rather than regulating based on the technique used to create the plant.[283] The GE plant should be subject to the same risk assessment regulations whether the novel trait was developed through transgenic recombinant DNA technology, gene editing, or induced mutation. This would effectively give "premarket scrutiny to plants that express traits that are new to established, cultivated crop species and that pose a potential for environmental harm, regardless of the process used."[284]

277. McHughen, *supra* note 56, at 131–32. National Research Council reports have consistently concluded that the breeding process of a novel GM crop is not a particularly useful indicator of new or increased hazards. NAT'L RSCH. COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 2 (1989); NAT'L RSCH. COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 6 (2000); NAT'L RSCH. COUNCIL, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS 4 (2004) [hereinafter NRC, SAFETY OF GENETICALLY ENGINEERED FOODS].

278. *See* Marchant & Stevens, *supra* note 276, at 239.

279. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 509; NRC, SAFETY OF GENETICALLY ENGINEERED FOODS, *supra* note 277, at 67.

280. *See* Ammann, *supra* note 58, at 11.

281. Steven H. Strauss & Joanna K Sax, *Ending Event-Based Regulation of GMO Crops*, 34 NATURE BIOTECH. 474, 476 (2016); Lei Zhangying et al., *From Wild to Cultivated Crops: General Shift in Morphological and Physiological Traits for Yield Enhancement Following Domestication*, 3 CROP & ENV'T 138, 138–39 (2024).

282. *See* Ammann, *supra* note 58, at 2.

283. Tagliabue, *supra* note 269, at 3.

284. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 509–10.

In a process-agnostic system, the regulating agency's primary responsibility is to conduct a risk assessment and evaluate the proposed GM crop relative to the priorities outlined in its statutory authority.[285] Categories could still be employed to increase regulatory efficiency, but these would be determined based on the properties of the plant and the environment into which the crop would be introduced.[286]

A process-agnostic system is the most scientifically and logically sound. The past 30 years have seen a blurring of the lines between natural and artificial plant reproduction and modification.[287] A process-based system risks forever chasing developments in gene editing science. It also creates false categories where there is still significant scientific debate about the nature and impact of various gene editing approaches.[288] The process-based system thus fails both the legal desire to provide an objective dichotomy and the scientific objective to prevent risk.[289] By focusing risk assessment on the result of genetic modification, regulators can focus on ensuring the health and safety of humans and their environment.[290] This approach also avoids exacerbating contentious ethical debates about the "naturalness" of genetic modification where they are not informed by meaningful scientific distinctions.[291]

3. Reserve Regulatory Authority for States

Next, Congress should explicitly reserve additional permitting authority to the states, subject to limitations. States must be able to exercise additional oversight over GM crops tested and grown within their jurisdiction. This authority should foster regional cooperation and create regional crop markets. One possible mechanism for this would be to adopt a cooperative federalism model, as seen in the Clean Water Act (CWA).[292] The USDA would create implementing regulations for crop certification and permitting, and authorities at the state and local levels

285. *See* Erwin & Glennon, *supra* note 174, at 379–80.
286. *Id.*
287. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 408.
288. Swetaleena Mishra et al., *CRISPR/Cas-Mediated Genome Engineering in Plants: Application and Prospectives*, PLANTS, July 2024, at 1, 17; GALLO & SARATA, *supra* note 26, at 11.
289. McHughen, *supra* note 56, at 130.
290. *See id.* at 142.
291. *See id.* at 129.
292. *See* Mark T. Pifher, *The Clean Water Act: Cooperative Federalism?*, NAT. RES. & ENV'T, Summer 1997, at 34, 34.

could define additional required elements.[293] This would increase transparency and accountability as the administrative process would be subject to public comment and input at the federal and state levels.[294] In such a scenario, state authorities could manage safety assessments with federal funding and guidance from the USDA.[295]

State input is critical because the impacts of GM crops are ecosystem-dependent and thus must be assessed at both a national level and a regional or local one.[296] This applies to the risks that a new GM crop variety may pose to its surrounding environment and to determining the appropriate mitigation and containment strategies. First, a GM crop may interact negatively with other organisms, especially if the GM crop is designed to produce a toxic substance as a built-in pest protection mechanism, which, in turn, could harm other insects.[297]

Also, since GM crops are engineered to have desirable traits, they can outcompete their wild relatives or reproduce to form new, more competitive hybrids.[298] A crop designed to thrive in a particular environment may become invasive or otherwise "contaminate" or disrupt the balance of an ecosystem when introduced elsewhere.[299] This can result in biodiversity impacts, including the loss

293. *See id.* at 38; *Overview of CWA Section 401 Certification*, U.S. ENV'T PROT. AGENCY (Aug. 30, 2024), https://www.epa.gov/cwa-401/overview-cwa-section-401-certification [https://perma.cc/M744-GT9F] (explaining how Section 401 of the CWA allows both federal and state-level permitting or certification).

294. *See* GENETICALLY ENGINEERED CROPS, *supra* note 10, at 504–05.

295. *See, e.g.*, CAL. STATE WATER RES. CONTROL BD., DRINKING WATER STATE REVOLVING FUND FREQUENTLY ASKED QUESTIONS (2015), https://www.waterboards.ca.gov/drinking_water/services/funding/documents/srf/dwsrf_faq.pdf [https://perma.cc/ASB9-SGSP] (describing how the Drinking Water State Revolving Fund provides both funding and implementation guidance for state and local programs).

296. *See, e.g.*, Dennis Engist et al., *The Impact of Genetically Modified Crops on Bird Diversity*, 7 NATURE SUSTAINABILITY 1149, 1151 (2024) (exploring how the use of herbicide-tolerant GM crops for commodity crop production has affected birds in the Eastern Temperate Forest and Great Plains ecoregions and noting that the environmental distinctions between regions make it hard to generalize their results).

297. *See* Anibal R. Oliveira et al., *Toxicological Evaluation of Genetically Modified Cotton (Bollgard) and Dipel WP on the Non-Target Soil Mite Scheloribates Praeincisus (Acari: Oribatida)*, 41 EXPERIMENTAL & APPLIED ACAROLOGY 191, 192 (2007).

298. Heather Landry, *Challenging Evolution: How GMOs Can Influence Genetic Diversity*, HARV. UNIV.: SCI. IN THE NEWS (Aug. 10, 2015), https://sitn.hms.harvard.edu/flash/2015/challenging-evolution-how-gmos-can-influence-genetic-diversity/ [https://perma.cc/L54D-7J66].

