

2013

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Recommended Citation

Rebecca Bratspies, *Is Anyone Regulating?: The Curious State of GMO Governance in the United States*, 37 *Vt. L. Rev.* 923 (2013).

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IS ANYONE REGULATING? THE CURIOUS STATE OF GMO GOVERNANCE IN THE UNITED STATES

Rebecca M. Bratspies^{*†}

INTRODUCTION

The promise of biotechnology has been tantalizingly just beyond reach for a number of years.¹

Conventional wisdom suggests that biotechnology may hold enormous promise for increasing agricultural production, improving sustainability, and offering more nutritious food to the public. Promises of increased yield²—more food for a hungry world³ and more profit for struggling farmers⁴—are dangled alongside claims that biotechnology crops result in decreased pesticide use⁵ and lower environmental impacts.⁶ Taken together, these claims buttress the oft-repeated assertion that agricultural biotechnology is a critical tool for improving human well-being. From this vantage point, it is relatively easy to caricature opponents of the technology as modern day Luddites⁷—or worse, unthinking elitists willing to sacrifice

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† I am particularly grateful to Greg Jaffe of the Center for Science in the Public Interest, Sheila Jasanoff of the Harvard Kennedy School, and Marti Mellon of the Union of Concerned Scientists for valuable feedback.

1. Ismail Serageldin, Speech: Agriculture's Role in Sustainable Human Development: An Action Agenda for the New Millennium, <http://www.serageldin.com/SpeechDetail.aspx?SID=g406tiDW2qmQ48TrjbViAw%3D%3D> (last visited Apr. 25, 2013).

2. *Do GM Crops Increase Yields*, MONSANTO, <http://www.monsanto.com/newsviews/Pages/do-gm-crops-increase-yield.aspx>. (last visited Apr. 25, 2013).

3. See, e.g., Maggie Urry, *Genetic products row worsens*, FINANCIAL TIMES, June 20, 1997, 4 (quoting former USDA Secretary Dan Glickman for the proposition that “[g]rowing pest-resistant crops would alleviate world hunger, reduce pesticide damage to the environment, and save rain forests from being cleared for food production”).

4. Graham Brooks & Peter Barfoot, *GM Crops: global socio-economic and environmental impacts 1996–2010*, 32–34, 80–82 (May 2012), <http://www.pgeconomics.co.uk/page/33/global-impact-2012>.

5. *Id.*; See also *Biotechnology*, MONSANTO, <http://www.monsantoafrica.com/biotechnology/default.asp> (last visited Apr. 10, 2013) (asserting that “other innovations” can contribute to decreased use of pesticides).

6. Brooks and Barfoot, *supra* note 4, at 83–88.

7. See *Biofortified rice as a contribution to the alleviation of life-threatening micronutrient deficiencies in developing countries*, THE GOLDEN RICE PROJECT, <http://www.goldenrice.org/index.php> (last visited Apr. 25, 2013) (“The shocking fact is that . . . more than 10 million children under the age of five are dying every year. A high proportion of those children die victim of common diseases that could be prevented through a better nutrition. This number has been equated with a ‘Nutritional Holocaust.’ It is unfortunate that the world is not embracing more readily a number of approaches with the potential to substantially reduce the number of deaths. It has been calculated that the life of 25

the hungry masses rather than confront their fears of science and change.⁸ And indeed, those charges are an integral part of the public discussion of agricultural biotechnology—sometimes made explicit, other times *sub rosa*.

Had biotech crops unambiguously delivered on its promoters' extravagant promises, this indictment would indeed be a serious one. However, after nearly two decades of experience with these crops, it is not altogether clear that these claims are valid. Despite overwhelming adoption of genetically engineered (GE) corn, soybeans, and cotton, crop yields have largely held steady or decreased,⁹ while pesticide use has skyrocketed.¹⁰ As a result, at least ten species of so-called “superweeds”—weed plants resistant to glyphosate—have been documented in more than twenty states.¹¹ Worse, the problem of food insecurity has increased rather than decreased—leaving more people hungry than at any other point in human history.¹² Many policymakers nevertheless insist that biotech crops are the future of global agriculture, and that these crops will ultimately deliver on the promises made from the very beginning.¹³

percent of those children could be spared by providing them with diets that included crops biofortified with provitamin A (beta-carotene) and zinc”).

8. See, e.g., ROBERT PAARLBERG, *STARVED FOR SCIENCE* 1 (2008) (arguing that while it costs rich countries nothing to drive out biotechnology through regulation, driving out biotechnology from poor countries impacts their farm-production and food-consumption needs). Norman Borlaug, Nobel Laureate and “Father” of Green Revolution, was widely quoted as characterizing biotechnology opponents as “[e]xtremists in the environmental movement, largely from rich nations . . . [that] seem to be doing everything they can to stop scientific progress in its tracks.” Norman E. Borlaug, *Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry*, 124 *PLANT PHYSIOL.* 487, 488 (2000), available at <http://www.plantphysiol.org/content/124/2/487.full>.

9. DOUG CURIAN-SHERMAN, *Failure to Yield: Evaluating the Performance of Genetically Engineered Crops*, UNION OF CONCERNED SCIENTISTS 13 (Apr. 2009), http://www.ucsusa.org/assets/documents/food_and_agriculture/failure-to-yeild.pdf; B.L. Ma & K. D. Subedi, *Development, yield, grain moisture and nitrogen uptake of Bt corn hybrids and their conventional near-isolines*, 93 *FIELD CROPS RESS* 199, 200, 209 (2005), http://www.saveourseeds.org/downloads/Btmaize_inferior_yield.pdf.

10. See Charles Benbrook, *Impact of Genetically Engineered Crops on Pesticide Use in the US—the First Sixteen Years*, ENVIRONMENTAL SCIENCES EUROPE, 24:24, at 1 (Sept. 2012), <http://www.enveurope.com/content/pdf/2190-4715-24-24.pdf> (finding that pesticide use has increased by approximately 404 million pounds or 7 percent).

11. William Newman & Andrew Pollack, *Farmers Cope With Roundup Resistant Weeds*, N.Y. TIMES, B1, May 3, 2010, available at <http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?pagewanted=print>. Indeed, Bayer CropScience's most pitch for its genetically engineered cotton begins with the following phrase: “With weed resistance exploding across America's farmland.” Bayer CropScience, *Stoneville Offers Two New Varieties With GlyTol and LibertyLink Traits*, (Jan. 9, 2013), <http://www.bayercropscience.us/news/product-news?storyId=0CB58C47-BE79-4A2C-9979-162CE57A055D>.

12. Rebecca Bratspies, *Food, Technology and Hunger*, 8 LAW CULTURE & THE HUMAN. 1, 7 (Oct. 1, 2012), available at <http://lch.sagepub.com/content/early/2012/09/24/1743872112456990>.

13. For example, Ismail Serageldin CGIAR Chief and World Bank Vice-President characterized biotechnology as “a crucial part of expanding agricultural productivity in the 21st century.” While he viewed biotechnology as “a tremendous help in meeting the challenge of feeding an additional three billion human beings, 95% of them in the poor developing countries, on the same

Even assuming for purposes of discussion that agricultural biotechnology can ultimately be able to live up to a portion of its extravagant billing, these public advantages will only be realized with a comprehensive and scientifically rigorous regulatory system that ensures environmental and human health issues are addressed in a transparent and credible fashion. To our detriment, we currently do not have such a system. As a result the United States is in the process of reaping a harvest of environmental harms associated with uncontrolled planting of GE crops, including: contamination of conventional and organic crops; an explosion of herbicide-resistant weeds; and a massive overall increase in herbicide use. The impact of these broad-based concerns, and the lack of regulatory attention they attract ought to give one pause when considering how thoroughly these crops are regulated.

The companies involved in developing and marketing transgenic agricultural crops take the position that regulation is stringent and omnipresent in their industry. For example, Aventis CropScience claimed that “[a]ll of our products, including those based on biotechnology, undergo thorough human, animal, and environmental safety evaluations. In order to be released commercially, they have to obtain the respective regulatory authorization. This involves rigorous governmental safety reviews and approval processes.”¹⁴ The assertion that “[e]xtensive testing and a long approval process accompany every GM crop introduction”¹⁵ is routinely offered as an antidote to doubt about the wisdom of approving these crops, as is the proposition that “[i]n the United States, three agencies regulate these crops.”¹⁶ The agencies are not far behind. The United States Department of Agriculture (USDA) claims to employ “a science-based regulatory system” that “allows for the safe development and use of agricultural goods derived from new technologies that provide increased production options to agricultural producers.”¹⁷ Indeed more than a decade

amount of land and water currently available,” he also recognized that for this to occur, the technology must first be “safely deployed.”

14. *Should We Grow GM Crops?*, article to special report *Harvest of Fear*, PBS, quoted in PBS *Harvest of Fear*, <http://www.pbs.org/wgbh/harvest/exist/no6.html> (last visited Apr. 10, 2013) (internal quotations and citation omitted). Bayer now owns this portion of Aventis. Bayer: A History, Gmwarh.org/gm-paper/11153-bayer-a-history.

15. *Pocket K No. 11: Contribution of GM Technology to the Livestock Sector*, INT’L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, <http://www.isaaa.org/resources/publications/pocketk/11/default.asp> (last updated 2006); SAN DIEGO CTR. FOR MOLECULAR AGRIC., *FOOD FROM GENETICALLY MODIFIED CROPS* 10, <http://www.brown.edu/ce/adult/arise/resources/docs/gmfoodbrochure.pdf>.

16. SAN DIEGO CTR. FOR MOLECULAR AGRIC., *supra* note 15, at 4.

17. USDA, STRATEGIC PLAN FY 2010–2015 23, <http://www.ocfo.usda.gov/usdasp/sp2010/sp2010.pdf>.

ago, former USDA Secretary Dan Glickman asserted, “[t]est after rigorous scientific test has proven these products to be safe.”¹⁸

These claims of rigorous regulation are not borne out in practice. The United States does not have a comprehensive regulatory scheme that considers all of the likely risks associated with GE crops prior to approval or, for that matter, on an on-going basis. Numerous reasons exist to bring more rigorous regulatory scrutiny to GE organisms. This Article highlights how, in the absence of such a regulatory scheme, critical risks associated with these crops escape regulatory scrutiny. The end result is that private actors, motivated by short-term interests, are able to engage in conduct that imposes risks on wider society without any democratic consideration of the acceptability of those risks.¹⁹ To be clear, this is an indictment of the decision-making process itself rather than a comment about particular regulatory outcomes. The objection is not so much to the exact contours of the ultimate decisions about these crops, but to the lack of democratic legitimacy in a regulatory structure that systematically transfers the power to make what should be public decisions—involving public participation and based on public interests—to private actors, motivated by private interests. Long experience has shown that in the absence of a transparent regulatory process, which forces a public weighing of costs and benefits, such private risk-benefit analyses too often disregard important public values and interests. Thus, this Article focuses on the kind of regulatory system necessary for appropriate decision-making and the kind of system that will build public confidence in biotechnology.

