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# *Center for Food Safety v. Vilsack:* Roundup Ready Regulations

## INTRODUCTION

On September 21, 2009, the Northern District of California held that the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) violated the National Environmental Policy Act (NEPA) by deregulating a genetically engineered (GE) variety of sugar beets without first taking a "hard look" at the environmental impact of its introduction.<sup>1</sup> The decision, which turned on the potential socio-economic impact deregulation would have on producers of non-GE sugar beets and related crops, has been heralded by advocates for tighter controls on GE food as an important victory, and interpreted as a sign that these groups might be able to achieve through federal courts what they have been unable to achieve through Congress or the regulatory agencies.<sup>2</sup> However, celebration may be premature. Subsequent developments surrounding *Geertson Seed Farms v. Johanns*,<sup>3</sup> a case involving APHIS's deregulation of Roundup Ready alfalfa, raise questions about the capacity of federal courts to bring about the sought-for substantive regulatory changes.

## I. BACKGROUND

In just over a decade, GE food has become dominant in agriculture, both domestically and abroad.<sup>4</sup> Some suggest that the magnitude and speed of GE's transformation of agricultural production is unmatched in history, save for the introduction of the tractor in the 1800s.<sup>5</sup> Monsanto's

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1. *Center for Food Safety v. Vilsack*, No. C 08-00484 JW, 2009 WL 3047227, at \*6 (N.D. Cal. Sept. 21, 2009).

2. *See infra* notes 42–43 and accompanying text.

3. *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007), *aff'd*, 570 F.3d 1130 (9th Cir. 2009), *cert. granted sub nom.* *Monsanto Co. v. Geertson Seed Farms*, No. 09-475, 2010 WL 144075 (U.S. Jan. 15, 2010).

4. Professor Debra Strauss, writing in 2007, notes that, "since biotech crops were first commercialized in 1996, the global biotech crop area has increased more than fifty-fold." Debra Strauss, *Defying Nature: The Ethical Implications of Genetically Modified Plants*, 3 J. OF FOOD L. & POL'Y 5, 6 (2007).

5. *Id.*

Roundup Ready seeds, engineered to resist Monsanto's patented Roundup herbicide, are among the most widely used GE products, particularly for commodities like corn and soy beans.<sup>6</sup> Moreover, Monsanto's influence is magnified by its licensing of the Roundup Ready gene to other companies for use in their seeds, including the sugar beets at issue in *Center for Food Safety*.<sup>7</sup>

GE food has generated significant opposition.<sup>8</sup> Farmers, consumers, and scholars who object to the introduction of these products into food systems have sought increased scrutiny over this technology.<sup>9</sup> These advocates seek substantially stronger regulatory mechanisms to control and monitor this new, unproven technology and to counter the threat of potential devastation posed by its introduction.<sup>10</sup> They point to effective schemes abroad, most notably in Europe, which exercise stronger regulatory measures, ranging from mandated labeling of GE foods to outright bans, until proven completely safe for consumers, farming, and

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6. For instance, in 2009, just the second year that the Roundup Ready sugar beets at issue in *Center for Food Safety* were planted commercially, genetically modified beets already accounted for 95 percent of total sugar beet cultivation. Andrew Pollack, *Judge Rejects US Approval of Biotech Sugar Beets*, N.Y. TIMES, Sept. 23, 2009. Over 87 percent of the Soybeans planted in 2005 were Monsanto's Roundup Ready Soybeans. Elizabeth I. Winston, *What if Seeds were not Patentable?*, 2008 MICH. ST. L. REV. 321, 330.

7. Pollack, *supra* note 6.

8. See generally John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 813–18 (2001) (evaluating the political and legal opposition to GE foods in the United States); Strauss, *supra* note 4, at 19–32 (articulating and defending ethical objections to GE foods).