299. Andreas Bauer-Panskus et al., *Cultivation-Independent Establishment of Genetically Engineered Plants in Natural Populations: Current Evidence and Implications for*

of wild species or other alterations to the genetic variety of a regional gene pool.[300] The invasiveness of a crop depends on factors related to the crop species, its placement in the environment, the existing diversity of the ecosystem, and much more.[301] Finally, numerous approaches exist to mitigate the environmental risks of GM crops.[302] These include containment, post-release monitoring, and intentional seed sterilization.[303] These approaches are highly case-specific because their efficacy can depend on the underlying ecosystem.[304]

The complexity with which GM crops can interact with their environment requires a regulatory body to apply expertise regarding local ecosystems when determining whether and how to permit its cultivation. More localized oversight of which crops are approved and, more importantly, what permitting conditions are placed on their cultivation, could better support a case-by-case approach to environmental risk mitigation.

Similarly, localized oversight could better facilitate public participation and input in GM crop regulation.[305] The current federal system has been described as having a "top-down 'deficit model' approach to communication."[306] APHIS's "public comment periods occur downstream in the innovation process, following product development and shortly after the receipt of a petition for nonregulated status."[307] Meanwhile, FDA evaluation is carried out without broader public

---

EU Regulation, ENV'T SCI. EUR., Dec. 19, 2013, at 1, 5; *see* Ghoshray, *supra* note 151, at 504 ("[GE] crops propagate pollution via transgenic pathways by triggering widespread contamination as they alter and enhance gene flow from [GE] crops to target organic entities and species.").

300. Homer, *supra* note 125, at 97–98; Bao-Rong Lu & Chao Yang, *Gene Flow from Genetically Modified Rice to Its Wild Relatives: Assessing Potential Ecological Consequences*, 27 BIOTECH. ADVANCES 1083, 1086 (2009).

301. Lu & Yang, *supra* note 300, at 1087.

302. *What Can Be Done to Prevent Cross Breeding of GM Crops*, THE ROYAL SOC'Y (May 2016), https://royalsociety.org/topics-policy/projects/gm-plants/what-can-be-done-to-prevent-cross-breeding-of-gm-crops/ [https://perma.cc/D3UR-3T2C].

303. *Id.*; Dhan Prakash et al., *Risks and Precautions of Genetically Modified Organisms*, INT'L SCHOLARLY RSCH. NETWORK, Nov. 22, 2011, at 1, 7–8.

304. *See* Keri Carstens et al., *Genetically Modified Crops and Aquatic Ecosystems: Considerations for Environmental Risk Assessment and Non-Target Organism Testing*, 21 TRANSGENIC RES. 813, 817, 837 (2012).

305. *See* Furgurson et al., *supra* note 110, at 1.

306. *Id.* at 3.

307. *Id.*; *see* Biotechnology Regulatory Services; Changes Regarding the Solicitation of Public Comment for Petitions for Determinations of Nonregulated Status for Genetically

input.[308] By contrast, state-level processes could be accessible to a more comprehensive range of stakeholders and surface more regional concerns.

4. Modify Intellectual Property Rights

Finally, Congress should alter existing IP protections to permit independent crop research and allow farmers to re-seed crops for subsequent harvests. To individuals not deeply familiar with patent law, linking patent rights to proposed changes in biotechnology regulation might appear unusual. Society generally views patents as a mechanism to encourage investment in research and development, creating new and improved technologies.[309] However, of particular concern to regulators should be the possibility that a patent holder might use their patent to hinder or control the research necessary to develop public policies that address a technology's health, environmental, and security impacts.[310] For example, proponents of agroecology have often argued that patent protections in biotechnology have allowed companies to "lock out" agricultural innovations, including agroecological practices.[311]

The purpose of protecting IP rights to GM plants should be to encourage the development of novel varieties. Unfortunately, existing IP protections have resulted in crops that maximize the patent holder's return rather than the farmer's or the public's.[312] They have also created economic dependency by farmers on seed manufacturers, an inability to conduct independent research on GM crops, and extreme market consolidation.[313]

Engineered Organisms, 77 Fed. Reg. 13258, 13259 (Mar. 6, 2012) (describing APHIS's public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms).

308. Furgurson et al., *supra* note 110, at 3.

309. *R&D, Innovation and Patents*, WORLD INTELL. PROP. ORG. (Oct. 26, 2024, 2:18 PM), https://www.wipo.int/patent-law/en/developments/research.html [https://perma.cc/BPG7-TEC9].

310. *See* GENETICALLY ENGINEERED CROPS, *supra* note 10, at 320.

311. Aniket Aga & Maywa Montenegro De Wit, *How Biotech Crops Can Crash — and Still Never Fail*, SCI. AM. (Dec. 27, 2021), https://www.scientificamerican.com/article/how-biotech-crops-can-crash-and-still-never-fail/.

312. *See id.*

313. *See id.*

Before 1970, most crop breeding was done in the public sector, with private companies multiplying and distributing seeds developed by public institutions.[314] "Farmers often saved a portion of their harvest for use as seed in subsequent seasons, periodically purchasing new seed to reestablish purity and quality or to adopt an improved variety."[315] Now, four seed manufacturing conglomerates dominate the global market for GM crops.[316] A recent merger between two seed behemoths (Bayer and Monsanto) was met with deep concern from farmers who fear that the company will control industry data, pressure farmers into buying its chemical products, and reduce the quality and quantity of seed varieties.[317] This market consolidation has primarily been made possible due to stringent IP protections offered to GM crop varieties in the United States.[318]

Historically, seed varieties were publicly funded and freely distributed.[319] This was so until Congress passed the Plant Patent Act of 1930 (Patent Act) to encourage private investment.[320] The Patent Act only protects asexually reproduced plants (i.e., cuttings or grafting) that "also meet the general patent eligibility requirements of novelty, originality, and nonobviousness."[321] In 1970, Congress passed the Plant Variety Protection Act (PVPA).[322] The PVPA protects potatoes and seed crops that produce heritable traits consistent throughout subsequent generations of seed.[323] The PVPA authorizes the USDA to issue plant variety protection certificates, which protect commercial IP rights but provide exemptions for research and for re-seeding by farmers.[324] In 1994, Congress

314. JAMES M. MACDONALD ET AL., ECON. RSCH. SERV., U.S. DEP'T OF AGRIC., CONCENTRATION AND COMPETITION IN U.S. AGRIBUSINESS 7 (2023), https://ers.usda.gov/sites/default/files/_laserfiche/publications/106795/EIB-256.pdf?v=61978 [https://perma.cc/VRR5-QSG3].