It is no secret that protecting the public’s interest in this context requires the government to assume a far more active role than the hands-off attitude that has been the hallmark of conventional agricultural policy. To that end, this Article argues that the United States needs an effective regulatory system for GE crops—one that is not only comprehensive and scientifically rigorous, but also transparent and credible to the public it is intended to protect and benefit. To make the case that we do not currently have such a regulatory system, Section I of this Article begins with a brief historical overview of how we arrived at this juncture in the first place—identifying some key technological breakthroughs and regulatory decisions. Section II then lays out the current United States regulatory system for transgenic crops, detailing the patchwork of statutes and agencies pressed into service. Section III highlights some key considerations that routinely fall through the gaps in our current patchworked regulatory system. Section

18. Maggie Urry, *supra* note 3 (quotations omitted).

19. See Serageldin, *supra* note 1 (referencing this transition to private research and decisionmaking).

IV concludes with some thoughts on how this regulatory situation impacts broader democratic legitimacy questions.

I. BACKGROUND AND OVERVIEW

The United States current regulatory system for biotechnology dates back to the Reagan Administration. It emerged not from careful, proactive government decision making, but in response to a lawsuit brought against the federal government over the first field trials of a genetically modified organism. After Watson and Crick discovered the structure of DNA in 1953, molecular genetic research exploded. By the early 1970s, academic researchers had developed the capacity to transfer genes from one organism to another, and to create recombinant DNA molecules. The prospects for this new technology were both exciting and frightening. Prompted by a concern that the speed of technology's advance had outpaced any controls, one-hundred-fifty scientists from around the world gathered at the Asilomar Conference Center in Pine Grove, California to hammer out a set of safety precautions for genetic research.²⁰ Known as the Asilomar Consensus Statement,²¹ the conference recommended a series of guidelines for genetic engineering research. This consensus formed the basis for the Recombinant DNA Research Guidelines issued by the National Institute of Health (NIH) in 1976.²²

The first real challenge to these guidelines came soon afterwards. In 1983, a California company applied for permission to field test a GE bacterium called "Ice-minus."²³ In its conventional, unmodified form, this bacteria was responsible for causing frost damage to plants.²⁴ A researcher at University of California–Berkeley modified the bacteria so that it no longer promoted the ice crystal formation that damages plants as frost.²⁵ The idea was that by replacing the common bacteria with the GE "Ice-minus" bacteria, plants would be better able to resist frost damage.²⁶

20. For a discussion of the Asilomar Conference and its consequences, see Rebecca M. Bratspies, *Consuming (F)ears of Corn*, 30 AM. J.L. & MED. 371, 378–79 (2004).

21. ASSEMBLY OF LIFE SCI., NAT'L ACAD. OF SCI., SUMMARY STATEMENT OF THE ASILOMAR CONFERENCE ON RECOMBINANT DNA MOLECULES (1975), <http://profiles.nlm.nih.gov/qq/B/C/G/D/qqbcgd.pdf>.

22. Charles Weiner, *Is Self-Regulation Enough Today? Evaluating the Recombinant DNA Controversy*, 9 HEALTH MATRIX 289, 293–98 (1999) (providing history of Recombinant DNA self-regulation).

23. See generally SHELDON KRIMSKY & ALONZO PLOUGH, ENVIRONMENTAL HAZARDS: COMMUNICATING RISKS AS A SOCIAL PROCESS 75 (1988) (providing an account of the "Ice-minus" controversy).

24. *Id.* at 78.

25. *Id.* at 77–78.

26. *Id.* at 75.

After successful greenhouse testing, the developer applied for permission to field-test the “Ice-minus” bacteria by spraying it on potato, tomato, and bean plants.²⁷ The NIH, which at the time was the only federal agency exercising *any* regulatory authority over biotechnology, approved the field trials through its Recombinant DNA Advisory Committee.²⁸ Jeremy Rivkin and the Foundation on Economic Trends (FET) sued in federal court, arguing that the NIH had violated the National Environmental Policy Act (NEPA) by approving the release without conducting an Environmental Impact Assessment.²⁹ In a landmark decision by Judge Skelley Wright, the D.C. Circuit issued an injunction prohibiting NIH from approving the field trial until it considered the “broad[er] environmental issues attendant on deliberate release” of genetically modified organisms.³⁰ Striking on themes that continue to haunt regulation of genetically modified organisms, the court “emphatically” concluded that NIH had failed to “display[] . . . rigorous attention to environmental concerns.”³¹ In particular, the court found that NIH had completely failed to consider “the possibility of various environmental effects”—identifying as the most “glaring deficiency” NIH’s failure to consider the effects of dispersal of the genetically modified organisms.³²

This successful legal challenge forced the Reagan Administration to develop a more overarching regulatory policy to guide federal decision-making about biotechnology research and its products. To that end, in 1984 the Office of Science and Technology Policy proposed the Coordinated Framework for Regulation of Biotechnology, which was finalized in

27. *Id.* at 90–91.

28. Recombinant DNA Research; Actions Under Guidelines, 48 Fed. Reg. 24,548, 24,548–52. (June 1, 1983).

29. *Found. on Econ. Trends v. Heckler (I)*, 587 F. Supp. 753, 757 (D.D.C. 1984) [hereinafter *Heckler I*], *aff’d in part & vacated in part*, 756 F.2d 143 (D.C. Cir. 1985). For a detailed discussion of this case, see Elizabeth Pizzulli, *Foundation on Economic Trends v. Heckler: Genetic Engineering and NEPA’s EIS Requirement*, 2 PACE ENV’T L. REV. 138, 138–139 (1984).

30. *Found. on Econ. Trends v. Heckler (II)*, 756 F.2d 143, 146 (D.C. Cir. 1985) [hereinafter *Heckler II*]. At the time, very little was known about the ramifications of this technology. EPA had already concluded that the Ice-minus bacteria would likely escape the test plot and persist indefinitely in the environment. Indeed, in an unusually frank contemporaneous comment, a researcher commented “You remember the space program, when all those rockets were blowing up on the launching pad? Well, the science (of gene-splicing) is at that stage now.” See Andrew Maykuth, *Genetic Wonders to Come: Some See Boon, Others Calamity*, PHILA. INQUIRER (Jan. 10, 1986), <http://www.maykuth.com/Archives/gene86.htm> (quoting William R. Harvey, then a researcher at Temple University).

31. *Heckler II*, 756 F.2d at 146.

32. *Id.* at 153–54. After the *Foundation on Economic Trends* lawsuit, EPA reviewed and ultimately approved the proposed “Ice-minus” field tests. Local protests continued to hinder the experiments, as municipalities and citizens groups objected to having the test plots in their communities. The company did not help its cause—during the pendency of the proceeding, they illegally applied recombinant insects to trees on a rooftop patio at its Oakland headquarters. The field tests ultimately took place in 1987 amidst a media storm.

1986.³³ From its inception, the Coordinated Framework's drafters made it clear that their primary goal was addressing industry needs for "sensible" regulation that would not stifle innovation,³⁴ rather than responding to a public desire for rigorous regulation to protect public safety. Thus, the resulting Coordinated Framework emphasized the United States' commitment to reducing trade barriers in biotechnology.³⁵ A comparable degree of commitment to preserving environmental safety was less evident.

With virtually no modifications in the intervening decades, this Coordinated Framework continues to govern regulatory decisions about agricultural biotechnology. The central assumption guiding the Coordinated Framework is "substantial equivalence,"³⁶ which is the assessment that the products of genetic engineering are functionally equivalent to their unmodified counterparts and should be treated accordingly.³⁷ This starting point led the United States to develop a regulatory system built on four key principles:

[1] biotechnology poses no unique risks; [2] the products of biotechnology should be regulated, not the process; [3] existing laws should be used to regulate the products of biotechnology (no new legislation was needed); and [4] any gaps should be

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

34. The proposal provided in relevant part:

The Working Group recognizes the need for a coordinated and sensible regulatory review process that will minimize the uncertainties and inefficiencies that can stifle innovation and impair the competitiveness of U.S. industry. . . . The importance of addressing the emerging commercial aspects of biotechnology in a coordinated and timely fashion is captured in the recent report by the Congressional Office of Technology Assessment which warned: 'Although the United States is currently the world leader in both basic science and commercial development of new biotechnology, continuation of the initial preeminence of American companies in the commercialization of new biotechnology is not assured.

Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856, 50,857 (proposed Dec. 31, 1984). Indeed, responding to the political and economic climate characterized by a general anxiety that the United States was losing its competitive edge, the Reagan Administration sent a clear message that "regulatory agencies were not to stand in the way of biotechnology." Mary Jane Angelo, *Embracing Uncertainty. Complexity and Change: An Eco-Pragmatic Reinvention of First Generation Environmental Law*, 33 *ECOLOGY L.Q.* 105, 171 n. 328 (2006).

35. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,308.

36. See generally Jan-Peter Nap et al., *The Release of Genetically Modified Crops into the Environment*, 33 *PLANT J.* 1, 9 (2003); See also *Consuming (F)ears of Corn*, supra note 20, at 390 (discussing the problems that arise with the United States lack of a comprehensive statute addressing genetically engineered products and the division of regulation among various agencies).

37. Rebecca Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16 *KAN. J. L. & PUB. POL'Y* 393, 406 (2007).

addressed through coordination among agencies and designation of lead agencies as appropriate.³⁸

A key consequence of this approach is that the United States did not adopt any new laws directly targeting regulation of this new technology. That means there is no unified statutory authority for regulating these crops, and no regulator with an unambiguous regulatory mandate. Instead of one single federal agency charged with comprehensively governing the regulation of GE crops, regulatory responsibility was spread across three different federal agencies, with three very different mandates. These federal agencies pressed into service a patchwork of statutes, all of which predated the advent of this technology, in order to cobble together some kind of regulatory system. The resulting system divides up regulatory authority in ways that do not particularly make sense and leave some key risks unregulated.

The three decades since the “Ice-Minus” debacle have seen a dramatic growth of regulatory apparatuses and a dramatic increase in the agencies’ decision making about GE organisms. Yet, if we look at the questions that still do not fit neatly into the regulatory process, we find that they are precisely the same kinds of issues that prompted an injunction in 1983. There are three categories of risk that this cobbled-together regulatory scheme is particularly poor at addressing: systemic environmental risks, food safety risks, and risks of social and economic disruption flowing from unresolved liability and property issues.

II. THE AGENCIES AND THEIR REGULATORY AUTHORITY

Before turning to some recent disputes that highlight the regulatory gaps identified above, it is worthwhile to first lay out the relative regulatory roles the Coordinated Framework assigned to the USDA, Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA)—the main actors in this regulatory space.³⁹ Thus, the next three subsections offer a thumbnail sketch of the agencies and their primary roles under the

38. *Id.*

39. I have elsewhere explored these regulatory roles in some detail. Interested readers are encouraged to seek out those earlier works. For an in-depth discussion of EPA’s role in regulating *Bt* crops, see Rebecca M. Bratspies, *The Illusion of Care Regulation: Uncertainty and Genetically Modified Food Crops*, 10 NYU ENVTL L. J. 297, 314–16 (2002) (arguing that deficiencies exist in EPA’s regulation due to statutory inadequacies); for information about FDA’s regulatory role, see Rebecca M. Bratspies, *Glowing in the Dark: How America’s First Transgenic Animal Escaped Regulation*, 6 MINN. J. L. SCI. & TECH. 457, 471–72 (2005) (describing FDA’s failure to regulate transgenic fish); and for an explanation of USDA-APHIS’s role, see *Consuming (F)ears of Corn*, *supra* note 20, at 390 (discussing the USDA’s authority to regulate genetically engineered organisms).