9. For instance, many criticize the U.S. "patchwork" regulatory framework, under which the U.S. Department of Agriculture, Food and Drug Administration, and Environmental Protection Agency are each assigned a portion of the responsibility for regulating GE foods, leaving no agency looking at the big picture. Kunich, *supra* note 8, at 862–63 (comparing the current patchwork regulatory system to "forcing a nonspecialist to perform brain surgery with a fingernail clipper" because it forces these agencies to act beyond their expertise); see also Blake Denton, *Regulating the Regulators: The Increased Role for the Federal Judiciary in Monitoring the Debate over Genetically modified Crops*, 25 UCLA J. ENVTL. L. & POL'Y 333, 368 (2006–2007) ("the current regulatory system is typified by self-enforcement and lax regulations"); Gregory N. Mandel, *Toward Rational Regulation of Genetically Modified Food*, 4 SANTA CLARA J. INT'L L. 21 (2006).

10. The Center for Food Safety, the named plaintiff in this case, cites harms caused by GE crops to both human health ("Doctors around the world have warned that GE foods may cause unexpected health consequences that may take years to develop.") and the environment ("GE crops can harm beneficial insects, damage soils and transfer GE genes in the environment, thereby contaminating neighboring crops and potentially creating uncontrollable weeds.") Center for Food Safety, *Myths and Realities of GE Crops*, available at <http://truefoodnow.org/campaigns/genetically-engineered-foods/ge-crops/myths-realities-of-ge-crops/> (last visited Apr. 12, 2010).

natural ecosystems.<sup>11</sup> However, most domestic efforts towards substantive regulatory reform have been unsuccessful.<sup>12</sup>

The USDA's APHIS is charged with the regulation of "organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests."<sup>13</sup> APHIS's decision making is governed by NEPA's procedural rules,<sup>14</sup> which require federal agencies to "undertake analyses of the environmental impact of their proposals and actions."<sup>15</sup> Under NEPA, federal agencies must ask whether a proposed action will "significantly affect" the environment before proceeding.<sup>16</sup> Where the answer is uncertain or not categorically determinable, the agency must prepare an Environmental Assessment (EA), a "concise public document that briefly provide[s] sufficient evidence and analysis" to answer this threshold question.<sup>17</sup> If the EA finds that the proposed project will "significantly affect" the environment or may cause "significant degradation of some human environmental factor,"<sup>18</sup> the agency must prepare an Environmental Impact Statement (EIS) analyzing this effect in more detail prior to taking action.<sup>19</sup> If the EA finds no significant impact, the agency can proceed without further analysis.

Courts may set aside an agency's decision not to prepare an EIS where there is a showing that the decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."<sup>20</sup> Well

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11. Kunich, *supra* note 8, at 847–48.

12. Attorney Blake Denton writes that prior to the recent pattern of federal litigation, "the public seemed powerless to effect change in the GE regulatory system," while agencies "continued the long-standing American practice of writing off the public's concerns, by adopting a passive role and refusing to impose labeling requirements on GM food." Denton, *supra* note 9, at 368.

13. 7 C.F.R. § 340.0(a)(2) (2010).

14. *Center for Food Safety v. Vilsack*, No. C 08-00484 JW, 2009 WL 3047227, at \*4 (N.D. Cal. Sept. 21, 2009); 42 U.S.C. § 4321–4347 (2006).

15. *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 756–57 (2004).

16. *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1212 (9th Cir. 1998).

17. *Id.*

18. *Id.*

19. Federal agencies are required to

include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on: the environmental impact of the proposed action; any adverse environmental effects which cannot be avoided should the proposal be implemented; alternatives to the proposed action; the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

42 U.S.C. §§ 4332 (C)(i)-(v) (2006).

20. *Pub. Citizen*, 541 U.S. at 763 (quoting 5 U.S.C. § 706(2)(A) (2006)).

established precedents dictate that courts ensure the agency has taken a “hard look” at the environmental consequences of its action.<sup>21</sup>

## II. THE CASE

Approximately half of the sugar produced in the United States comes from sugar beets.<sup>22</sup> When Monsanto first introduced Roundup Ready sugar beets, APHIS categorized them as “regulated article[s],”<sup>23</sup> thereby prohibiting farmers from planting them without special permits.<sup>24</sup> Monsanto and others petitioned APHIS to deregulate Roundup Ready sugar beets.<sup>25</sup> Pursuant to NEPA, APHIS prepared an EA.<sup>26</sup> Because this report found that deregulating Roundup Ready sugar beets would produce no significant environmental impact, APHIS determined that it was unnecessary to prepare an EIS before deregulating Roundup Ready sugar beets.<sup>27</sup>