315. *Id.*

316. *Id.* at 10–11.

317. *See id.* at 11; *Farmers Overwhelmingly Oppose Bayer Monsanto Merger*, FARM AID (Mar. 8, 2018), https://www.farmaid.org/issues/corporate-power/farmers-overwhelmingly-oppose-bayer-monsanto-merger/ [https://perma.cc/7SJU-ZC3X].

318. MACDONALD ET AL., *supra* note 314, at iii; Brickey, *supra* note 215, at 289, 298–99.

319. MACDONALD ET AL., *supra* note 314, at 15.

320. *Plant Patents*, NC STATE UNIV. LIBRS. (Jan. 7, 2025, 8:25 PM), https://www.lib.ncsu.edu/formats/plant-patents/patents [https://perma.cc/K24S-WE3L]; 35 U.S.C. § 161.

321. Roorda, *supra* note 170, at 664; Brickey, *supra* note 215, at 292; 35 U.S.C. § 161.

322. MACDONALD ET AL., *supra* note 314, at 7.

323. *Plant Variety Protection*, NC STATE UNIV. LIBRS. (Nov. 18, 2024, 4:50 PM), https://www.lib.ncsu.edu/formats/plant-patents/variety-protection [https://perma.cc/BUB6-GCH6]; Roorda, *supra* note 170, at 665; 7 U.S.C. § 2402.

324. *Plant Variety Protection*, *supra* note 323; 7 U.S.C. § 2482, 2543, 2544.

amended the PVPA to eliminate the ability of farmers to sell saved seed to others for replanting while retaining their right to save seed for replanting on their farms.[325] Hybrid seeds, which do not perform similarly across generations, are instead protectable as trade secrets.[326] Farmers "repurchase hybrid seed each season from the seed companies that control the parental lines."[327]

In 2001, the United States Supreme Court concluded that plants are eligible for utility patents under 35 U.S.C. § 101.[328] This decision built on the 1980 Supreme Court decision in *Diamond v. Chakrabarty*, where the Court held that GE organisms are patentable under § 101.[329] Unlike the protections provided by the Patent Act and the PVPA, utility patents last 20 years and allow the patent holder to exclude others from "saving their seeds for replanting and conducting research with the patented plant."[330] This has significantly strengthened the market power of seed conglomerates.[331] The resulting market consolidation among seed conglomerates has had a series of negative impacts, including increasing up-front costs for farmers, aggressive patent enforcement against farmers, and the creation of debt cycles.[332]

For crops like corn, soybeans, and cotton, which are planted mostly with GM seed, average seed prices have grown by more than double that of non-GM crops, by as much as 600% above 1990 levels.[333] These price increases are particularly harmful given most farmers' inability to save the seeds for subsequent harvests.[334] Instead, they must purchase seeds from seed manufacturers for each crop cycle, often due to restrictive contracts that farmers must enter into to acquire the seeds.[335] Additionally, since the prohibition on reseeding has been judicially codified into

325. OFF. OF TECH. TRANSFER, UNIV. OF IDAHO, SINCE 1994, BROWN-BAG SALES OF PVP-PROTECTED SEED HAS BEEN ILLEGAL IN THE UNITED STATES (2025), https://www.uidaho.edu/-/media/uidaho-responsive/files/research/ott/faculty-researchers/learning/seed-ip-flyer.pdf? [https://perma.cc/85E7-6HRM].

326. MACDONALD ET AL., *supra* note 314, at 7.

327. *Id.*

328. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 124–25 (2001).

329. 447 U.S. 303, 303 (1980); Brickey, *supra* note 215, at 293.

330. Roorda, *supra* note 170, at 667; 35 U.S.C. § 154.

331. Brickey, *supra* note 215, at 298–99.

332. *See supra* note 217 and accompanying text.

333. MACDONALD ET AL., *supra* note 314, at 16–17.

334. OFF. OF TECH. TRANSFER, *supra* note 325.

335. *Id.*

patent law, the use of patented seeds for second-generation crops can also create liability for infringement of IP rights.[336]

Consolidation has also rendered farmers dependent on agrochemicals, often produced by seed manufacturers. For example, one of Monsanto's most widely used GM crops is engineered to resist the herbicide glyphosate, which Monsanto produces and sells.[337] Thus, farmers must use Monsanto's crops to produce competitive yields, but using those crops requires more of Monsanto's other products.[338] This increased use of chemicals, in turn, produces resistance in pests and weeds, which requires the use of more costly chemical inputs.[339]

Additionally, the spread of GM crops to neighboring fields can precipitate a series of negative economic impacts.[340] Farmers can face patent infringement claims if GM crops are found on their land, regardless of whether they were planted intentionally or arrived through pollen drift.[341] This is because patent infringement is a strict liability offense, and thus, the intent or fault of the infringer is irrelevant.[342] Courts have generally not found it relevant to consider whether the alleged infringer may have suffered harm due to the contamination of their fields.[343] This is of particular concern for organic farmers who can lose their organic certification due to the introduction of GM crops into their fields.[344]

336. *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 124–25 (2001).

337. Daniel Kim, *Seeds of Greed: America's Growing Agricultural Monopolies*, COLUM. POL. REV. (Apr. 25, 2022), https://www.cpreview.org/articles/2022/4/seeds-of-greed-americas-growing-agricultural-monopolies [https://perma.cc/B7W7-4Q72]; MACDONALD ET AL., *supra* note 314, at 23.

338. *See* Kim, *supra* note 337.

339. Scott, *supra* note 66, at 150.

340. *See* Homer, *supra* note 125, at 96 (describing how the spread of a GM strain of corn resulted in millions of dollars of damage when the unapproved corn was found in food products, despite the use of EPA-mandated buffer zones and segregation methods around the GM corn).

341. Austin Glascoe, Comment, *Genetically Modified Nuisance: Your Right to Recovery Is Barred, if You Catch My Drift*, 6 LA. STATE UNIV. J. ENERGY L. & RES. 533, 540 (2018).

342. *Id.* at 541.