Coordinated Framework. The short version is that the USDA, EPA, and FDA divide up regulatory authority based on their pre-existing statutory authorities. At least ten different laws and numerous agency regulations and guidelines are pressed into service to regulate GE plants, animals, and microorganisms. Each of these laws predates the advent of biotechnology, and they reflect widely different regulatory approaches and procedures.

In theory, this division of labor means that the EPA evaluates whether a GE plant is safe for the environment,⁴⁰ the USDA evaluates whether the plant is safe to grow,⁴¹ and the FDA evaluates whether the plant is safe to eat.⁴² In practice, that distinction rapidly breaks down because of the artificialities introduced by the need to rely on pre-existing statutory authority. Statutes written well before the advent of genetic engineering do not map perfectly onto the issues raised by this new technology. The result is an odd series of overlaps and gaps. For example, the EPA is responsible for testing and regulating GE plants that endogenously produce pesticides, like *Bt* corn, but not those that are modified nutritionally or for increased herbicide tolerance or disease resistance.⁴³ The USDA has a wider scope in terms of GE organisms within its regulatory ken, but its focus is exclusively on whether those novel plants pose a plant pest risk.⁴⁴ The FDA nominally regulates food safety but limits its inquiry by beginning with the assumption that GE foods are substantially equivalent to non-modified versions of the same food.⁴⁵ In general, exactly what the FDA regulates with regards to GE foods is uncertain and confusing.⁴⁶

A. *USDA Regulatory Authority*

The USDA-Animal Plant Health Inspection Service (APHIS) uses the Plant Protection Act to regulate the introduction of GE crops.⁴⁷ This statute

40. See Bratspies, *Illusion of Care Regulation*, *supra* note 39, at 314 (noting that under FIFRA, EPA has the primary responsibility of environmental protection from biotechnology).

41. Bratspies, *Consuming (F)ears of Corn*, *supra* note 20, at 390.

42. See Bratspies, *Glowing in the Dark*, *supra* note 39, at 473 (describing the FDA's regulatory role).

43. Bratspies, *The Illusion of Care Regulation*, *supra* note 39, at 316.

44. See Bratspies, *Consuming (F)ears of Corn*, *supra* note 20, at 391 (discussing the constraints and conflicts within the USDA's regulation of genetically modified plants).

45. See Bratspies, *Glowing in the Dark*, *supra* note 39, at 487 (explaining the FDA's assumptions in the regulatory scheme).

46. *Id.* at 43 (discussing FDA's inadequate and unclear regulations of transgenic fish).

47. See Plant Protection Act, 7 U.S.C. § 7712(a) (2006) (granting USDA authority to regulate "any plant, plant product, biological control organism, noxious weed, article, or means of conveyance . . . that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States").

gives the USDA authority to regulate movement of organisms that may endanger plant life.⁴⁸ But, because the Plant Protection Act is a quarantine statute intended to prevent the introduction and transmission of plant pests, the USDA's primary duty is to evaluate whether there is a risk that an organism will pose a plant pest risk when introduced into the environment, or interstate commerce.⁴⁹ Indeed, the USDA touts this evaluation as evidence that the United States engages in a science-based regulatory strategy.⁵⁰

Many GE plants use *Agrobacterium*, a known plant pest, as the mechanism for transformation. As a result, these plants fall under the USDA-APHIS's Plant Protection Act authority. However, plants transformed by use of a gene gun do not fall within the agency's authority—leaving the introduction of those plants wholly unregulated unless they happen to fall within the EPA's narrow regulatory ambit, which is discussed below. Even for plants transformed by *Agrobacterium*, and therefore under the USDA-APHIS's authority, a plant pest analysis does not capture many of the most likely risks posed by these crops. The statute's implementing regulations defines a plant pest as:

[A]ny living stage . . . of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing . . . [that] directly or indirectly injure[s] or cause[s] disease or damage to [a] plant.⁵¹

Under section 7711(a) of the Plant Protection Act, the Secretary of Agriculture may issue regulations “to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States.”⁵² The Secretary has delegated this authority to APHIS, which has drafted regulations to regulate “organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests.”⁵³ These regulations give APHIS the authority to regulate GE organisms and products if the genetic engineering involves use of an

48. *Id.*

49. *Id.* at § 7712(c).

50. In its strategic plan, USDA touts the fact that “before a genetically engineered crop can be commercialized, the Department evaluates it thoroughly to ensure that it does not pose a plant-pest risk. This process ensures safe introduction and agricultural production options and enhances public and international confidence in these products.” STRATEGIC PLAN FY 2010–2015, *supra* note 17, 23.

51. 7 C.F.R. § 340.1 (2012).

52. 7 U.S.C. § 7711(a).

53. 7 C.F.R. § 340.0(a)(2), n. 1.

organism that is considered a plant pest and APHIS has reason to believe that the GE organism may be a plant pest, or if APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.⁵⁴

Pursuant to this authority, APHIS regulates “organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests.”⁵⁵ The statute might authorize APHIS to exercise broad regulatory authority because it defines plant pest as “any [microorganism] . . . that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.”⁵⁶ The USDA interprets this authority narrowly, treating GE crops exactly like their conventional counterparts and evaluating them for the same risks.

GE crops pose many risks for which there is no ready conventional plant pest parallel. Yet, because it interprets its regulatory authority as limited solely to plant pest considerations, the USDA-APHIS brackets many of the clear risks associated with these crops. The bracketed risks include: the likelihood of excessive herbicide application with the accompanying evolution of weed resistance;⁵⁷ contamination of conventional crops from pollen drift or pollinator activity;⁵⁸ and the impact on domestic and global trade that flows from cross-fertilization, cross-contamination, or co-mingling conventional—or organic—and GE crops.⁵⁹ This latter omission is particularly perverse given that the USDA identifies “facilitating access to international markets” and “supporting the development of new domestic markets,” particularly organics, as key tasks for achieving its self-declared goal of “ensuring a financially sustainable and competitive national agricultural system.”⁶⁰

There is no reason for the USDA to limit its consideration of GE crops in this fashion. The Plant Protection Act gives the USDA broad authority to regulate “plant pests.” The Act gives the agency even broader authority to regulate “noxious weeds,” which are defined as “any plant or plant product that can directly or indirectly injure or cause damage to crops . . . or other interests of agriculture . . . the natural resources of the United States, the public health, or the environment.”⁶¹

54. *Id.* §§ 340.0(a)(2); 340.2(a).

55. *Id.* § 340.0(a)(2), n. 1.

56. 7 U.S.C. § 7702(14).

57. See discussion, *infra* Part III A.

58. See discussion, *infra* Part III B.

59. *Id.*

60. STRATEGIC PLAN, *supra* note 17, at 8.

61. 7 U.S.C. § 7702(10).

Under the Plant Protection Act, the APHIS has the authority to prohibit or restrict the movement in interstate commerce of any plant in order to prevent the introduction or dissemination of a plant pest or noxious weed.⁶² Moreover, any plant may “be subject to remedial measures the Secretary determines to be necessary to prevent the spread of plant pests or noxious weeds.”⁶³ Because Congress gave the agency broad authority to prevent noxious weed growth by restricting “any plant,”⁶⁴ APHIS need not limit itself to the narrow inquiry of evaluating GE crops for the same harms associated with traditional noxious weeds.

It should not be surprising that the agronomic and environmental risks of harm associated with GE crops are novel. There is no reason, other than internal agency culture, that APHIS does not consider transgenic contamination of conventional crops or the proliferation of superweeds from overuse of glyphosate to be issues that “directly or indirectly injure or cause damage to . . . agriculture, . . . the natural resources of the United States, the public health, or the environment.”⁶⁵

Not only does the agency conceive of its regulatory authority too narrowly, it also fails to rigorously enforce the regulations it does apply. Specifically, the Plant Protection Act’s implementing regulations make it unlawful for any person to introduce without a permit any organism that has been GE from one or more enumerated organisms that are considered plant pests.⁶⁶ Anyone may petition APHIS to deregulate a GE crop.⁶⁷ Before a GE crop may be deregulated, APHIS must review an applicant’s deregulation petition and make a determination that the particular GE crop does not present a plant pest risk and should not be regulated.⁶⁸

If APHIS decides that a GE organism poses no greater plant pest risk than an equivalent non-GE organism, it will approve a petition for non-regulated status. At that point, APHIS claims to have no further regulatory authority, and the agency ceases to monitor or regulate the environmental release and movement of the crop.⁶⁹ This means that deregulated genetically engineered organisms may be planted anywhere in the United States with no further regulatory oversight. Two recent lawsuits successfully challenged the environmental assessments APHIS prepared before deciding

62. *Id.* §7712(a).

63. *Id.* §7712(c)(3).

64. *Id.* § 7712(a).

65. *Id.* § 7702(10).

66. 7 C.F.R. § 340.2(a).

67. *Id.* § 340.6(a).

68. *Id.* § 340.6(d)–(e).

69. *Id.* § 340.6(e)(1).

to deregulate two Roundup Ready crops as cursory and wholly inadequate.⁷⁰

B. The EPA's Regulatory Authority

The USDA is not alone in having its hands tied by an unduly narrow and inadequate statutory mandate. The EPA is probably the most logical regulator to consider environmental impacts of GE crops. Yet, the agency's regulatory authority over these crops is actually extremely limited. Indeed, the EPA's regulatory authority over these crops flows wholly from the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), which gives the agency control over a narrow slice of GE crops. Under FIFRA, the EPA regulates microorganisms, herbicides, and pesticides.⁷¹ With few exceptions, no person may sell or distribute a pesticide that is not registered under FIFRA.⁷² Under FIFRA, the EPA "shall register a pesticide if . . . it will perform its intended function without unreasonable adverse effects to the environment; and when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment."⁷³ Unreasonable adverse effects are defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of use of any pesticide."⁷⁴

For GE crops that endogenously produce pesticides, *Bt* crops, the EPA has some reasonable regulatory tools available. The EPA has identified the evolution of resistance to *Bt* as an adverse environmental impact under FIFRA.⁷⁵ To prevent (or delay) this evolution, the EPA imposed planting restrictions as part of the pesticide registration for *Bt* crops.⁷⁶ The goal of these restrictions is to preserve effectiveness of *Bt* by maintaining insect

70. *Ctr. for Food Safety v. Vilsack*, No. C 08-00484 JSW, 2009 WL 3047227, at *9 (N.D. Cal. Sept. 21, 2009); *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, at *12 (N.D. Cal. Feb. 13, 2007), *aff'd*, 570 F.3d 1130 (9th Cir. 2009), *rev'd sub nom. on other grounds Monsanto Co. v. Geertson Seed Farms*, 130 S.Ct. 2473 (2010).

71. 7 U.S.C. § 136a(a); *Id.* § 136(t)-(v) (defining pests, pesticides, and plant regulators).

72. 7 U.S.C. § 136a(a). The pesticide regulations are set out in 40 C.F.R. Parts 150-189.

73. *Id.* § 136a(c)(5)(C)-(c)(5)(D).

74. *Id.* § 136(bb)(1).

75. OFFICE OF PESTICIDE PROGRAMS, ENVTL. PROT. AGENCY, BIOPESTICIDES REGISTRATION ACTION DOCUMENT: *BACILLUS THURINGIENSIS* (BT) PLANT-INCORPORATED PROTECTANTS IID2 (2001), http://www.epa.gov/pesticides/biopesticides/pips/bt_brad2/4-irm.pdf.

