

WILL COURT CASE BRING REGULATORY CERTAINTY TO GENETICALLY ENGINEERED PLANTS?

by
Alison Suthers and Nancy Bryson

The Northern District of California recently upheld the U.S. Department of Agriculture's ("USDA") deregulation of a type of genetically engineered ("GE") alfalfa called Roundup Ready® alfalfa against a legal challenge brought by the Center for Food Safety and other plaintiffs.¹ The GE alfalfa is genetically engineered to withstand application of the herbicide glyphosate. Before the current decision, the Center for Food Safety, a frequent plaintiff and opponent of GE foods, had successfully challenged other deregulation decisions involving GE crops in the Northern District of California using the National Environmental Policy Act ("NEPA"). The current decision may therefore finally reflect a turn in the USDA's fortunes in Federal court with respect to genetic engineering. The decision also articulates, for the first time, limits on the USDA's obligations under the Endangered Species Act ("ESA") and the Plant Protection Act ("PPA") when the agency evaluates GE crops. The decision is currently on appeal to the U.S. Court of Appeals for the Ninth Circuit, but if upheld, this clarification of regulatory authority could provide the biotechnology industry with additional certainty regarding future regulatory decisions.

Background

Regulatory Background. Under the PPA, the Animal and Plant Health Inspection Service ("APHIS"), an agency of the USDA, has authority to adopt regulations preventing the introduction and dissemination of plant pests. 7 U.S.C. § 7711(a).² Under APHIS's regulations, GE plants are presumed plant pests if the source or agent of the genetic modification is a known plant pest, so many GE crops such as GE alfalfa are initially subject to APHIS's plant pest regulations. See 7 C.F.R. § 340.1. Under those regulations, the GE plant can only be grown with APHIS's approval, for example by a permit. See 7 C.F.R. part 340. If APHIS determines based on the available data that a GE plant is not in fact a plant pest, the agency can grant a petition for non-regulated status, also known as "deregulation," and the plant may be grown with no restrictions. See 7 C.F.R. § 340.6.³

¹ *Ctr. for Food Safety v. Vilsack*, No. 11-1310, 2012 WL 27787 (N.D. Cal. Jan. 5, 2012).

² A "plant pest" is one of a specifically-defined list of organisms "that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product." 7 U.S.C. § 7702(14).

³ Under the Coordinated Framework for the Regulation of Biotechnology, APHIS shares authority for the regulation of

Alison Suthers is an associate and Nancy Bryson is a partner in the law firm Holland and Hart LLP's Washington, D.C. office. Ms. Bryson previously served as General Counsel for the Department of Agriculture.

Prior Deregulation Decision. In 2005, APHIS initially deregulated GE alfalfa after preparing an Environmental Assessment (“EA”) pursuant to NEPA. APHIS concluded that GE alfalfa was not a plant pest under the PPA and that its deregulation would not pose a significant environmental impact. NEPA requires all federal agencies to examine whether their actions will cause significant environmental impacts. If so, the agency must prepare an Environmental Impact Statement (“EIS”), a comprehensive analysis of the action’s impacts and alternatives. See 40 C.F.R. § 1502.2. If the agency determines, often after preparing a shorter document called an EA, that a federal action will not cause significant environmental impacts, no EIS is required. Because APHIS concluded that the deregulation would not cause significant environmental impacts, APHIS deregulated GE alfalfa without preparing an EIS.

Prior Litigation. Center for Food Safety and other plaintiffs quickly challenged APHIS’s 2005 deregulation decision in the Northern District of California in *Geertson Seed Farms v. Johanns*.⁴ Among other things, Center for Food Safety argued that APHIS was required to prepare an EIS because the deregulation of GE alfalfa would result in significant environmental impacts. The court agreed, concluding that APHIS had failed to examine in sufficient detail the potential for transmission of the engineered gene to organic and conventional alfalfa through the movement of pollen.⁵ The process by which pollen fertilizes another plant and the resulting seeds exhibit genetic characteristics of the pollinator plant is often called “gene flow.” The court concluded that APHIS was required to prepare an EIS examining the potential for gene flow.⁶