343. *Id.*

344. Austin Warehime, Note, *Death by Crosspollination: The Uncontrollable Natural Occurrence That Could Kill Organic Farming and the Legal Solutions to Save an Industry*, 7 BELMONT L. REV. 408, 429 (2020).

Unfortunately, tort recovery theories have often proved ineffective for farmers seeking redress from GM drift in their fields.[345]

Finally, patent restrictions and forceful licensing strategies also pose challenges for research aimed at shaping public policy. Patent owners who employ a stringent approach to licensing hold significant influence over future scientific investigations, regardless of whether the research seeks to explore new technologies or to understand their impact on health, the environment, or security.[346]

IP rules must be amended at the seed and plant levels to realign GM crop development with the interests of farmers and the broader public. At a minimum, legislation must codify, once and for all, a broad research exemption that would immunize all acts of research with a patented invention from infringement liability.[347]

Additionally, legislators should consider rendering GM plants ineligible for utility patents and removing the PVPA restriction on reseeding, or at least create exceptions to utility patents for research and reseeding.[348] If GM plants were ineligible for utility patents, Patent Act patents and PVPA certificates would be the primary form of IP protection.[349] These patents and certificates would still provide meaningful incentives for research and development, as evidenced by the fact that seed manufacturers continue to seek these protections today as alternatives to utility patents.[350] However, this could leave some crops without IP protection if they do not qualify for the Patent Act or PVPA certificates based on their

345. *See* Glascoe, *supra* note 341, at 542 (for a discussion of the limitation of tort recovery theories in providing redress for farmers who suffer harm from GMO drift). *But see* Debra M. Strauss, *We Reap What We Sow: The Legal Liability Risks of Genetically Modified Food*, 16 J. LEGAL STUD. BUS. 149, 160–66 (2010) (discussing several successful lawsuits using negligence cause of actions against large GM crop manufacturers for contamination of farm fields).

346. Elizabeth A. Rowe, *Patents, Genetically Modified Foods, and IP Overreaching*, 64 SMU L. REV. 859, 873–75 (2011).

347. *See* OYE ET AL., *supra* note 130, at 17–18.

348. *See* Roorda, *supra* note 170, at 685, 688–89 (advocating for an access requirement for food safety testing on all food products and raw ingredients in the United States food supply, possibly as a threshold requirement for a food to qualify as GRAS by FDA); Brickey, *supra* note 215, at 299–300 (advocating for creating expansive research exceptions to utility patent protections for GM crops).

349. *See* Brickey, *supra* note 215, at 292–93.

350. *See* Fuglie & MacDonald, *supra* note 217 (reporting that from "2016 to 2020, a total of 5,137 plant patents, 5,010 utility patents, and 2,028 PVPCs were issued for new crop varieties, more than double the rate of a decade earlier").

reproductive mechanisms or specific genetic modification.[351] Therefore, to ensure uniformity in market incentives, adding exemptions to utility patents or extending the coverage of the Patent Act would be more effective.[352]

Most importantly, this would reopen the door to independent scientific scrutiny of crop safety. This is critical, as some scientists have said that the current IP structure makes it so "[n]o truly independent research can be legally conducted on many critical questions" regarding GM crops.[353]

5. Best Practice Policy Tools

In addition to the four core reforms proposed above, additional policy tools are necessary to further the Public Interest Principles outlined in this Article. These tools are primarily administrative and could be adopted across state and federal levels. Thus, they represent how regulators can animate this reform's core Public Interest Principles, building on the new statutory framework described above.

First, regulators should balance the costs and benefits of a proposed plant variety in a way that requires developers to internalize the product's externalities. Second, restructuring the GM crop market system will require empowering stakeholders, improving local, state, and regional institutions, and modifying market structures and incentives. Finally, systemic change will require an

351. *See supra* notes 320–25 and accompanying text.

352. Commentators and legislators have alternatively proposed a license fee that farmers would pay when they save seed, which would be distributed to IP holders. Kevin E. Noonan, *House Considers Alternative Patent Royalty Scheme for Genetically Engineered Seed*, PATENT DOCS (Jan. 14, 2013), http://www.patentdocs.org/2013/01/house-considers-alternative-patent-royalty-scheme-for-genetically-engineered-seed.html [https://perma.cc/WS63-K99E]. Proposals of this nature have been rejected in Congress, largely because of the bureaucratic costs involved in creating an agency to deal with the financial and administrative aspects. *See* Seed Availability and Competition Act of 2013, H.R. 193, 113th Cong. (2013); Noonan, *supra* note 352 ("But regardless of which side has the better policy argument in that debate, Rep. Kaptur's bill is not a remedy required by the politics or economics of the situation. Indeed, it would just impose another government bureaucracy on [United States] agriculture that would not promote either agriculture or technological progress."). These proposals also fail to redistribute market power away from seed manufacturers and toward farmers, as farmers would continue to face financial burdens for re-seeding. By comparison, a restructuring of utility patents would not require additional bureaucracy, but would redistribute market power to farmers, with the added benefit of allowing independent research and development using patented plant varieties.

353. Andrew Pollack, *Crop Scientists Say Biotechnology Seed Companies Are Thwarting Research*, N.Y. TIMES (Feb. 19, 2009), https://www.nytimes.com/2009/02/20/business/20crop.html.

investment in a robust research infrastructure, stakeholder education, and institutions that can support and promote the adoption of new practices.

i. Balancing Costs and Benefits Through Clear Statutory Mandates and True Cost Accounting

Balancing costs and benefits in GM crop approval should be guided by clear statutory language that minimizes agency discretion and decreases regulatory uncertainty.[354] Natural resource statutes provide strong examples of how Congress can lay out values-based language that recognizes multiple interests, leaving federal regulators to interpret and apply it.[355] Policymakers can look to the National Park Service Organic Act,[356] the Federal Land Policy and Management Act,[357] and the National Forest Management Act[358] as models for incorporating values-based considerations into biotechnology regulation.[359]

The statutory language should also incorporate substantive requirements for evaluating the potential impacts of GM crops. This would go beyond the procedural requirements of NEPA and allow regulators to make decisions based on ecological considerations.[360] It would also push regulators beyond a one-dimensional risk assessment focused singularly on strict safety considerations.[361] Thus, the statutory mandate should require regulators to take a more comprehensive assessment approach to quantify and qualify a proposed crop's various risks and benefits, in line with agroecological principles.