76. ENVTL. PROT. AGENCY, RESPONSE OF THE ENVIRONMENTAL PROTECTION AGENCY TO PETITION FOR RULEMAKING AND COLLATERAL RELIEF CONCERNING THE REGISTRATION AND USE OF GENETICALLY ENGINEERED PLANTS EXPRESSING *BACILLIUS THURINGIENSIS* ENDOTOXINS 8 (2000), <http://www.epa.gov/oppbppd1/biopesticides/pips/greenpeace-petition.pdf>.

vulnerability to the pesticide.⁷⁷ The cornerstone of this plan was a high-dose/structured refuge strategy.⁷⁸ Under this strategy, every *Bt* planting must be accompanied by a refuge zone—a planting of non-*Bt* crops not sprayed with *Bt* foliar spray.⁷⁹ For this strategy to work, three critical conditions that must be met: the GE *Bt* plants' tissue must be very toxic to kill all individuals heterozygous for resistance; resistance alleles must be sufficiently rare that nearly all alleles will be in heterozygotes susceptible to the very toxic plants; and refuges must be planted to maximize the probability that any resistant homozygote insect will mate with susceptible homozygote insect, thus producing heterozygous progeny that cannot survive the toxicity of the crop.⁸⁰

This all seems very scientific and at first glance might support industry contentions that regulation of GE crops is both rigorous and science-based. Yet, when the EPA first registered *Bt* crops in 1996, and when it re-registered them in 2001, the agency had no information from which to conclude that any of these conditions were actually being met.⁸¹ Some GE crops were approved despite not producing a particularly high dose of the *Bt* toxins.⁸² *Bt* crops were approved without an estimate of resistance allele frequency and required in-field sampling techniques were inadequate to catch resistance before it had taken hold.⁸³ Most disturbingly, *Bt* crops were approved without a refuge requirement.⁸⁴ Only when it became graphically clear that the EPA's initial planting estimates and assumptions about voluntary compliance were wrong did the EPA use its regulatory authority to mandate refuges.⁸⁵ Even then, the agency imposed a refuge requirement less stringent than virtually every scientific estimate of adequacy, and the agency also permitted growers to spray these refuges with pesticides if crop damage exceeded an economic loss threshold.⁸⁶ While any or all of these

77. *Id.* at 9.

78. *Id.*

79. *Id.*

80. *Id.*

81. For an in-depth discussion of this point, see Bratspies, *The Illusion of Care Regulation*, *supra* note 39, at 330–31 (arguing that in light of the available scientific evidence, EPA's approval of non-high dose *Bt* hybrids was unreasonable); see also, Rebecca M. Bratspies, *Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco*, 27 WM & MARY ENVTL. L. & POL. REV. 593, 615 (2003).

82. ENVTL. PROT. AGENCY, *supra* note 76, at 9. Bratspies, *The Illusion of Care Regulation*, *supra* note 43, at 329–30.

83. Bratspies, *Illusion of Care*, *supra* note 39, at 331–32.

84. *Id.* at 333–34.

85. *Id.* at 337.

86. *Id.* at 339–40.

regulatory choices may be good policy from a grower-economics perspective, not one of them is about science.

Moreover, even given the limited rigor of the refuge requirement, major questions remain about compliance and enforcement. Because the EPA does not regulate the crop itself, but only the pesticide produced by the plant, it has no ability to require reporting of where *Bt* crops are planted. This lack of relevant authority makes enforcement next to impossible. Reports suggest that the planting distances are routinely ignored.⁸⁷

C. The FDA's Regulatory Authority

The FDA is perhaps the most limited of the three agencies with regard to GE crops, even though that limitation is wholly self-imposed. The Federal Food, Drug, and Cosmetics Act (FFDCA) prohibits “the introduction . . . into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.”⁸⁸ A food is “adulterated” if it bears or contains any poisonous or deleterious substance.⁸⁹ Substances that are added to food fall into two possible categories: food additives and substances that are “generally recognized as safe” or GRAS.⁹⁰ The statutory definition of food additive is “any substance . . . [that] may reasonably be expected to . . . becom[e] a component or otherwise affect[] the characteristics of any food” unless the substance is generally recognized as safe (GRAS) for its intended use by scientific experts.⁹¹

Food additives require premarket review and approval by the FDA as “safe,” which is defined as “reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.”⁹² If a food additive is deemed unsafe, the food containing the additive is deemed adulterated.⁹³ Moreover, a food additive is deemed to be unsafe unless used in conformity with a regulation specifying the conditions under which the additive may be safely used.⁹⁴ If the substance added to food, however, is “generally recognized as safe,” then it is not considered a food additive for purposes of the FFDCA and no prior FDA approval is required.⁹⁵

87. *Id.* at 343.

88. 21 U.S.C. § 331(a).

89. *Id.* § 342(a)(1).

90. *Id.* § 321(s).

91. *Id.* § 321(s).

92. 21 C.F.R. §170.30(i).

93. 21 U.S.C. § 331(a), 342(a)(1), 342(a)(2)(C).

94. *Id.* § 348(a)(2).

95. *Id.* § 321(s); 21 C.F.R. § 170.30.

The definition of food additive is clearly broad enough to encompass GE foods. Thus, the FDA might have used its authority to rigorously regulate GE crops under its food additive authority by requiring premarket approval of the introduced genetic material they contain and the proteins that genetic material produces. However, building on the “substantial equivalence” mindset of the Coordinated Framework, the FDA concluded that GE crops are presumptively GRAS.⁹⁶ The consequences of this decision are monumental—a GRAS determination means that these products are exempted from the FDA’s food safety regulations. The FDA’s GRAS presumption for GE foods was upheld in *Alliance for Bio-Integrity v. Shalala*.⁹⁷

FDA regulations do permit those developing GE foods—mostly ag-biotech companies like Monsanto—to *voluntarily* consult with the FDA before marketing a new GE food product.⁹⁸ The company’s obligation is to satisfy itself that its product is safe rather than to prove safety to the FDA.⁹⁹ This leads to a developer-driven consultation process in which the proponent of a new GE food decides what safety tests to conduct, and what data to submit to the FDA. The FDA reviews only the data that is voluntarily submitted by the company, and imposes no obligation on the developer to share all its data, including negative or inconclusive results with the agency.¹⁰⁰ The FDA conducts no independent testing of these food products.¹⁰¹ Thus, the highly touted FDA premarket approval amounts to the FDA reviewing GRAS determination made by private manufacturers based on a select subset of supporting data that the manufacturers voluntarily submit for review.

Not only is there no requirement that GE food developers consult with the FDA, those companies are also *not required* to follow any

96. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992).

97. *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 178 (D.D.C. Cir. 2000).

98. Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 99, at 22,991. In 2001, FDA proposed regulations that would have changed this regulatory stance significantly. Proposed Rule: Pre-market Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,706, 4,706 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 and 592). Under the proposed rules, FDA would have required submission of data and information about plant-derived bioengineered foods or animal feeds at least 120 days prior to commercial distribution. This mandatory process would have replaced voluntary consultations, and would have required the agency, not industry to make the GRAS determination in the first instance. One of the first acts of the incoming George W. Bush administration was to suspend and withdraw these rules for further consideration. They have never been re-introduced.

99. FOOD & DRUG ADMIN., GUIDANCE ON CONSULTATION PROCEDURES FOODS DERIVED FROM NEW PLANT VARIETIES, (1997), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096126.htm>.

100. *Id.*

101. *Id.*

recommendations that the FDA makes during or after such a consultation. This consultation process, which the FDA itself characterizes as “comprehensive scientific review of the data generated by the developer,”¹⁰² culminates merely in an agency statement that it has “no further questions.”¹⁰³ This no-action letter is the sum total of the agency’s involvement—a role rather remote from the industry characterization suggesting that the agency actually reviews data and makes a decision that the food is safe.

This is not a recipe for building public confidence. So, perhaps it is no surprise that the public remains ambivalent about the safety of these foods,¹⁰⁴ and that support for labeling is nearly universal.¹⁰⁵ Given the rhetoric about “science-based regulation” of GE crops and foods, it is important to highlight just how much of the FDA’s “review” of these products is actually based on unproven assumptions rather than on actual scientific data.

Most of the time, food manufacturers have a fairly clear incentive not to expose the public to known, unacceptable risks—although we have seen some high profile instances of failure, such as the recent peanut butter scandal. But, known risks are not the main concern with these novel crops. This policy creates little incentive for manufacturers to explore *possible* risks or to develop the kind of information that would enable a full assessment of food safety. And, because these food safety decisions are not made in a participatory, transparent process, the public has no information about how those private actors assessed the acceptability of any risks they did uncover. Placing decisions about risk acceptability in the hands of private actors with a private stake in the decision creates conflicting

102. *Id.*

103. *Id.*

104. INTERNATIONAL FOOD INFORMATION COUNCIL, 2012 CONSUMER PERCEPTIONS OF FOOD TECHNOLOGY SURVEY, 3 (2012),

<http://www.foodinsight.org/Content/5438/FINAL%20Executive%20Summary%205-8-12.pdf>. This industry funded study reported that only 38% of Americans had a favorable or somewhat favorable impression of biotechnology. This result is consistent with other polling. Thompson Reuters reported in 2010 that 21.4% of Americans believed that genetically-engineered food was safe. THOMPSON REUTERS, NATIONAL SURVEY OF HEALTHCARE CONSUMERS: GENETICALLY ENGINEERED FOOD (2010), http://www.factsforhealthcare.com/pressroom/NPR_report_GeneticEngineeredFood.pdf

105. Thompson Reuters reported that 93.1% of Americans supported labeling of genetically engineered foods. THOMPSON REUTERS, *supra* note 104. This result contradicted the International Food Information Council survey which reported that 66% of respondents were satisfied with FDA’s current regulation of genetically-engineered crops. INTERNATIONAL FOOD INFORMATION COUNCIL, *supra* note 104, at 3. The difference may be accounted for by the fact that in the Food Council survey, only 30% of respondents were aware that foods produced from biotechnology are currently sold in supermarkets stores. *Id.* at 5. In the Thompson Reuters poll, by contrast, 69.2% of respondents knew that genetically-engineered foods were currently available in supermarkets. THOMPSON REUTERS, *supra* note 104.

interests that can work to the public's disadvantage. It is precisely these risk acceptability determinations that would benefit most from a public airing of the risks and benefits associated with a new technology, and the value that the public puts on risk avoidance in any given situation.

So, when the producers of these crops talk about scientific regulation, those representations should be taken with a grain or two of salt. Unpacking the regulatory decisions reveals a tremendous amount of uncertainty, and extensive policy judgments made in the absence of critical information. To fill the gaps, agencies have relied on the Coordinated Framework's directive to promote this technology as a substitute for missing information.

III. PROBLEMS THAT FLOW FROM OUR REGULATORY POLICY FOR GMOS

In the thirty years since the "Ice-minus" dispute, the United States has witnessed a dramatic growth in the development and commercialization of GE organisms. Yet if we look at the questions that still do not fit neatly into our regulatory process, we find that they are precisely the same issues that prompted the D.C. Circuit to issue an injunction in 1983—a lack of attention to systemic environmental risks, or the unintended social and economic dislocations that accompany this technology.¹⁰⁶ Among the serious concerns that deserve more rigorous attention from regulators are: the increased use of pesticides associated with GE crops and the emergence of "superweeds" resistant to pesticides; damage to traditional and organic farmers; and the lack of transparency and consumer choice associated with a failure to label GE foods.¹⁰⁷ Yet the United States tripartite regulatory scheme virtually assures that these concerns will continue to fall through the cracks.