Judge Jeffrey S. White’s decision hinged on the potentially significant socio-economic impacts that deregulation of these crops could have on producers of non-GE sugar beets and some of its close genetic relatives, like red table beets and Swiss chard.<sup>28</sup> Although sugar beets are grown in a wide variety of locations—from California’s Imperial Valley to the Midwest—sugar beet *seed* is almost entirely cultivated in a single valley in Oregon.<sup>29</sup> The same is true for table beets and Swiss chard.<sup>30</sup>

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21. *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 962 (9th Cir. 2006); *see also* *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (holding that “the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment”); *Nat’l Lime Ass’n v. EPA*, 627 F.2d 416, 452–53 (D.C. Cir. 1980) (holding that judicial review of administrative decisions should “evinced a concern that variables be accounted for, that the representativeness of test conditions be ascertained, that the validity of tests be assured and the statistical significance of results determined”).

22. R. Johnson, *The Forecast Looks Sweet*, MONSANTO TODAY, (October 9, 2009), [http://www.monsanto.com/monsanto\\_today/2009/sweet\\_sugarbeet\\_forecast.asp](http://www.monsanto.com/monsanto_today/2009/sweet_sugarbeet_forecast.asp).

23. *Center for Food Safety v. Vilsack*, No. C 08-00484 JW, 2009 WL 3047227, at \*1 (N.D. Cal. Sept. 21, 2009).

24. These permits are obtainable only by submitting scientific evidence to be “carefully reviewed by APHIS scientists, provid[ing] details about the nature of the GE organism to be introduced and the conditions that will be used to prevent the spread and establishment of the organism in the environment.” Animal and Plant Health Inspection Service, Biotechnology, <http://www.aphis.usda.gov/biotechnology/permits.shtml> (last visited Feb. 14, 2010).

25. *Center for Food Safety*, 2009 WL 2047227, at \*1.

26. ANIMAL AND PLANT HEALTH INSPECTION SERVICE, ENVIRONMENTAL ASSESSMENT: MONSANTO COMPANY AND KWS SAAT AG PETITION 03-323-01P FOR DETERMINATION OF NON-REGULATED STATUS FOR ROUNDUP READY® SUGAR BEET EVENT H7-1 (2004), *available at* [http://www.aphis.usda.gov/brs/aphisdocs/03\\_32301p\\_pea.pdf](http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_pea.pdf) [hereinafter ENVIRONMENTAL ASSESSMENT].

27. *Id.*

28. *Center for Food Safety*, 2009 WL 3047227 at \*9.

29. *Id.*

30. *Id.*

Because these seeds are wind-pollinated, geographically concentrated, and closely genetically related, the court found that the Roundup Ready gene could migrate to non-GE seed, thereby contaminating the crop.<sup>31</sup> Although the EA recognized that gene migration between GE and conventional seed would likely occur, the agency nevertheless found “significant environmental impacts” unlikely.<sup>32</sup> Regarding the impact such gene migration might have on producers who sought to avoid GE foods, the EA flatly stated “it is not likely that organic farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic sugar beets, will be significantly impacted by the expected commercial use of this product . . . .”<sup>33</sup> APHIS later acknowledged that it had not fully analyzed this question in its EA, but argued that it was not “required to analyze the full socio-economic impacts of an action.”<sup>34</sup>

The court rejected APHIS’s narrow interpretation of the scope of its duties under NEPA.<sup>35</sup> Relying on *Geertson*, the court held that although economic effects are not generally covered by NEPA, these effects “are relevant and must be addressed in the environmental review when they are ‘interrelated’ with ‘natural or physical environmental effects.’”<sup>36</sup> Here, as in *Geertson*, the district court found that the rights of consumers and producers to choose to eat and produce non-GE foods was a socio-economic effect interrelated with environmental effects, and so must be considered in agency review.<sup>37</sup> Judge White found that the biological contamination by gene migration posed a risk of effectively eliminating the “farmer’s choice to grow non-genetically engineered crops, or a consumer’s choice to eat non-genetically engineered food . . . .”<sup>38</sup> Such a threat, the court reasoned, would, if realized, amount to a “significant effect on the human environment.”<sup>39</sup> Because APHIS did not adequately analyze this socio-economic impact in its EA, the court found that it had not taken a “hard look” at the environmental impact of its proposed deregulation as required under NEPA, and ordered it to prepare a more detailed EIS.<sup>40</sup>

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31. *Id.*

32. ENVIRONMENTAL ASSESSMENT, *supra* note 26, at 19–20.

33. *Id.* at 13.

