FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY; SIERRA CLUB; TRASK FAMILY FARMS; GEERTSON SEED FARMS; BEYOND PESTICIDES; NATIONAL FAMILY FARM COALITION; THE CORNUCOPIA INSTITUTE; DAKOTA RESOURCE COUNCIL; WESTERN ORGANIZATION OF RESOURCE COUNCILS; NORTHEAST ORGANIC DAIRY PRODUCERS ALLIANCE; CALIFORNIA FARMERS UNION, *Plaintiffs-Appellants*, v. THOMAS J. VILSACK, Secretary of Agriculture; CINDY SMITH, Administrator of the Animal & Plant Health Inspection Service, U.S. Department of Agriculture, *Defendants-Appellees*, FORAGE GENETICS INTERNATIONAL LLC; JOHN GROVER; DANIEL MEDEROS; DAN SCHEPS; CARL SIMMONS; MARK WATTE; MONSANTO COMPANY; CALIFORNIA ALFALFA AND FORAGE ASSOCIATION; EUREKA SEEDS, INC.;	No. 12-15052 D.C. No. 3:11-cv-01310-SC OPINION

GARDENA ALFALFA SEED GROWERS ASSOCIATION; MIDWEST FORAGE ASSOCIATION,
Intervenor-Defendants-Appellees.

Appeal from the United States District Court
for the Northern District of California
Samuel Conti, Senior District Judge, Presiding

Argued and Submitted
October 24, 2012—San Francisco, California

Filed May 17, 2013

Before: Mary M. Schroeder, Sidney R. Thomas,
and N. Randy Smith, Circuit Judges.

Opinion by Judge Schroeder

SUMMARY*

Environmental Law / Plant Protection Act

The panel affirmed the district court's summary judgment in favor of federal officials and intervenor-defendants, comprised of corporate seed manufacturers and industry trade groups, in an action brought by environmental groups and farmer organizations challenging the Record of Decision issued by the United States Department of Agriculture's Animal Plant and Health Inspection Service unconditionally deregulating Roundup Ready Alfalfa, a plant genetically engineered or modified by the Monsanto Company.

The panel held the Plant Protection Act does not regulate the type of harms that the plaintiffs complain of, and therefore the Animal Plant and Health Inspection Service correctly concluded that Roundup Ready Alfalfa was not a "plant pest" under the Act. The panel held that once the agency concluded that Roundup Ready Alfalfa was not a plant pest, it no longer had jurisdiction to continue regulating the plant, and this obviated the need for the agency to consult with the Fish and Wildlife Service under the Endangered Species Act and to consider alternatives to unconditional deregulation under the National Environmental Policy Act. The panel also held that the Animal Plant and Health Inspection Service did not violate the Plant Protection Act by not considering, sua sponte, whether Roundup Ready Alfalfa was a noxious weed.

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

COUNSEL

George A. Kimbrell (argued), Center for Food Safety, San Francisco, California; Paul H. Achitoff, Earthjustice, Honolulu, Hawaii, for Plaintiffs-Appellants.

Shaun A. Goho, Emmett Environmental Law & Policy Clinic, Cambridge, Massachusetts, for amici curiae CROPP Cooperative, et al.

Deborah A. Sivas, Alicia E. Thesing, Leah J. Russin, and Matthew H. Armsby, Environmental Law Clinic, Stanford, California, for amici curiae Center for Biological Diversity and Natural Resources Defense Counsel.

Stuart F. Delery, Acting Assistant Attorney General, Michael Jay Singer and Dana Kaersvang (argued), Appellate Staff, United States Department of Justice, Civil Division, Washington, D.C.; Ignacia S. Moreno, Assistant Attorney General, Andrew C. Mergen and Robert J. Lundman, United States Department of Justice, Environmental & Natural Resources Division, Washington, D.C.; James A. Booth, Carlynne S. Cockrum, Susan C. Golabek, and Andrew R. Varcoe, Of Counsel, United States Department of Agriculture, for Defendants-Appellees.

Richard P. Bress (argued), Philip J. Perry, Drew C. Ensign, and Andrew D. Prins, Latham & Watkins LLP, Washington, D.C., for Intervenor-Defendant-Appellee Monsanto Company.

B. Andrew Brown, Dorsey & Whitney LLP, Minneapolis, Minnesota; Martha C. Luemers, Dorsey & Whitney LLP, Palo Alto, California, for Intervenors-Appellees Forage Genetics International, LLC, California Alfalfa and Forage Association, Eureka Seeds, Inc., Midwest Forage Association, and Gardena Alfalfa Seed Growers Association.