There are some very serious environmental, social, and economic risks that the existing regulatory regime is systematically unable to address. Among the most notable of the ignored risks are: (1) the cumulative effects of multiple GE crops on the evolution of pest resistance due to increased herbicide use; (2) gene transfer (also called "gene pollution") to non-GE plants through cross-pollination; and (3) the "consumer right-to-know" and "food choice" issues. Indeed, in 2010, the National Academy of Sciences identified a series of "information gaps on certain environmental, economic,

106. *Heckler I*, 587 F. Supp. 753, 757 (D.D.C. 1984), *aff'd in part & vacated in part*, 756 F.2d 143 (D.C. Cir. 1985).

107. There are certainly other risks, including: potential health risks associated with existing or likely genetically engineered crops consumed as food; collateral harms to protected species; and an overall loss of crop biodiversity and industry consolidation.

and social impacts”¹⁰⁸ of these crops that made it difficult, if not impossible to conduct a full sustainability assessment of GE crops. The next section examines how the existing regulatory structure exacerbates these problems.

A. Spread of “Superweeds”:

Failure to Consider Cumulative Effects Has Produced Resistance Evolution in Response to Rapid Increase of Glyphosate Use

Glyphosate-resistant crops¹⁰⁹ epitomize many of the greatest regulatory challenges posed by GE food crops. These crops involve plants genetically engineered to be resistant to the herbicide glyphosate.¹¹⁰ Planted on 69 million hectares (107.5 million acres) of U.S. farmland in 2011,¹¹¹ Roundup Ready crops are the dominant form of commodity crop planted in the United States.¹¹² In 2012, Roundup Ready plantings constituted 88% of the corn crop, 94% of the cotton crop, and 93% of the soybean crop.¹¹³ In 2011, Roundup Ready crops constituted 95% of the sugar beet crop.¹¹⁴ This last statistic is particularly interesting because the crop did not have the necessary regulatory approvals.¹¹⁵ Indeed the saga of Roundup Ready sugar beets, and the parallel story of Roundup Ready alfalfa—which was similarly not approved for planting in 2011—highlights just how broken the United States regulatory system has become.

One undesirable side effect of widespread adoption of Roundup Ready crops has been an increasing and often exclusive reliance on glyphosate to manage weeds. Independent scientists have documented that, contrary to industry claims, GE crops were responsible for a 383 million pound

108. Nat’l. Acad. of Sciences, *Impact of Genetically Engineered Crops on Farm Sustainability in the United States* 3 (2010), http://www.nap.edu/openbook.php?record_id=12804.

109. The majority of glyphosate resistant crops have been developed and patented by Monsanto under the trade name Roundup Ready. However, Bayer, Pioneer and DeKalb also market crops genetically engineered to be resistant to glyphosate. Jerry M. Green, *Evolution of Glyphosate-Resistant Crop Technology*, 57 WEED SCIENCE 108, 108–09 (2009), http://allenpress.com/pdf/wees_57.1_108_117.pdf

110. *Id.* at 108.

111. CLIVE JAMES, INT’L SERV. FOR THE ACQUISITION OF AGRIBIOTECH APPLICATIONS, EXECUTIVE SUMMARY BRIEF 43: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS, 5 (2011), available at <http://www.isaaa.org/resources/publications/briefs/43/executivesummary/default.asp>.

112. USDA-ECONOMIC RESEARCH SERVICE, RECENT TRENDS IN GE ADOPTION, http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_fpra.pdf (last updated July 5, 2012).

113. *Id.*

114. USDA-ECONOMIC RESEARCH SERVICE, BACKGROUND: SUGAR & SWEETENERS, <http://www.ers.usda.gov/topics/crops/sugar-sweeteners/background.aspx> (last updated Oct. 9 2012).

115. Monsanto Company and KWS SAAT AG; Determination of Nonregulated Status of Sugar Beet Genetically Engineered for Tolerance to the Herbicide Glyphosate, 77 Fed. Reg. 42,693, 42,693 (July 20, 2012) (granting deregulated status in 2012 and allowing adoption of crop).

increase in herbicide use from 1996–2008.¹¹⁶ The bulk of this increase was associated with increased glyphosate use on Roundup Ready crops.¹¹⁷

According to the National Academy of Sciences, this overreliance on glyphosate has reduced the pesticide's effectiveness as a weed management tool.¹¹⁸ Indeed, the increase in glyphosate use associated with widespread adoption of Roundup Ready crops has resulted in a growing epidemic of glyphosate-resistant weeds.¹¹⁹ Millions of acres are now infested with glyphosate-resistant horseweed, pigweed, ragweed, and waterhemp—with many fields harboring two or more resistant weeds.¹²⁰ Growers report that glyphosate-resistant weeds significantly increase their costs per acre.¹²¹ Unfortunately, since the introduction of glyphosate-resistant crops in 1996, ten species of Roundup-resistant weeds have been identified across more than twenty-two states.¹²² These so-called “superweeds” are also sprouting up in other countries that have embraced these GE crops.¹²³ Currently, “a total of 19 weeds have evolved resistance to glyphosate worldwide.”¹²⁴ These “superweeds,” are not only driving substantial increases in the use of glyphosate, but also the increased use of more toxic herbicides, including paraquat and 2,4-D.¹²⁵ To deal with resistant weeds, farmers are resorting to more toxic chemicals and more frequent spraying, and also to more intense

116. Charles Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years*, THE ORGANIC CENTER CRITICAL ISSUE REPORT i (2009), http://www.organic-center.org/reportfiles/13Years20091126_ExSumFrontMatter.pdf.

117. *Id.* at 3. This dramatic increase in herbicide applications vastly exceeded the decreased use of insecticide attributable to *Bt* corn and cotton, making the overall chemical footprint of today's GE crops decidedly negative. According to USDA data shows that since the introduction of herbicide tolerant crops in 1996, glyphosate application has increased by 18.2 % on cotton, 9.8% on soybeans and 4.3% on corn. *Id.* at 4–6.

118. Nat'l Acad. of Sciences, *Impact of Genetically Engineered Crops on Farm Sustainability in the United States* 3 (2010), http://www.nap.edu/openbook.php?record_id=12804.

119. *Id.*

120. Benbrook, *supra* note 116, at 4.

121. *Id.* at 5–6.

122. Michael D.K. Owen, *Weed species shifts in glyphosate-resistant crops*, 64 PEST MANAGEMENT SCIENCE 377–82 (2008). For perspective, in areas not growing Roundup Ready crops, only seven weed species have evolved resistance in the nearly forty years that glyphosate has been commercially available. *Are Superweeds an Outgrowth of USDA Biotech Policy: Hearing before the Subcomm. on Domestic Policy of the H. Comm. on Oversight and Government Reform*, 111th Cong. 3 (2010) (statement of Michael D.K. Owen, Ph.D., Professor of Agronomy at Iowa State University), available at http://www7.nationalacademies.org/ocga/testimony/t_Herbicide_Resistant_Weeds_in_GE_Crops.asp.

123. Stephen B. Powles, *Evolved Glyphosate-Resistant Weeds Around the World: Lessons to be Learnt*, 64 PEST MGMT. SCI. 360, 362 (2008).

124. *Are Superweeds an Outgrowth of USDA Biotech Policy*, *supra* note 122. See also *International Survey of Herbicide Resistant Weeds*. WEEDSCIENCE.ORG, <http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12> (last visited April 25, 2013) (describing types of glyphosate-resistant weeds around the world, by species and country).

125. *Are Superweeds an Outgrowth of USDA Biotech Policy*, *supra* note 122; Benbrook, *supra* note 116, at 4.

tillage of their fields—all actions with negative environmental consequences.

According to experts, this behavior reflects the fact that growers:

Value the convenience and simplicity of these crops without appreciating the long-term ecological and economic risks attributable to the unvaried tactics they used. . . . That behavioral response might be expected given many farmers' desire to meet short-run financial needs and the fact that other growers may not take similar control actions.¹²⁶

This phenomenon, known as the “tragedy of the commons,” is well-documented.¹²⁷ There is no question that “unless growers collectively adopt more diverse weed-management practices, individual farmer’s actions will fail to delay herbicide resistance to glyphosate because the resistant genes in weeds easily cross farm boundaries.”¹²⁸ Indeed, it is precisely because individuals make decisions based on individual and short-term considerations that environmental regulation is necessary. Regulators, acting in the public interest, are supposed to put brakes on individual behaviors that, when viewed in isolation are beneficial to the actor, but when viewed in context produce socially-undesirable results.

The average citizen may be surprised by the lack of consideration given to the weed resistance problem in GE plant regulatory oversight. The risk is an obvious one and its ramifications quite serious. Nevertheless, it has not been part of the regulatory calculus to date.

For example, in 2005, APHIS granted Monsanto’s petition to deregulate Roundup Ready alfalfa, a version of alfalfa genetically engineered to be resistant to Monsanto’s Roundup herbicide.¹²⁹ In granting this petition, APHIS concluded that the plant “should not reduce the ability to control pests and weeds in alfalfa or other crops.”¹³⁰ That same year, APHIS also concluded that deregulation of GE sugar beets “should not reduce the ability to control pests and weeds in sugar beet or other crops.”¹³¹ It was quite remarkable that at a time when reports of the

126. *Are Superweeds an Outgrowth of USDA Biotech Policy*, *supra* note 122 at 5/7.

127. *Id.*

128. *Id.*

129. *Id.*

130. USDA-APHIS, Notice: Monsanto Co. and Forage Genetics International; Availability Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate, 70 Fed. Reg. 36,917, 36,918–19 (June 27, 2005).

131. USDA, Monsanto Co. and KWS SAAT AG; Determination of Nonregulated Status for Sugar Beet Genetically Engineered for Tolerance to the Herbicide Glyphosate, 70 Fed. Reg. 13,007, 13,008 (March 17, 2005.)

evolution of weed resistance to glyphosate were beginning to pour in, the agency managed to reach this conclusion.¹³² It did so by bracketing the question of herbicide use associated with these crops from its plant pest analysis.¹³³ The Sugar Beet Environmental Assessment specifically indicated that it “does not address the separate issue of the potential use of the herbicide glyphosate in conjunction with these plants.”¹³⁴ Organic and conventional farmers challenged both decisions in federal court, alleging that the agency’s decision to deregulate these crops without first conducting an environmental impact statement (EIS) violated NEPA.¹³⁵ The farmers alleged various significant impacts that necessitated an EIS, *inter alia*, that widespread, uncontrolled planting of glyphosate-tolerant alfalfa would increase the likelihood of glyphosate resistant weeds.¹³⁶

NEPA is an action-forcing statute.¹³⁷ It instructs federal agencies to conduct a “coherent and upfront environmental analysis”¹³⁸ to ensure informed decision making. Whenever substantial questions are raised as to whether a project *may* cause significant environmental degradation, NEPA requires that an agency conduct an EIS in order to ensure that the agency “will not act on incomplete information, only to regret its decision after it is too late to correct.”¹³⁹ NEPA requires federal agencies to analyze not only the direct impacts associated with a proposed action, but also the indirect and cumulative impacts.¹⁴⁰ The statute deliberately casts a wide net—and defines broadly the environmental impacts to be evaluated. It is therefore somewhat astonishing that the agency claimed that it could fulfill its NEPA obligations by evaluating glyphosate-resistant crops without considering the effect that increased glyphosate use would have on the evolution of weed resistance.