34. *Center for Food Safety*, 2009 WL 3047227 at \*8.

35. *Id.* at \*8–9.

36. *Id.* at \*8 (citing *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 944 (9th Cir. 2005)) (emphasis in original).

37. *Id.* at \*9; *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), *cert. granted sub nom. Monsanto Co. v. Geertson Seed Farms*, No. 09-475, 2010 WL 144075 (U.S. Jan. 15, 2010).

38. *Center for Food Safety*, 2009 WL 3047227, at \*9.

39. *Id.*

40. *Id.*

## III. IMPLICATIONS

This decision has been called a “major consumer victory for preserving the right to grow and eat organic foods in the United States.”<sup>41</sup> Some have even interpreted it as a turning point in the way genetically modified foods are regulated.<sup>42</sup> However, developments in the ongoing *Geertson* case cast doubt on the meaning of this apparent victory for advocates of tighter regulations, and raise questions as to whether NEPA’s procedural tools are sufficient to achieve the substantive regulatory changes advocates seek.

*Geertson*, also a Northern District of California case, involved similar facts to the sugar beets case. The *Geertson* court found that APHIS had unlawfully deregulated Roundup Ready alfalfa without taking a “hard look” at the effects on non-GE producers and consumers, and ordered it to prepare an EIS.<sup>43</sup> The decision was accompanied by a temporary injunction against planting Roundup Ready alfalfa until APHIS prepared this report.<sup>44</sup> The Ninth Circuit affirmed the injunction, but the Supreme Court has granted a writ of certiorari. Supreme Court intervention could make it more difficult for advocates to get similar injunctions in the future.<sup>45</sup> However, regardless of how the Supreme Court decides, another development casts even more doubt on optimistic readings of the sugar beet case. APHIS issued a preliminary 1476-page draft EIS on Roundup Ready alfalfa on December 18, 2009, which found, once again, no significant impact from the proposed deregulation.<sup>46</sup>

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41. Heather Whitehead, *Victory! Court Finds USDA Violated Federal Law by Allowing Genetically Engineered Sugar Beets on the Market*, THE TRUE FOOD NETWORK (September 22, 2009), <http://truefoodnow.org/2009/09/22/victory-court-finds-usda-violated-federal-law-by-allowing-genetically-engineered-sugar-beets-on-the-market> (quoting Neil Carman of the Sierra Club).

42. The Center for Food Safety’s Executive Director Andrew Kimbrell stated that the ruling “made it clear that USDA’s job is to protect America’s farmers and consumers, not the interests of Monsanto.” *Id.* Denton, writing about an evolving pattern of successful federal litigation, including the *Geertson* case, noted that “activists may have found [in the federal courts] a new realm to voice their grievances about biotechnology.” Denton, *supra* note 9, at 367, 369. And, he surmised, through this kind of litigation, “the federal judiciary will come to be a crucial player in the discussion about GM crops.” *Id.*

43. *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), *cert. granted sub nom.* *Monsanto Co. v. Geertson Seed Farms*, No. 09-475, 2010 WL 144075 (U.S. Jan. 15, 2010).

44. *Id.* (enjoining farmers from planting Roundup Ready Alfalfa, not enjoining them from harvesting seeds already planted).

45. *Geertson*, 570 F.3d 1130 (9th Cir. 2009), *cert. granted sub nom.* *Monsanto Co. v. Geertson Seed Farms*, No. 09-475, 2010 WL 144075 (U.S. Jan 15, 2010).

46. ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DRAFT ENVIRONMENTAL IMPACT STATEMENT: GLYPHOSATE-TOLERANT ALFALFA EVENTS J101 AND J163: REQUEST FOR NONREGULATED STATUS (2009), *available at* [http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa\\_deis.pdf](http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa_deis.pdf) [hereinafter ENVIRONMENTAL IMPACT STATEMENT].

The section of the report evaluating “potential economic and social impacts of [Roundup Ready] alfalfa . . . on organic and conventional alfalfa farmers” begins by noting that APHIS did not receive any “specific economic data or information related to the economic ramifications for organic producers” to use in predicting the economic costs associated with organic alfalfa rejected from buyers “due to unintended presence of excluded methods [genetically engineered crops] . . . .”<sup>47</sup> Lacking data to fully quantify its analysis of the economic impact of possible gene transmission on organic or conventional alfalfa farmers, the EIS lays out the premises for such an analysis and details scenarios in which this alleged economic harm from gene-flow might occur to producers and consumers of conventional<sup>48</sup> and organic alfalfa.<sup>49</sup> Relying on earlier studies showing minimal impact of GE on the market for organic produce,<sup>50</sup> the wide availability of “common, reasonable practices,” which “provide many effective measures that greatly reduce the likelihood of accidental gene flow,”<sup>51</sup> and some revealing assumptions about the “philosophical” preferences of organic producers and consumers,<sup>52</sup> APHIS concludes that none of these scenarios is likely to result in serious economic harm.

APHIS’s use of these preferences is particularly telling, and raises questions about whether the litigation strategy pursued by anti-GE advocates is likely to achieve the sought-for regulatory changes. The EIS refers repeatedly to the “philosophical” factors or values that underlie the preferences and choices of organic consumers and producers.<sup>53</sup> Because these “philosophical” values are seen as transcending economic motivations, they insulate organic farmers and consumers from the pressures of the market. On this assumption, even if farmers faced an increase in gene flow prevention costs, the “philosophical” values make it unlikely that they will be forced out of the organic market.<sup>54</sup> By recognizing the lifestyle commitments behind the economic behavior of organic producers and consumers, the EIS actually undermines the basis for their claimed economic harm: “to the extent that organic farmers

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47. *Id.* at 132.

48. *Id.* at 125–31.

49. *Id.* at 132–40.

50. “The vast majority (92 percent) of U.S. organic farmers had not incurred any direct additional costs or incurred losses due to GE crops having been grown near their organically produced crops.” *Id.* at 135 (citing G. Brookes & P. Barfoot, *Global Impact of Biotech Crops: Socio-Economic and Environmental Effects in the First Ten Years of Commercial Use*, 9 *AGBIOFORUM: J. AGROBIOTECHNOLOGY MGMT. & ECON.* 139, 139–51 (2006)).

51. *Id.* at 137.

52. See *infra* notes 51–54 and accompanying text.

53. ENVIRONMENTAL IMPACT STATEMENT, *supra* note 46, at 136–38, 144.

54. *Id.* at S-28.

have chosen organic production out of philosophical values, the economic incentive to switch to conventional farming should not have an impact.”<sup>55</sup> According to APHIS, since the motivations of organic producers, consumers, and those who advocate on their behalf are “philosophical,” they are economically and environmentally hollow, and not legally cognizable under the existing regulatory framework.

Insofar as this claim about the philosophical nature of the advocates’ complaints about GE food is an accurate one, the federal litigation strategy pursued by advocates in the alfalfa and sugar beets cases seems to face an insurmountable obstacle. If advocates for greater regulation of GE foods cannot point to quantifiable economic or environmental harms, but only “philosophical” concerns, then enforcement of existing law through litigation in federal courts may not produce the sought-for regulatory reform. For that, change at the policy-making level may be required. Advocates hope that public comments on the draft EIS will convince APHIS to change its decision. For now, though, APHIS seems inclined to agree with Monsanto spokesman Steve Welker’s claim: “[W]hether it’s from cane or sugar beets, or Genuity™ Roundup Ready® sugar beets, sugar is sugar. There is no detectable difference in any way.”<sup>56</sup>

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55. *Id.*

56. Johnson, *supra* note 22.

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