For example, despite the lack of direct health hazards from consuming GM foods,[362] GM cultivation may indirectly impact human health through pesticide and herbicide-resistant crops.[363] This type of cultivation has substantially increased the volume of herbicides and pesticides used in the United States.[364] Glyphosate, a herbicide widely used alongside herbicide-resistant GM crops, can be a significant

354. Emmert, *supra* note 25, at 550–51.
355. Monast, *supra* note 163, at 2424.
356. 54 U.S.C. § 100101.
357. 43 U.S.C. § 1732.
358. 16 U.S.C § 1604.
359. Monast, *supra* note 163, at 2428.
360. *Id.*; *see* GENETICALLY ENGINEERED CROPS, *supra* note 10, at 473.
361. Monast, *supra* note 163, at 2412.
362. Teferra, *supra* note 28, at 5326.
363. Charles M. Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the U.S.— The First Sixteen Years*, ENV'T SCI. EUR., Sept. 28, 2012, at 1, 5.
364. *Id.* at 2–3.

pollutant in water and food systems and is possibly carcinogenic.[365] More broadly, pesticides and herbicides are associated with various harms to human health.[366]

This exemplifies how the impacts of a GM crop variety are often multi-dimensional and indirect. While a crop might not be unsafe for human consumption, its cultivation can have ripple effects throughout an ecosystem.[367] These harms must be considered comprehensively in the permitting process to understand the costs and benefits of allowing a crop to enter circulation in the food system.

This multifaced balancing as part of the permitting process is an ideal application of True Cost Accounting (TCA). TCA, described as an improved variant of Cost-Benefit Analysis, is an economic assessment that seeks to understand an activity's broader human, social, and ecological impacts.[368] Using relevant metrics, TCA can establish a baseline for assessing new plant varieties through the lens of agroecology.[369]

Applying TCA principles to permitting decisions for GM crops would involve considering the full range of environmental, social, and economic costs associated with these crops, as defined in the relevant statutory mandate.[370] For example, TCA could involve an ecological assessment of the impacts of the GM crop on biodiversity, soil health, water usage, and greenhouse gas emissions.[371] The analysis would then balance these ecological considerations with the crop's social and economic impacts, such as the effect on local farming communities, direct and secondary health impacts, the cost of seed, dependency on agrochemicals, and market monopolization risks. This holistic approach ensures

365. *See* John Peterson Myers et al., *Concerns Over Use of Glyphosate-Based Herbicides and Risks Associated with Exposures: A Consensus Statement*, ENV'T HEALTH, Feb. 17, 2016, at 1, 1, 3.

366. *See* Ngangbam Sarat Singh et al., *Pesticide Contamination and Human Health Risk Factor*, *in* MODERN AGE ENVIRONMENTAL PROBLEMS AND THEIR REMEDIATION 49, 59 (Mohammad Oves et al. eds., 2018).

367. *See* Brookes, *supra* note 212, at 263.

368. Kathleen A. Merrigan, *Embedding TCA Within US Regulatory Decision-Making*, *in* TRUE COST ACCOUNTING FOR FOOD 179, 179–80 (Barbara Gemmill-Herren et al. eds., 2021) (presenting a detailed comparison of True Cost Accounting and Cost-Benefit Analysis).

369. Guillermo Castilleja, *Foreword: Why True Cost Accounting?*, *in* TRUE COST ACCOUNTING FOR FOOD xxxi, xxxiv (Barbara Gemmill-Herren et al. eds., 2021).

370. *See* Merrigan, *supra* note 368, at 179–80.

371. *See* FOOD & AGRIC. ORG. OF THE UNITED NATIONS, THE STATE OF FOOD AND AGRICULTURE: REVEALING THE TRUE COST OF FOOD TO TRANSFORM AGRIFOOD SYSTEMS xx, 21 (2023), https://openknowledge.fao.org/server/api/core/bitstreams/5aac5078-625d-4b94-b964-bea40493016c/content [https://perma.cc/Z69L-RJTF].

that decisions about GM crop cultivation reflect their actual impact on ecosystems, communities, and economies.[372] Finally, the TCA could require a comparison of the GM crop with available alternatives in terms of overall cost, yield, sustainability harms, and more.

For example, herbicide or pesticide-resistant plants that lead to the overuse of synthetic additives would fail the TCA analysis because while they might increase yields and do not directly cause harm to human health, they create significant downstream externalities through runoff and ecosystem harm.[373] Put another way, this process would require that a product deliver a certain amount of benefit or be below a certain threshold of social cost. The result would be a transparent risk/benefit analysis on a case-by-case basis using "conventional crops and farming practices as a baseline comparator."[374]

ii. Empowering Regional GM Crop Markets

Scholars have noted that the availability of trait varieties suited to local conditions is an important precondition for genetic engineering to be compatible with agroecological practices.[375] Therefore, lawmakers should work to promote regional markets for GM crops, which will better address farmers' needs and regional ecologies.

Very high capital costs and regulatory barriers limit entry into the GM crop market.[376] This prevents small companies and public sector breeders from competing effectively.[377] Consolidation has slowed innovation and reduced the development of regional varieties because large conglomerates are focused on

372. *See* Alexander Müller & Jenn Yates, *How True Cost Accounting Can Transform Our Food Systems – and Lives – for the Better*, THINK TANK FOR SUSTAINABILITY (Oct. 26, 2024, 12:37 PM), https://www.tmg-thinktank.com/news/how-true-cost-accounting-can-transform-our-food-systems-and-lives# [https://perma.cc/X4LB-VNMP].

373. *See* Valerie Brown & Elizabeth Grossman, *How Monsanto Captured the EPA (and Twisted Science) to Keep Glyphosate on the Market*, IN THESE TIMES (Nov. 1, 2017), https://inthesetimes.com/features/monsanto_epa_glyphosate_roundup_investigation.html [https://perma.cc/A44B-4QTH] (describing the pervasive exposure to glyphosate in foods and drinking water nationwide).