132. Green, *supra* note 109, at 108.

133. USDA-APHIS, PLANT PEST RISK ASSESSMENT OF EVEN H7-1 SUGAR BEET 3, http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_pea.pdf (last visited Apr. 25, 2013).

134. USDA-APHIS, ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT MONSANTO CO. AND KWS SAAT AG PETITION 03-323-01P, FOR DETERMINATION OF NON-REGULATED STATUS FOR ROUNDUP READY SUGAR BEET EVENT H7-1 3 (2004), http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_pea.pdf.

135. The National Environmental Policy Act (NEPA) is “our basic national charter for protection of the environment.” 40 C.F.R. § 1500.1(a). NEPA directs federal agencies to prepare an EIS before undertaking “major Federal actions significantly affecting the quality of the human environment.” 42 U.S.C. § 4332(2)(C).

136. *Geertson Seed Farms v. Johanns*, 2007 WL 518624, at *1 (N.D. Cal. Feb. 13, 2007), *aff’d*, 570 F.3d 1130 (9th Cir. 2009), *rev’d sub nom. on other grounds*, *Monsanto Co. v. Geertson Seed Farms*, 130 S.Ct. 2473 (2010).

137. *Andrus v. Sierra Club*, 442 U.S. 347, 350 (1979).

138. *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1216 (9th Cir. 1998).

139. *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 371 (1989).

140. 42 U.S.C. § 4332(C); 40 C.F.R. §§ 1508.7, 1508.8(b).

In a February 2007 decision, the Northern District of California issued a stinging rebuke of the agency's "cavalier" treatment of this serious question in *Geertson Seed Farms v. Johanns*.¹⁴¹ In particular, the court applied that adjective to APHIS's explanation for its decision not to require an EIS, which hinged on the assertion that "weed species often develop resistance to herbicides."¹⁴² The *Geertson Seed Farms* court noted that although "one would expect that some federal agency is considering whether there is some risk to engineering all of America's crops to include the gene that confers resistance to glyphosate,"¹⁴³ it is not at all clear that any agency has explored this question, or even considers the question to be within its regulatory jurisdiction.

The court decried APHIS's failure to consider the cumulative impacts of its decision to deregulate glyphosate-resistant GM crops. The court noted that "[w]hile the deregulation of one crop in and of itself might not pose a significant risk for the development of glyphosate resistant weeds, when all the crops are considered cumulatively such a risk may become apparent."¹⁴⁴ Thus, the court found that APHIS had failed to take the "hard look" required under NEPA.¹⁴⁵

After conducting the court ordered EIS, APHIS concluded in 2011 that Roundup Ready alfalfa "is unlikely to pose a greater plant pest risk than . . . other unmodified" alfalfa varieties even after acknowledging the risks and impacts of gene flow, increased herbicide use, threats to endangered species, and various socioeconomic impacts.¹⁴⁶ APHIS's rationale was that it had no authority under the Plant Protection Act to regulate herbicide use associated with glyphosate-tolerant plants, and that the EPA had concluded "there is no unreasonable environmental risk if the [glyphosate] user adheres to the labeled directions."¹⁴⁷ Readers should be clear about what that means. Based on the EPA's decision to register the pesticide *at all*, APHIS concluded that the particular use of glyphosate associated with

141. *Geertson Seed Farms v. Johanns*, 2007 WL 518624, at *1.

142. *Id.*; see also, USDA-APHIS, ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT: MONSANTO COMPANY AND FORAGE GENETICS INTERNATIONAL PETITION 04-110-01P FOR NONREGULATED STATUS FOR ROUNDUP READY ALFALFA EVENTS J101 AND J163 6 (2005), http://www.aphis.usda.gov/brs/aphisdocs2/04_11001p_com.pdf ("Some commenters are concerned that glyphosate use on glyphosate tolerant alfalfa may result in additional glyphosate resistant weeds. APHIS agrees that this may occur. Weed species have developed resistance to every widely used herbicide.").

143. *Geertson Seed Farms*, 2007 WL 518624, at *11.

144. *Id.* at *10, *12.

145. *Id.* at *12.

146. ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT: MONSANTO COMPANY AND FORAGE GENETICS INTERNATIONAL PETITION 04-110-01P FOR NONREGULATED STATUS FOR ROUNDUP READY ALFALFA EVENTS J101 AND J163 6, at v-vii.

147. *Id.* at vi.

Roundup Ready alfalfa production will not adversely impact the environment.¹⁴⁸

APHIS's plant pest evaluation of Roundup Ready sugar beets was even more flimsy. It did not even address the problem of increased weed resistance, focusing instead only on the likelihood that the genetically engineered sugar beet would itself become a weed.¹⁴⁹

To be clear, this means that no regulator considers the cumulative environmental impacts of glyphosate use before glyphosate-resistant crops are approved for market even though the entire *raison d'être* for these plants is their tolerance to glyphosate. Monsanto markets—and farmers purchase—these seeds *because* the fields can be treated with glyphosate. The fact that these plants will be sprayed with glyphosate is their most salient characteristic—one that should be front and center in any assessment of this technology's environmental impact. It makes no sense to evaluate the potentials for impacts to the human environment from these crops while excluding as somehow unrelated glyphosate use in conjunction with these plants.

This absurd result flows directly from the thirty-year-old choice to regulate the products of genetic engineering without creating any new laws. The EPA's sole regulatory authority is to decide whether to register the herbicide glyphosate for sale at all.¹⁵⁰ While the EPA has authority over glyphosate, it has no authority to regulate the plantings of glyphosate-tolerant crops, or to regulate the actual pesticide use associated with those crops.¹⁵¹ The USDA-APHIS does have authority over the plants, but considers the use of glyphosate in conjunction with those plants to be outside its regulatory authority.¹⁵² As a result, glyphosate-tolerant crops have been deregulated without considering whether growing these crops will increase or change glyphosate use.¹⁵³

The evolution of weed resistance from overplanting glyphosate-resistant crops is entirely predictable, and thoroughly well-understood. Indeed, critics have been vocal since the mid-1990s about this risk. Agency neglect of this obvious and critical environmental issue was perhaps less

148. *Id.*

149. USDA-APHIS, PLANT RISK ASSESSMENT OF EVENT H7-1 SUGAR BEET, *supra* note 133, at 8–11.

150. See 7 U.S.C. § 136a(a) (describing EPA's pesticide regulatory authority).

151. See *id.* (authorizing EPA to approve pesticides for sale).

152. USDA-APHIS, FINAL EIS FOR ROUNDUP READY ALFALA, *supra* note 134, at vi.

153. In assessing the likelihood that glyphosate-resistant sugar beets would change cultivation practices, USDA notes that “[o]ther than the use of glyphosate to control weeds, none of the management practices currently employed for conventional sugar beet cultivation is expected to change.” USDA-APHIS, PLANT RISK ASSESSMENT OF EVENT H7-1 SUGAR BEET, *supra* note 133, at 11.

blameworthy in the early days of GE crops, when regulators were writing on something of a *tabula rasa*. However, it is astonishing that even as “superweeds” resistant to glyphosate continue to proliferate, the regulatory scheme is unable to catch up. This massive regulatory gap means that a major and obvious environmental impact of these crops remains unexamined. There is no question that widespread planting of yet-another glyphosate crop can only worsen the well-documented and growing problem of glyphosate-resistant weeds. A regulatory system that cannot, or will not, analyze the cumulative effects of glyphosate-resistant crops on the development of glyphosate-resistant weeds in deciding whether to approve commercialization of these crops defies logic. Whatever other adjectives might apply to this decision, “scientific” is surely not one of them.

APHIS artificially limits its inquiry to an assessment of whether the GE plant poses a greater plant pest risk than an equivalent non-GE organism. In making this assessment, APHIS considers each modified plant in isolation, rather than for cumulative impacts in conjunction with use of the glyphosate herbicide that these plants have been engineered to tolerate.¹⁵⁴ Concluding that each such engineered plant, in isolation, poses no greater plant pest risk than its unmodified counterpart, APHIS has routinely approved petitions for deregulated status. Once a crop is granted deregulated status it can be planted anywhere in the country.

B. Social and Economic Impacts of the Technology: Grower Inability to Grow Organic or Conventional Crops because of Pollen Drift

A second major gap in the regulatory oversight of glyphosate-resistant crops has been the regulators’ failure to address the problems associated with pollen drift—specifically the potential for GE crops to contaminate nearby fields. This concern particularly impacts organic farmers, but is increasingly a concern in a globalized commodity market because the United States allows production of many GE varieties not approved for sale in the European Union, Japan, and other major markets.¹⁵⁵ Even though this impact from GE crops is well documented and obvious, the convoluted regulatory scheme created by the Coordinated Framework virtually assures that it goes unconsidered.

154. *Geertson Seed Farms v. Johanns*, 2007 WL 518624, at *10 (N.D. Cal. Feb. 13, 2007), *aff’d*, 570 F.3d 1130 (9th Cir. 2009), *rev’d sub nom. on other grounds*, *Monsanto Co. v. Geertson Seed Farms*, 130 S.Ct. 2473 (2010).

155. *See, e.g., id.* (discussing alfalfa farmers concerns of contaminated crops when 75% of U.S. exported alfalfa is exported to Japan, which does not permit glyphosate tolerant alfalfa).

In two recent deregulation decisions, the USDA-APHIS took the position that it was not required to consider this question before approving glyphosate-resistant crops.¹⁵⁶ The agency's rationale was that NEPA directed the agency only to consider physical environmental harms and not social or economic harms flowing from physical environmental impacts.¹⁵⁷ Moreover, the USDA-APHIS also interpreted its Plant Protection Act authority narrowly to avoid treating cross-contamination as an "indirect" plant pest risk under the Act.¹⁵⁸

Two different federal courts rejected this interpretation of the agency's regulatory authority.¹⁵⁹ The *Center for Food Safety* court characterized the USDA-APHIS's treatment of this issue as "cursory."¹⁶⁰ The *Geertson Seed Farms* court found the agency's analysis to be "wholly inadequate."¹⁶¹ In both cases, the USDA-APHIS's refusal to consider the question of pollen drift and cross-contamination issue drew sharp judicial rebuke.

Both courts began with the proposition that NEPA directs federal agencies to prepare an EIS before undertaking "major Federal actions significantly affecting the quality of the human environment."¹⁶² The courts noted that "human environment" has been comprehensively interpreted "to include the natural and physical environment and *the relationship of people with that environment*."¹⁶³ To determine whether NEPA requires an agency to consider a particular effect, the Supreme Court has directed agencies to "look at the relationship between that effect and the change in the physical environment caused by the major federal action at issue."¹⁶⁴ The plaintiffs in both cases succeeded in persuading federal courts that this capacious

156. *Id.* at *7; *Ctr. for Food Safety v. Vilsack*, No. C 08-00484 JSW, 2009 WL 3047227, at *8 (N.D. Cal. Sept. 21, 2009).

157. *Geertson Seed Farms*, 2007 WL 518624, at *7.