The Northern District of California’s decision in *Geertson* created significant regulatory uncertainty for the agricultural biotechnology industry. For example, in a later case challenging the deregulation of genetically engineered sugarbeets on the basis of an EA, the court relied extensively on *Geertson* to vacate the deregulation decision and mandate an EIS.⁷ The court vacated the deregulation of GE sugarbeets five years after APHIS initially deregulated the crop, and after farmers and the sugar industry had come to rely on it.⁸ Center for Food Safety and allied plaintiffs have had less success litigating *in fora* other than the Northern District of California. For example, the Southern District of Florida recently rejected a NEPA challenge to an APHIS permit for the production of genetically engineered eucalyptus.⁹

genetically engineered organisms with the U.S. Environmental Protection Agency (for the safety of pesticide traits) and the Food and Drug Administration (for the safety of any food derived from genetic engineering). 51 Fed. Reg. 23,303 (June 26, 1986). Genetically engineered crops must be approved by the FDA and the EPA as necessary before they can be deregulated by APHIS.

⁴No. 06-1075 (N.D. Cal.).

⁵*Geertson*, No. 06-1075, 2007 WL 518624 at *12 (N.D. Cal. Feb. 13, 2007).

⁶The court also enjoined any planting of GE alfalfa pending the completion of an EIS. *Geertson*, No. 06-1075, 2007 WL 1302981 at *9 (N.D. Cal. May 3, 2007), *aff’d* 570 F.3d 1130 (9th Cir. 2009). The decision was ultimately appealed to the Supreme Court, which overturned the injunction as overbroad because it infringed on APHIS’s authority to take interim regulatory measures. *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2761-62 (2010). None of the parties appealed the district court’s finding that an EIS was required.

⁷*Ctr. for Food Safety v. Vilsack*, No. 08-0484, 2009 WL 3047227 at *8-9 (N.D. Cal. Sept. 21, 2009); *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 955 (N.D. Cal. 2010) (vacatur).

⁸APHIS has continued to authorize limited production of GE sugarbeets under its current regulatory structure pending the completion of an EIS, although each step has been legally challenged by Center for Food Safety. See *Ctr. for Food Safety v. Vilsack*, 753 F. Supp. 2d 1051 (N.D. Cal. 2010) (enjoining permits issued for production of GE sugarbeets), *rev’d* 636 F.3d 1166 (9th Cir. 2011); *Ctr. for Food Safety v. Vilsack*, No. 11-586 (D.D.C.) (challenging partial deregulation of GE sugarbeets).

⁹See *Ctr. for Biological Diversity v. APHIS*, No. 10-14175, 2011 WL 4737405 (S.D. Fla. Oct. 6, 2011).

Current Litigation on the Alfalfa EIS

In the current case, Center for Food Safety challenged the EIS which APHIS prepared for GE alfalfa as directed by the *Geertson* decision. Center for Food Safety argued (1) the EIS was inadequate because it failed to adequately consider the environmental consequences of deregulation such as gene flow and the development of herbicide resistant weeds; (2) APHIS violated the ESA by failing to consult with the U.S. Fish and Wildlife Service to ensure that deregulation of GE alfalfa would not harm protected species; and (3) APHIS violated the PPA because it failed to consider noxious weed risks that will result from deregulation and failed to consider plant pest risks associated with gene flow and the use of glyphosate. The court rejected all of these challenges.

NEPA Issues. In the most important contrast to *Geertson* and other Northern District of California cases, the court held that APHIS adequately analyzed the potential for gene flow and the development of herbicide resistant weeds. The court also held that APHIS's EIS complied with NEPA in all other respects. The GE alfalfa EIS therefore provides APHIS and the biotechnology industry with a blueprint for a NEPA analysis that will pass muster with the court. Some uncertainty about what is required under NEPA for deregulation nevertheless remains. While the current case provides an example of an EIS that can withstand judicial scrutiny, APHIS often deregulates genetically engineered crops on the basis of an EA and a "finding of no significant impact" ("FONSI") under NEPA, without preparing an EIS. Plaintiffs like the Center for Food Safety have argued that *Geertson* effectively requires an EIS if there is any possibility of gene flow. Such a bright line rule seems to conflict with the careful, case-specific analysis required by NEPA, but a court has yet to approve the deregulation of a GE crop on the basis of an EA where plaintiffs have raised gene flow as an issue in a NEPA challenge. The biotechnology industry argues that, depending on the biological characteristics of a particular species and other agronomic factors, the risk of gene flow may be so remote and the consequences so minor and easily remediable, that the potential impact of gene flow cannot be considered significant for NEPA purposes. Other industry proponents have argued that the impact of gene flow is purely economic and should not be considered an environmental impact at all. Future cases, including a currently-pending case in the D.C. Federal District Court, will determine whether a deregulation on the basis of an EA/FONSI will withstand legal scrutiny.¹⁰