374. Huw D. Jones, *Regulatory Uncertainty Over Genome Editing*, NATURE PLANTS, Jan. 2015, at 1, 3.

375. Lotz et al., *Genetically Modified Crops and Sustainable Agriculture*, *supra* note 21, at 95.

376. Globus & Qimron, *supra* note 10, at 1297.

377. *Id.*

producing seeds they can sell across the United States and to global markets.[378] This, in turn, creates challenges for adapting to climate change because there will be less biodiversity to draw on when breeding seeds locally adapted to extreme weather events.[379]

Most researchers agree that increasing the diversity of crops is an essential part of reducing crop loss.[380] To improve the impact of GM crops on biodiversity, it is necessary to develop regionally specific crop varieties that can better hedge against pest and disease resistance and adapt to local climate patterns.[381]

Seed banks, operated by states or regional institutions, could protect existing biodiversity and maintain a broader gene pool for major crop species.[382] These seed banks could be used to preserve wild varietals and assist with the equitable dissemination of beneficial GM varietals. Seed banks can preserve indigenous crop varieties, ensure that species are not lost due to genetic drift, and provide an ever-growing gene pool to breed new crop varieties.[383] They could also compensate farmers for biodiversity losses experienced from GM crop gene drift. By preserving a wide variety of traditional and indigenous seed species, seed banks could also ensure the availability of replacement seeds if GM crops cause unforeseen ecological issues.[384] This could provide a safety net against the potential environmental and economic risks of GM crop cultivation and address

378. Samantha Harrington, *Can Genetically Engineered Seeds Prevent a Climate-Driven Food Crisis?*, YALE CLIMATE CONNECTIONS (Nov. 19, 2021), https://yaleclimateconnections.org/2021/11/can-genetically-engineered-seeds-prevent-a-climate-driven-food-crisis/ [https://perma.cc/C4HR-UYDY].

379. *Id.*

380. *Id.*; *Agricultural Diversification: Practice and Policy*, NAT'L SUSTAINABLE AGRIC. COAL. (July 14, 2023), https://sustainableagriculture.net/blog/agricultural-diversification-practice-and-policy/ [https://perma.cc/TB8V-FZMF].

381. *See* Montenegro de Wit, *Can Agroecology and CRISPR Mix?*, *supra* note 203, at 738, 748.

382. Ciara Ryan, Comment, *Seed Banks and Their Sprouting Need for Stricter Contracts*, 47 CAL. W. INT'L. L.J. 81, 92 (2016); *EU Rethinks Genome Editing*, 9 NATURE PLANTS 1169, 1169 (2023) ("[B]eneficial traits that have been achieved through genome editing are collected and made publicly available by the European Sustainable Agriculture through Genome Editing (EU-SAGE) organization.").

383. *Seed Banks Help Build Biodiversity, Resilience in the Face of Disaster*, GLOB. RESILIENCE INST. AT NE. UNIV. (Oct. 26, 2024, 1:43 PM), https://globalresilience.northeastern.edu/seed-banks-help-build-biodiversity-resilience-in-the-face-of-disaster/ [https://perma.cc/HS97-TL3H].

384. *See* Harrington, *supra* note 378 (describing how seed sharing and seed banks are already being used as a tool to prevent biodiversity loss and could be a complementary tool alongside GM crops in the fight for climate resilient agriculture).

some of the limitations in existing tort recovery structures for unintentional gene drift.[385] Seed banks could additionally store and distribute GM seeds with climate-friendly properties as part of broader climate adaptation strategies.[386] This can support sustainable agricultural practices by providing farmers access to a diverse range of seeds, reducing dependence on monocultures, and increasing climate resiliency.

Another approach to redistributing market power would be to adopt open-source licensing for crop varieties developed by public institutions or "protected commons" licensing models for privately developed crops. Open-source licensing has proved popular in the software industry and is also used by some actors in the agricultural space, including the Open Source Seed Initiative.[387] It allows the recipient to use, modify, and share information in a manner that both drives down profit and encourages innovation.[388] Open-source seed licensing programs present an avenue to guide farmers, private developers, and researchers toward equity and sustainability by altering market incentives and reducing the cost of adopting sustainable methods.[389] Research has also indicated that private ownership of GM crops is a source of resistance in agroecological communities.[390] Therefore, making GM crop IP publicly available could play a key role in driving the acceptance of new technologies in a manner compatible with agroecological practices.

"Protected Commons" is an alternative approach adopted by the Biological Innovation for Open Society Initiative that provides a secure platform for discussing inventions without invalidating intellectual property rights.[391] Parties who join a protected commons share innovations to develop products for the public

385. *See supra* note 345 and accompanying text.

386. Harrington, *supra* note 378.

387. *The Open Source Seed Initiative*, OPEN SOURCE SEED INITIATIVE (Oct. 26, 2024, 1:48 PM), https://osseeds.org [https://perma.cc/74R9-D9HD].

388. *From Commodification to Conservation: Restoring Agrobiodiversity Through Seed Breeding – Part II*, NAT'L SUSTAINABLE AGRIC. COAL. (Oct. 25, 2023), https://sustainableagriculture.net/blog/from-commodification-to-conservation-restoring-agrobiodiversity-through-seed-breeding-part-ii/ [https://perma.cc/7PP6-YSX2].

389. *Id.*; Valeria Piñeiro et al., *A Scoping Review on Incentives for Adoption of Sustainable Agricultural Practices and Their Outcomes*, 3 NATURE SUSTAINABILITY 809, 810 (2020).

390. Sullivan, *Ag-Tech*, *supra* note 207, at 915.

391. BIOLOGICAL INNOVATION FOR OPEN SOC'Y, THE CAMBIA BIOS INITIATIVE 3 (2006), https://cambia.org/wp-content/uploads/2017/10/BiOS-Initiative-Phase-2006-2008.pdf [https://perma.cc/4RBZ-ZJ7S].

good.[392] This approach is less market-disrupting than an open-licensing approach because it would still allow seed producers to patent their seeds when necessary.[393] However, it could allow for independent safety research and facilitate stakeholder participation in crop design.[394] Numerous successful approaches to information sharing and interdisciplinary research are already operating in agroecological technology.[395]

Market power can also be re-distributed by providing meaningful means of redress for farmers harmed by GM gene drift or charged with IP violations. This could be accomplished by compensating farmers through a public remedy pool funded through levies on the intellectual property holders.[396] GM crop developers holding IP rights over their crops would finance a remedy pool for farmers unintentionally harmed by genetic drift into their fields.[397] Alternatively, crop developers could be held strictly liable under a tort theory cause of action, forcing them to internalize the risks of their product.[398] This would incentivize them to "ensure its safety, conduct rigorous testing, and disseminate critical information" about preventing or mitigating gene drift.[399]

Conversely, adding an intent requirement to pollen-drift patent infringement cases could protect farmers whose fields neighbor a GM crop field from being prosecuted for inadvertent patent violations caused by pollen drift.[400] Several states

---

392. *Id.* at 4.