158. *Id.* at *6 (discussing how APHIS did not determine that no cross-contamination would occur; rather, it interpreted the responsibility for preventing cross-contamination as belonging to farmers themselves—that is, even though APHIS did not contemplate how farmers could prevent cross-contamination, farmers are still responsible for preventing their own crops from undergoing contamination).

159. *Id.* at *9.

160. *Ctr. for Food Safety*, 2009 WL 3047227, at *8–9 (noting that APHIS offered the following "conclusory" statement in the EA:

It is not likely that organic farmers, or other farmers who chose not to plant transgenic varieties or sell transgenic sugar beets, will be significantly impacted by the expected commercial use of this product since: (a) non-transgenic sugar beet will likely still be sold and will be available to those who wish to plant it; (b) farmers purchasing seed will know this product is transgenic because it will be marked and labeled as glyphosate tolerant.)

161. *Geertson Seed Farms*, 2007 WL 518624, at *7.

162. 42 U.S.C. § 4332(2)(C).

163. CEQ Definition of Human Environment, 40 C.F.R. § 1508.14 (1978) (emphasis added).

164. *Metro. Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 773 (1983).

definition gave the agency scope to consider and address the desire of organic and conventional farmers not to have their fields and crops contaminated with GE pollen.¹⁶⁵ By ignoring this question, the USDA-APHIS failed to take the requisite “hard look” at the economic impacts of its deregulation determination on conventional and organic farmers.¹⁶⁶

The courts directed the USDA-APHIS to go back to the drawing board and to consider whether pollen flows from fields planted with GE crops to those growing conventional or organic crops was an unacceptable environmental impact.¹⁶⁷ Embedded in this inquiry was an important subtext: Who should bear the costs and risks associated with avoiding this impact?¹⁶⁸ The *Center for Food Safety* allegations that wind-blown pollen from GE sugar beets would contaminate conventional sugar beets and other closely related crops, such as chard and red table beets placed this question squarely before the court.¹⁶⁹ The *Geertson Seed Farms* court found that cross-contamination of seed alfalfa was not only a “realistic potential” but “especially likely” given the geographic concentration of alfalfa seed production.¹⁷⁰

Conventional and organic growers expressed concern that if Roundup Ready sugar beets and alfalfa were deregulated, pollen from the GE crops would contaminate their fields.¹⁷¹ The consequences of this pollen flow¹⁷²

165. In *Geertson Seed Farms*, for example, the court concluded that “the economic effects on the organic and conventional farmers of the government’s deregulation decision are interrelated with, and, indeed, a direct result of, the effect on the physical environment.” *Geertson Seed Farms*, 2007 WL 518624, at *8.

166. *Id.*

167. *Id.* at *12.

168. *Id.* at *6 (raising concerns that conventional farmers were being forced to bear the burden of preventing cross-contamination to their own crops).

169. Complaint for Decl. & Injunctive Relief at ¶ 2 *Ctr. for Food Safety v. Conner*, No. C 08-00484 JSW, 2009 WL 4724033 (N.D. Cal. 2008), <http://www.centerforfoodsafety.org/pubs/Final%20Complaint.pdf>. Upon his January 2009 appointment as Secretary of Agriculture, Tom Vilsack replaced acting-Secretary Charles Conner as the named defendant.

170. *Geertson Seed Farms*, 2007 WL 518624, at *5.

171. *Id.* at *2.

172. Monsanto’s Technology/Stewardship Agreement with its growers shifts all risk of liability for cross-contamination to the growers themselves. The 2011 Monsanto Technology/Stewardship Agreement provides, in relevant part:

REMEDY OF THE GROWER AND THE LIMIT OF THE LIABILITY OF MONSANTO OR ANY SELLER FOR ANY AND ALL LOSSES, INJURY OR DAMAGES RESULTING FROM THE USE OR HANDLING OF SEED (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, PRODUCT LIABILITY, STRICT LIABILITY, TORT, OR OTHERWISE) SHALL BE THE PRICE PAID BY THE GROWER FOR THE QUANTITY OF THE SEED INVOLVED OR, AT THE ELECTION OF MONSANTO OR THE SEED SELLER, THE REPLACEMENT OF THE SEED. IN NO EVENT SHALL MONSANTO OR ANY SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE DAMAGES.

would be very serious for those growers—contamination can result in organic farmers losing their organic status, and can subject conventional or organic growers to patent-infringement claims if GE crops are found, even inadvertently, on their land.¹⁷³ In addition, cross-contamination can disrupt export markets because many GE crops approved in the United States are not similarly approved in the European Union, Japan, and other major markets.¹⁷⁴

The deregulation decision was the critical moment to address this issue of cross-contamination because it was the only moment at which the agency had the ability to impose isolation distances on the growers of the GE crops. Once a crop is granted deregulated status, it can be planted anywhere in the country.¹⁷⁵ But, if the USDA-APHIS concluded that the problem of contamination was a significant one, it could have decided to approve a partial deregulation that allowed glyphosate resistant crops to be grown only in certain geographic areas, or under certain conditions, including isolation distances from conventional or organic crops.¹⁷⁶ The deregulation petition was thus a “now-or-never” moment for considering the question of cross-contamination. Yet, even after finding that the agency’s sugar beet

2011 *Monsanto Technology/Stewardship Agreement*, WORDPRESS.COM, http://thefarmerslife.files.wordpress.com/2012/02/scan_doc0004.pdf (capitals in original) (last visited April 25, 2013).

173. Between 1997–2010, Monsanto filed 144 patent infringement lawsuits against US farmers, with at least 700 and maybe thousands of cases settled out of court. This issue is of such concern that growers sought to protect themselves with a pre-emptive suit seeking to enjoin Monsanto from suing them for patent infringement based on pollen drift. *See Organic Seed Growers & Trade Ass’n v. Monsanto Co.*, 851 F. Supp. 2d 544, 547–49 (S.D.N.Y. 2012) (seeking declaratory judgment that farmers, seed companies, and organizations are not infringing on Monsanto’s patents, that those patents are unenforceable, and even if they are enforceable, Monsanto is not entitled to remedies against farmers, seed companies, and organizations). The case was dismissed in February 2012 for lack of standing and is currently on appeal to the Second Circuit.

174. This concern was particularly acute for alfalfa because 75% of the alfalfa exported from the United States goes to Japan, and Japan does not permit the import of glyphosate-resistant alfalfa. *Geertson Seed Farms*, 2007 WL 518624, at *2. In its deregulation determination issued after this litigation, USDA-APHIS acknowledged that “the extent to which GE sensitive domestic and foreign markets are affected by GT alfalfa deregulation depends on the extent to which gene flow can be controlled through stewardship programs.” USDA-APHIS, RECORD OF DECISION: GLYPHOSATE-TOLERANT ALFALFA EVENTS J101 AND J163: REQUEST FOR NONREGULATED STATUS 13 (2011). Without demanding any showing about the possibility or effectiveness of stewardship programs, USDA used the possibility of such programs to disregard this clear environmental and social impact from deregulating a GM crop.

175. *Geertson Seed Farms*, 2007 WL 518624, at *3.

176. USDA-APHIS, FINAL ENVIRONMENTAL IMPACT ASSESSMENT: GLYPHOSATE-TOLERANT ALFALFA EVENTS J-101 AND J-163: REQUEST FOR NONREGULATED STATUS 10–16 (2010), <http://blogs.desmoinesregister.com/dmr/wp-content/uploads/2010/12/AlfalfaEIS.pdf>; USDA-APHIS, FINAL ENVIRONMENTAL IMPACT ASSESSMENT: H7-1 SUGAR BEET: REQUEST FOR NONREGULATED STATUS 20–32 (May 2012), available at http://www.aphis.usda.gov/biotechnology/sugarbeet_documents.shtml.

decision violated NEPA,¹⁷⁷ the *Center for Food Safety* court expressed concern that the agency was still “not taking the process seriously.”¹⁷⁸

The USDA-APHIS did not dispute that cross-contamination had already occurred and might continue to occur. The agency nevertheless decided to deregulate the glyphosate-tolerant crops despite this problem.¹⁷⁹ The USDA-APHIS justified deregulating these crops by concluding that such cross-contamination did not amount to a significant environmental impact because it was the organic and conventional farmer who had the burden of preventing contamination, not the farmer planting glyphosate-resistant crops.¹⁸⁰ The agency made no inquiry into whether those farmers who do not want to grow GE alfalfa or GE sugar beets could, in fact, protect their crops from contamination.¹⁸¹ Instead, in both cases, the USDA-APHIS concluded that the risk of gene transmission was not significant because “organic production operations must develop and maintain an organic production system plan that outlines the steps it will take to avoid cross pollination from neighboring operations.”¹⁸²

Once again, claims that regulation of these crops is science-based crumble on closer examination. The agency simply assumed, without investigation, that farmers intending to grow conventional or organic crops would be able to cope with the effects of cross-contamination. Indeed, the agency noted that it would be up to the individual organic or conventional grower to take measures to assure that their crops will not include any GE contamination.¹⁸³ In other words, the agency dodged the question by placing the responsibility squarely on those who objected to cross-contamination without considering whether it was possible for those actors to prevent cross-contamination. Whatever else this decision is, it is hardly an example of evidence-driven, scientific regulation.

177. *Ctr. for Food Safety v. Vilsack*, No. C 08-00484 JSW, 2009 WL 3047227, at *9 (N.D. Cal. Sept. 21, 2009).

178. *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 953 (N.D. Cal. 2010).

179. USDA-APHIS, FINAL EIS FOR ROUNDUP READY ALFALA, *supra* note 176, at 10–16; USDA-APHIS, SUGAR BEET FINAL EIS, *supra* note 176, at 20–32.

180. USDA-APHIS, FINAL EIS FOR ROUNDUP READY ALFALA, *supra* note 176, at 15.

181. *Geertson Seed Farms*, 2007 WL 518624, at *6.

182. USDA-APHIS, ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT: MONSANTO COMPANY AND FORAGE GENETICS INTERNATIONAL PETITION 04-110-01P FOR NONREGULATED STATUS FOR ROUNDUP READY ALFALFA EVENTS J101 AND J163 2 (2005) http://www.aphis.usda.gov/brs/aphisdocs2/04_11001p_com.pdf; USDA-APHIS, ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT MONSANTO CO. AND KWS SAAT AG PETITION 03-323-01P, FOR DETERMINATION OF NON-REGULATED STATUS FOR ROUNDUP READY SUGAR BEET EVENT H7-1 13 (2004), http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_pea.pdf.