ESA Issues. Center for Food Safety argued that APHIS was required to consult with the Fish and Wildlife Service regarding potential effects of deregulation on endangered species because increased use of glyphosate as an herbicide in alfalfa-growing areas could potentially affect wildlife.¹¹ The court rejected this claim, applying the reasoning of *Department of Transportation v. Public Citizen*, 541 U.S. 752 (2004) for the first time in this context. In *Public Citizen*, the Supreme Court held that, because the Federal Motor Carrier Safety Administration lacked the discretion to prevent cross-border operations of Mexican-domiciled trucks, the agency did not need to consider the environmental effects of those operations in its NEPA analysis. 541 U.S. at 770. The Court applied this principle to ESA consultations in *National Association of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 667 (2007).

Based on *Public Citizen* and *Home Builders*, the court held that APHIS's deregulation was not the legally relevant cause of any increased glyphosate use that could result from the deregulation because the EPA, not APHIS, has the authority to regulate how glyphosate is used. APHIS properly

¹⁰ The D.C. District Court case challenges APHIS's partial deregulation of GE sugarbeets on the basis of an EA/FONSI. See *Ctr. for Food Safety v. Vilsack*, No. 11-586 (D.D.C.).

¹¹ See 16 U.S.C. § 1536 (outlining procedures for interagency cooperation to protect listed species).

determined the GE alfalfa plant itself does not affect endangered species. EPA has already authorized the use of glyphosate on GE alfalfa, and EPA has stated that it intends to conduct an endangered species assessment when it completes its registration review of glyphosate in 2015. The court concluded that it could not evaluate EPA's compliance on the record before the court and without EPA as a party.

PPA Issues. APHIS deregulated GE alfalfa because it determined that GE alfalfa does not pose a plant pest risk. Center for Food Safety argued that APHIS was required by the PPA to investigate whether GE alfalfa also presented noxious weed risks, because Congress has also granted APHIS authority to regulate noxious weeds.¹² APHIS argued that it was not required to consider noxious weed issues because the regulatory structures under which APHIS regulates plant pests and noxious weeds are different, and the regulatory procedures for noxious weeds had not been triggered.¹³ The court accepted the agency's interpretation of its own limited regulatory authority under the PPA, and concluded that the agency was not required to assess noxious weed risk as a part of its plant pest risk assessment.

The court also accepted APHIS's limited definition of its plant pest risk authority, concluding that the PPA does not require APHIS to assess risks that fall outside the narrow definition of a plant pest as set forth in the PPA and APHIS's regulations.¹⁴ Center for Food Safety had argued that the PPA required APHIS to assess as plant pest risks the risk of gene transmission by cross-pollination and the consequences of glyphosate use. The court upheld APHIS's conclusion that, although these consequences were considered as a part of the NEPA analysis, they were not a part of the plant pest risk determination required by the PPA. The court also upheld APHIS's conclusion that once it determined that GE alfalfa did not present a plant pest risk, it had no authority to impose regulations on its production under the PPA.

Impact

In addition to providing government and industry with an example of a NEPA analysis supporting deregulation that can withstand judicial scrutiny, the decision also establishes several helpful guideposts to define APHIS's obligations when the agency reviews a petition for deregulation. Plaintiffs like Center for Food Safety frequently use generally-applicable statutes like NEPA and the ESA to challenge agency decisions, but the court's decision in *Center for Food Safety v. Vilsack* focuses on the narrow role Congress created for APHIS with the Plant Protection Act. The decision therefore gives the biotechnology industry greater certainty about the scope of APHIS's review, and an increased ability to rely on a science-based conclusion that a product does not pose a plant pest risk as the sole basis for deregulation.

¹² See 7 U.S.C. § 7712(f).

¹³ Compare 7 C.F.R. part 340 (for GE organisms presumed to be plant pests) with 7 C.F.R. part 360 (for noxious weeds).

¹⁴ See 7 C.F.R. § 340.1.