393. Press Release, CAMBIA, The BIOS Initiative - Open Source Biotechnology Is Born (Feb. 10, 2005), https://cambia.org/wp-content/uploads/2017/10/open_source_biotechnology_is_born.pdf [https://perma.cc/4QWR-M692].

394. *See* BIOLOGICAL INNOVATION FOR OPEN SOC'Y, *supra* note 391, at 4.

395. *See* CUMULUS CONSULTANTS LTD, AGROECOTECH: HOW CAN TECHNOLOGY ACCELERATE A TRANSITION TO AGROECOLOGY? 25, 48–49 (2021), https://www.soilassociation.org/media/22821/agroecotech-soil-association-report.pdf [https://perma.cc/Z7H5-PXCV].

396. U.S. DEP'T OF AGRIC. ADVISORY COMM. ON BIOTECH. & 21ST CENTURY AGRIC. (AC21), ENHANCING COEXISTENCE: A REPORT ON THE AC21 TO THE SECRETARY OF AGRICULTURE 9 (2012), https://www.usda.gov/sites/default/files/documents/ac21_report-enhancing-coexistence.pdf [https://perma.cc/4MZC-YWZN]. The AC21 Advisory Committee on Biotechnology and Twenty-First Century Agriculture, commissioned in 2011, considered such a compensation mechanism but ultimately rejected it due to disagreements among the Committee's members about whether it would fairly distribute burdens and whether it would send negative signals about the safety of GM products. *Id.*

397. *Id.*

398. *See* Debra M. Strauss, *Liability for Genetically Modified Food: Are GMOs a Tort Waiting to Happen?*, SCITECH LAW., Fall 2012, at 8, 10.

399. *Id.* at 11.

400. Warehime, *supra* note 344, at 430; *see supra* text accompanying notes 340–44.

have attempted to provide more robust protections for farmers from patent infringement or contract breach charges if GE plant materials contaminate their fields.[401] However, these laws are at risk of being struck down as preempted, and thus, federal intervention is necessary to provide uniform protections for farmers across the country.[402]

iii. Investing in Independent Research and Education Infrastructure

There is a significant need for increased research funding for GM crops to "provide peer-reviewed and publicly accessible information."[403] There is a basis to believe that seed manufacturers have exerted considerable pressure on researchers, causing them to be hesitant about voicing concerns regarding the safety of specific GM crops.[404] Scientists have warned that if agrochemical companies can control the research available in the public domain, they can reduce the potential repercussions of adverse research outcomes.[405] Numerous reports have documented regulatory capture and pressure on researchers by seed conglomerates.[406] "Biotech researchers themselves are closely linked to, and often funded by, industry."[407] The scientific review of GM crops must move toward "completely transparent" submissions, "open to full review by scientific peers."[408] These "are axioms of the scientific method, and part of the very meaning of the objectivity and neutrality of science."[409]

Independent research should be supplemented with a registry of biotechnological products on the market.[410] This would create public access to

401. *Id.* at 431.

402. *See id.* at 433.

403. *See* GENETICALLY ENGINEERED CROPS, *supra* note 10, at 505–06.

404. Freedman, *supra* note 47; Dan Charles, *Monsanto Attacks Scientists After Studies Show Trouble for Weedkiller Dicamba*, NPR (Oct. 26, 2017, 4:57 AM), https://www.npr.org/sections/thesalt/2017/10/26/559733837/monsanto-and-the-weed-scientists-not-a-love-story [https://perma.cc/LQ5P-QKUP].

405. Pollack, *supra* note 353.

406. Brown & Grossman, *supra* note 373; Leland Glenna & Analena Bruce, *Suborning Science for Profit: Monsanto, Glyphosate, and Private Science Research Misconduct*, RSCH. POL'Y, Sept. 2021, at 1, 3.

407. Glenn Davis Stone, *Biotechnology, Schismogenesis, and the Demise of Uncertainty*, 47 WASH. UNIV. J.L. & POL'Y 29, 47–48 (2015).

408. THE ROYAL SOC'Y OF CAN., ELEMENTS OF PRECAUTION: RECOMMENDATIONS FOR THE REGULATION OF FOOD BIOTECHNOLOGY IN CANADA 214 (2001), https://rsc-src.ca/sites/default/files/GMreportEN.pdf [https://perma.cc/Q8TU-FS28].

409. *Id.*

410. Erwin & Glennon, *supra* note 174, at 381–82.

information "such as the kind of crop being modified, the modification made, the technology used," the mechanisms used to develop the trait, the areas where a crop is approved for cultivation, and the identified risks and recommended mitigation measures.[411]

Robust and independent monitoring frameworks should also be established to return scientific rigor to the review and approval process, which has been sorely lacking and has contributed to public confusion about the safety of GM crops.[412] Where public institutions have largely been pushed out of the research and development market due to funding shortages,[413] federal funding could revitalize an essential set of institutions to serve as regional hubs for field and safety testing of GM crops.

The USDA could also utilize or promote newly developing omics technology, which sequences the DNA in a plant and "measures how that sequence is translated into physical and chemical plant characteristics."[414] Omics can effectively scan a plant's entire DNA sequence to understand and quantify a plant's proteins, epigenome, and metabolites.[415] It permits researchers to identify whether a new plant variety has substantially different characteristics from all current varieties.[416] With that information, regulators could determine the need for further safety testing. These relatively low-cost technologies could be provided through a public testing infrastructure, and where additional testing is needed, developers could undertake studies privately.[417]

Publicly funded research has been found to return ten-fold benefits to society for every tax-payer dollar spent.[418] Thus, one approach to creating lasting institutional support for agroecology-aligned GM crops would be to fund interdisciplinary design projects at public research institutions that involve farmers

411. *Id.* at 382.

412. *See* Stone, *supra* note 407, at 36–38 (discussing how contradictory studies can lead to a highly confusing scientific landscape regarding the efficacy and impact of the use of a GMO crop). Contradicting claims often result from non-rigorous study and documentation design, lack of control or comparison variables, and "certainty by repetition." *Id.*

413. Erwin & Glennon, *supra* note 174, at 355.

414. Gould et al., *supra* note 62, at 1052.

415. GENETICALLY ENGINEERED CROPS, *supra* note 10, at 511.

416. *Id.* at 200–01 (describing how omics technology can be used to identify any unexpected changes in composition on a GM crop beyond the natural range of variation in conventionally bred crops).