183. USDA-APHIS, FINDING OF NO SIGNIFICANT IMPACT FOR ROUNDUP READY ALFALFA, *supra* note 182.

C. *Consumer Disempowerment: Lack of Transparency*

In 2003, the European Union adopted regulations establishing a system to trace and label genetically modified organisms (GMOs) and to regulate the sale and labeling of food derived from them.¹⁸⁴ In 2008, the European Union reaffirmed the need for labeling thresholds for GMOs in conventional seeds, emphasizing that the thresholds must be set at the lowest practicable levels in order to ensure freedom of choice for producers and consumers.¹⁸⁵

In the United States, by contrast, there are no labeling requirements of any kind for GE foods. This remains the case even though polls consistently show that the majority of Americans support labeling of GE foods. Indeed, in a 2010 Thompson Reuters poll, 93% of respondents thought that foods should be labeled to indicate that they have been genetically engineered or contain GE ingredients.¹⁸⁶ This desire for labels did not necessarily mean that surveyed consumers wanted to avoid these products—60% expressed a willingness to eat GE vegetables, fruits, and grains but far fewer, 35–38%, were willing to eat GE animals.¹⁸⁷ The overwhelming support for labeling must therefore be read as a desire for transparency—a vote in favor of the Right to Know. For labeling advocates, the issue is “the fundamental right to know about the food we eat.”¹⁸⁸ Without access to key information, consumers have no means for expressing their preferences in a market economy. By contrast, Monsanto argues that “[r]equiring labeling for ingredients that don’t pose a health issue would undermine both our labeling laws and consumer confidence.”¹⁸⁹

Monsanto’s position might have been tenable if the risk assessment process for these novel foods was a transparent, public process in which concerned citizens could participate and review a well-developed body of safety information. However, no such process exists in the United States. Purveyors of these products make a GRAS determination on their own,

184. Council of the European Union, Genetically Modified Organisms (GMOs): Council Conclusions, No. 16882/08 of 5 Dec. 2008, <http://register.consilium.europa.eu/pdf/en/08/st16/st16882.en08.pdf>.

185. Council of the European Union, Genetically Modified Organisms – Council Conclusions, No. 16882/08 of Dec. 2008, <http://earthopensource.org/files/pdfs/EU-Commission-draft-GMO-regulation/Environment-Council-conclusions-GMO-4-12-08.pdf>

186. THOMPSON REUTERS, *supra* note 104.

187. *Id.*

188. *Bill Maher Show on GMO Labeling Features Just Label It Chair Gary Hirshberg*, Article in *Press Room*, JUST LABEL IT! (Oct. 19, 2012), <http://justlabelit.org/press-room> (quoting Just Label It Chair Gary Hirshberg).

189. *What’s the Problem With Labeling Genetically-Modified (GM/GMO) Foods?*, MONSANTO (June 21, 2012), <http://www.monsanto.com/newsviews/Pages/food-labeling.aspx>.

deciding whether the foods are substantially equivalent to non-modified foods.¹⁹⁰ Although these actors may consult with the FDA, they have no obligation to do so, nor do they have an obligation to present a full and complete record of all their data—including negative data—to the agency.¹⁹¹ Moreover, because companies claim that much of the submitted information amounts to confidential business information under the Trade Secrets Act, the FDA cannot make much of the information it does receive available to the public.¹⁹²

Why should consumers trust such a secretive process? It is a lack of transparency and perceived lack of democratic legitimacy that drives the labeling demand. The organization *Just Label It* has submitted a citizens' petition signed by more than one million citizens requesting that the FDA engage in rulemaking to require labeling of GE foods.¹⁹³ To date, the FDA has taken no action.

In the absence of federal action on this point, a number of states have expressed an interest in using state law to require labeling of GE foods.¹⁹⁴ Rather than recognizing and meeting a genuine demand for information, industry has not hesitated to spend liberally to thwart these measures.¹⁹⁵

The most recent example of how industry has flexed its muscles to prevent labeling was California's Proposition 37. Proposition 37 would have redefined "misbranded food" to include any food either produced by genetic engineering or containing an ingredient produced by genetic engineering unless the food was labeled accordingly.¹⁹⁶ The measure would also have prohibited any food produced with genetic engineering from being labeled "natural."¹⁹⁷ The "No on 37" campaign had the backing of large agribusiness and chemical companies.¹⁹⁸ The "Yes on 37" campaign

190. See *supra* Part III A (describing developer driven consultations for genetically modified foods).

191. *Id.*

192. EPA also struggles with the trade secrets issue. ENV'T'L PROT. AGENCY, FIFRA INFORMATION SECURITY MANUAL, http://www.epa.gov/oamhpod1/oppts_grp/0913541/ism.pdf (last visited Apr. 25, 2013); Bratspies, *Glowing in the Dark*, *supra* note 39, at n. 164.

193. *Bill Maher Show*, *supra* note 188.

194. Stephanie Strom, *Genetic Changes to Food May Get Uniform Labeling*, N.Y. TIMES (Jan. 31, 2013), http://www.nytimes.com/2013/02/01/business/food-companies-meet-to-weigh-federal-label-for-gene-engineered-ingredients.html?ref=geneticallymodifiedfood&_r=0.

195. *Prop. 37: Genetically Engineered Foods*, VOTER'S EDGE CALIFORNIA (Nov. 6, 2012), <http://votersedge.org/california/ballot-measures/2012/november/prop-37/funding> (totaling industry spending on opposing Proposition 37 as \$46 million).

196. KCET, *Proposition 37: Read the Text* § 110809(a), <http://www.kcet.org/news/ballotbrief/elections2012/propositions/prop-37-read-the-text.html> (last visited Feb. 24, 2013).

197. *Id.* § 110809.1.

198. *Proposition 37*, *supra* note 196.

was supported largely by the organic industry, consumer groups, and alternative medicine organizations.¹⁹⁹

The ballot initiative was initially extremely popular, holding a two-to-one lead in the polls for much of the election season.²⁰⁰ In the weeks leading up to the election, the “No on 37” campaign spent \$46 million blanketing the state with “No on 37” ads and mailers.²⁰¹ By contrast, supporters of the initiative collected and spent just over \$9 million.²⁰² The ballot initiative was ultimately defeated 51.4% to 48.6%.²⁰³ A similar referendum initiative is on tap in Washington State, while Vermont and Connecticut both considered legislative measures that would have required similar labeling.²⁰⁴ Both legislative measures were tabled after Monsanto threatened lawsuits.²⁰⁵ The industry argument against labeling boils down to the assertion that despite expressed consumer interest in obtaining this information, they are not entitled to the information because it is not relevant. And, the main reason that the information is not relevant is that these crops are the substantial equivalent of unmodified crops—a decision made behind closed doors by the very entities opposing the right to know. In short, consumers have no right to know this information because the industry has decided that there are no risks.

The industry desire for secrecy extends from consumers to growers. For many decades prior to genetic engineering, farmers relied on university agriculture extension scientists to perform tests comparing new and standard crop varieties.²⁰⁶ But it is increasingly difficult for university

199. *Id.*

200. Andrew Pollack, *After Loss, The Fight to Label Modified Food Continues*, N.Y. TIMES (Nov. 7, 2013), http://www.nytimes.com/2012/11/08/business/california-bid-to-label-genetically-modified-crops.html?_r=odgwh=7CD7AE29C0ECJA4976BEEC4B3615B355.

201. Producers of genetically-engineered crops, and major food processors funded the No on 37 campaign. Monsanto alone contributed over \$8 million—17% of the campaign’s total funding. DuPont contributed more than \$5 million. Dow, Kraft, Syngenta, Bayer CropScience, Pepsico, BASF Plant Science and the Grocery Manufacturers Association all contributed at least \$2 million each. All told, the top ten contributors, all agribusiness or food manufacturers contributed \$25 million dollars to defeat the initiative. Other large food producers, including Nestle, BumbleBee, Ocean Spray, Unilever Land’O’Lake, Heinz, CocaCola and Del Monte also made sizeable contributions to defeat the measure. *Prop. 37*, VOTERSEGDGE.ORG, <http://votersedge.org/california/ballot-measures/2012/november/prop-37/funding>. *Proposition 37*, *supra* note 196.

202. *Id.*

203. STATE BALLOT MEASURES 69 (2012), <http://www.sos.ca.gov/elections/sov/2012-general/15-ballot-measures.pdf>

204. Strom, *supra* note 194.

205. Anne Sewell, *GMO ‘Right to Know’ Campaign in CT fails-Lawsuit threatened*, DIGITAL JOURNAL (May 5, 2012), <http://www.digitaljournal.com/article/324345>.

206. Andrew Pollack, *Crop Scientists Say Biotechnology Seed Companies are Thwarting Research*, N.Y. TIMES (Feb. 20, 2009), http://www.nytimes.com/2009/02/20/business/20crop.html?_r=0 (describing industry’s chokehold on research).

scientists to evaluate GE seed varieties because they are prohibited from doing research on patented GE crops without company permission.²⁰⁷ And when scientists do receive permission to do research, it is usually with strings attached that restrict the usefulness of the studies for comparing crop varieties.²⁰⁸ Indeed, the situation has gotten so bad that, in a public statement to the EPA, twenty-six eminent entomologists warned that as a result of industry restrictions on access to GE seeds for research purposes, “no truly independent research can be legally conducted on many critical questions regarding the technology, its performance, [and] its management implications.”²⁰⁹

This chokehold on research gives companies “the potential to launder the data . . . [and] information that is submitted”²¹⁰ for agency consideration. With all information tightly controlled by an industry that doles out research permission based on perceived favorability of results, and whether the researcher is “friendly” or “hostile”²¹¹ is it any wonder that the public is suspicious?

This lack of information is particularly ironic given that the USDA and the EPA both identify transparency as a core value.²¹² Yet, in the context of GE crops, the agencies have not taken steps to promote much transparency. For example, the EPA could easily require that as a condition for registration of a *Bt* plant, the purveyor must agree to give university scientists unfettered research access to seeds. The USDA could do the same in its deregulation decisions. In refusing to take these basic transparency positions, the regulators have aligned themselves with industry in opposition to any moves toward transparency, including labeling.

IV. CONCLUSION

The United States regulatory system for genetically engineered crops is riddled with major gaps and omissions. Omitted from the regulatory inquiry

207. *Id.*

208. *Id.*

209. *Evaluation of the Resistance Risks from using a Seed Mix Refuge with Pioneer’s Optimum Acremax I Corn Rootworm-Protected Corn*, EPA-HQ-OPP-2008-0836-0043 (Feb 22, 2009).

210. Pollack, *supra* note 206 (quoting Elson J. Shields, a professor of entomology at Cornell University).

211. *See Do Seed Companies Control GM Crop Research?*, SCIENTIFICAMERICAN.COM (Aug. 13, 2009), <http://www.scientificamerican.com/article.cfm?id=do-seed-companies-control-gm-crop-research> (discussing how funding for research on genetically modified seeds is swayed by the seed industry’s perception of whether a scientist’s research is favorable to their industry).

212. USDA, STRATEGIC PLAN, *supra* note 17, at iv. ; EPA, FISCAL YEAR 2011-2015 STRATEGIC PLAN: ACHIEVING OUR VISION 1 (2010), <http://nepis.epa.gov/Adobe/PDF/P1008YOS.PDF>.

are systemic environmental issues²¹³ including the possibility of gene transfer to non-genetically engineered plants through cross-pollination; the cumulative effects of multiple genetically engineered crops on the evolution of pest resistance; and the probability of increased herbicide use. The neglected environmental, social, and economic issues have contributed to a profound lack of regulatory transparency in the regulation of genetically engineered crops, and the resulting erosion of trust in government more generally.

Nothing shatters public confidence in a regulatory system more than the sense that obvious public interests and concerns are not being addressed. The time is ripe to improve the regulation of agricultural biotechnology. It is past time to consider whether we can establish a rigorous regulatory process that independently reviews and approves products that are safe for consumers and the environment. Such a system is essential if consumers are to have confidence in biotechnology going forward.

213. Other neglected issues include, the effect of these crops on endangered species, the possibility of long-term, low-level health effects, epigenetic effects, and the impact that concentrated control over the food supply has on food security.