417. *See* Gould et al., *supra* note 62, at 1052.

418. Harrington, *supra* note 378.

in identifying needed crop traits and real-world applications.[419] Co-creation in agroecology has been recognized as a way to incorporate localized expertise into research, providing several benefits over top-down knowledge transfers.[420] Long-term investments in collaborative crop design could familiarize farmers with GM technology, involve them in its development, and produce crops that better meet regional needs.

Finally, smart farming networks could also be established to facilitate peer-to-peer learning between farmers, developers, and researchers at the intersection of agroecology and GMOs.[421] "Currently, agricultural advice on the use of technology is too often left to companies with incentives to perpetuate conventional, input-intensive farming."[422] Education on properly incorporating a GM crop into an agricultural strategy has been shown to be key in the effective and widespread adoption of GM crops.[423] Peer networks would increase data sharing and target the information asymmetries between scientists, private developers, farmers, and the public. Information sharing would also help to deal with what has been described as the "genetic treadmill," where so many new technologies and varieties are hitting the market that it's difficult for farmers to make informed purchasing decisions and utilize them correctly.[424]

VI. CONCLUSION

Since the dawn of agriculture, humans have had an instinct to manipulate and improve the plants they grow. We should not reject this instinct. It is why we have the delicious and nutritious crops we enjoy today, and it is a necessary approach to feeding people efficiently and sustainably. Our agricultural systems are faced with increasing stressors and risks. This is not a moment to turn away from potential solutions. Instead, it is a moment to rethink how we govern those solutions and in whose interest they are deployed. We must create a system that continues to foster GE technology while aligning its governance with changing norms and understandings about the needs of the American food system.

---

419. CUMULUS CONSULTANTS LTD, *supra* note 395, at 75.

420. Alisha Utter et al., *Co-Creation of Knowledge in Agroecology*, ELEMENTA: SCI. OF THE ANTHROPOCENE, Nov. 3, 2021, at 1, 1–2.

421. CUMULUS CONSULTANTS LTD, *supra* note 395, at 75.

422. *Id.*; *see supra* Section V.B.4.

423. *See* Jennifer A. Anderson et al., *Genetically Engineered Crops: Importance of Diversified Integrated Pest Management for Agricultural Sustainability*, FRONTIERS BIOENG'G & BIOTECH., Feb. 20, 2019, at 1, 1.

424. *See* Stone, *supra* note 407, at 41–42.

GM crop regulation thus far has failed to align biotechnological development with an agroecological transition. While biotechnology will not provide the entire solution to existing challenges, writing off technological innovation as fundamentally incompatible with sustainable farming will lead to missed opportunities for system transformation and place unnecessary political and economic barriers on future agroecological implementation.[425] Technology can multiply the benefits of agroecological production if it is specifically designed for, or at least effectively integrated into, agroecological practices.[426] It can also serve to make agroecological practices more affordable and scalable.[427]

Deploying GM crops that are compatible with agroecological principles requires a nuanced approach that balances technological innovation with ecological sustainability, social equity, and respect for traditional agricultural knowledge. This approach involves careful consideration of GM crops' environmental, economic, and social impacts and active participation and collaboration among various stakeholders. The reforms proposed in this Article seek to ensure the safety of GM crops as they are introduced into the environment and promote their development in a way compatible with agroecological principles, particularly biodiversity and ecosystem health. The reforms also address socio-political aspects of agroecology, which emphasize food sovereignty and the democratic design of food systems.[428]

As critics may be quick to point out, the changes proposed in this Article would likely shrink and redistribute the GM market. Additional regulation is often seen as stifling innovation or increasing production costs for GMOs.[429] However, this is premised on the assumption that GM crop regulation should maximize the speed and ease with which companies can bring products to market, as well as the profit margin at which they can do so. Instead, this Article urges lawmakers to consider gene editing as a tool that must be wielded in the public interest, and thus, in the public sphere. Private actors still have a significant role to play. Their position in the market should be to facilitate innovation within a public infrastructure that directs private efforts toward the public good. The significant decreases in costs promised by new CRISPR technology should facilitate this

425. Siyan Zeng et al., *Agroecology, Technology, and Stakeholder Awareness: Implementing the UN Food Systems Summit Call for Action*, iSCIENCE, Sept. 15, 2023, at 1, 2.

426. *See* Wanger, *supra* note 198, at 1.

427. *See* CUMULUS CONSULTANTS LTD, *supra* note 395, at 12. Examples of such technologies include drones and other robotics used to mitigate the increased labor demands of more diverse and complex farms. *Id.* at 26.

428. Bonny, *supra* note 21, at 29.

429. Erwin & Glennon, *supra* note 174, at 388.

transition, which must be paired with renewed public funding and support of regional crop markets.[430] Where the existing system creates costs and risks due to uncertainty,[431] this new proposed structure would instead create a controlled market for GM crops that prioritizes human and ecological health while supporting innovation.

With the European Union moving toward a relaxation of their historically stringent restrictions on GMO crops due to concerns from climate change,[432] it is a fitting moment for United States lawmakers to reconsider the patchwork of regulations that govern plant biotechnology. The changes proposed in this Article require a shift in the public appetite for biotechnology and the political courage to defy the concentrated private interests currently dominating this market.[433] It is critical for policymakers to reframe gene editing as a tool that can be harnessed and redirected toward a sustainable future. By prioritizing agroecological principles and market equity, this framing can bring together previously divided coalitions: those who advocate for a system-wide transition to agroecology and those who embrace biotechnology as part of the promise of an ever-evolving world.

430. *See id.* at 370.

431. In the author's conversations with researchers currently developing GM plants for commercialization, developers have described FDA's regulatory approach as a "wait and see" model. FDA retains the ability to inquire into the safety of a product at any time, and it is unclear what assessments they are using to determine the presence of safety concerns. *See* MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS, *supra* note 252, at 18. This creates uncertainty for developers and down-market risks after a product has been commercialized. By creating more robust safety and permitting assessments at the front end of the regulatory process, developers who have received authorization to commercialize would not be subject to lingering and indeterminate oversight.

432. *EU Rethinks Genome Editing*, *supra* note 382, at 1169.

433. *See* Brown & Grossman, *supra* note 373.