Thomas R. Lundquist and J. Michael Klise, Crowell & Moring, LLP, Washington, D.C., for amici curiae American Farm Bureau Federation and Biotechnology Industry Organization.

Gilbert S. Keteltas and John F. Bruce, Baker & Hostetler, LLP, Washington, D.C.; Christopher H. Marraro, McKenna Long & Aldridge, LLP, Washington, D.C., for amici curiae American Sugarbeet Growers Association, et al.

OPINION

SCHROEDER, Circuit Judge:

OVERVIEW

This appeal represents another chapter in the United States Department of Agriculture's ("USDA") regulation of Roundup Ready Alfalfa ("RRA"). RRA is a plant genetically "engineered" or "modified" by the Monsanto Company and Forage Genetics International to be resistant to the herbicide glyphosate, which Monsanto sells under the trade name Roundup. Farmers do not normally apply an herbicide like Roundup to alfalfa fields because the herbicide kills not only the weeds, but also the alfalfa crop. RRA's tolerance to Roundup thus allows farmers to control weeds through

herbicide application without harming the alfalfa plant. Monsanto markets RRA and Roundup together as a single crop system. From the outset, Monsanto and Forage Genetics's attempts to introduce RRA have been met with criticism and lawsuits from environmental groups concerned about the adverse effects that the plant may have on the environment and the organic food industry. An earlier phase of the litigation concerned the scope of an injunction prohibiting the planting of RRA pending completion of an Environmental Impact Statement ("EIS") by the USDA's Animal Plant and Health Inspection Service ("APHIS"). *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2761–62 (2010).

Here, we consider the Record of Decision ("ROD") issued by APHIS, which unconditionally deregulated RRA on the ground that RRA was not a "plant pest" within the meaning of the term in the Plant Protection Act ("PPA"), 7 U.S.C. §§ 7701–7772. The plaintiffs in this action seek review of APHIS's deregulation of RRA. The plaintiffs are comprised of environmental interest groups and farmer organizations concerned about RRA's potential harms. Their concerns include the possibility that RRA will cross-pollinate with and alter the genetic structure of conventional alfalfa plants. This phenomenon, referred to as transgenic contamination, contaminates conventional alfalfa plants with the glyphosate-resistant gene. The plaintiffs and amici supporting them contend that transgenic contamination will harm the multi-billion dollar organic food industry. For example, they argue that the threat of transgenic contamination will force ranchers who raise organic meat to spend money testing the alfalfa they feed their animals to ensure that none of the alfalfa is genetically modified. If the ranchers cannot show that their animals are fed nonmodified alfalfa, they cannot

market their meat as organic, which erodes the price premium they are able to charge. The plaintiffs also fear that the contamination of conventional alfalfa plants with the glyphosate-resistant gene could cause other countries to reduce or stop their importation of U.S.-grown alfalfa.

In addition to transgenic contamination, the plaintiffs in this action also fear that RRA's deregulation will lead to glyphosate-resistant weeds. The plaintiffs allege that farmers will respond to the weeds' increased glyphosate tolerance by applying even greater amounts of glyphosate as well as using mixtures of different herbicides. This increased herbicide use could harm plants and animals living near alfalfa fields, including species listed as threatened or endangered under the Endangered Species Act ("ESA").

Concerned about these environmental harms, the plaintiffs in this appeal argue that APHIS's unconditional deregulation of RRA was improper for three reasons: First, APHIS violated the PPA and the Administrative Procedure Act ("APA") in concluding that RRA was not a plant pest and failing to consider if RRA was a noxious weed; second, because of these errors in statutory interpretation, APHIS violated the ESA when it failed to consult with the Fish and Wildlife Service ("FWS") about RRA's effects on endangered and threatened species, *see* 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a); and third, APHIS also violated the National Environmental Policy Act ("NEPA") by unconditionally deregulating RRA without considering the option of partially deregulating the crop, an action that the agency had included in the EIS.

After the plaintiffs filed this action against the government in the district court, Monsanto, Forage Genetics,

the corporate seed manufacturers and industry trade groups intervened as defendants. The district court upheld the agency's deregulation decision in a published opinion. *Ctr. for Food Safety v. Vilsack*, 844 F. Supp. 2d 1006 (N.D. Cal. 2012). It held that RRA is not a "plant pest" within the meaning of the statute, and that the agency's deregulation of the plant therefore did not violate the ESA or NEPA, because the agency's jurisdiction did not extend to organisms that are not plant pests. *Id.* at 1015–16, 1020–22.

We affirm, because the statute does not regulate the types of harms that the plaintiffs complain of, and therefore APHIS correctly concluded that RRA was not a "plant pest" under the PPA. Once the agency concluded that RRA was not a plant pest, it no longer had jurisdiction to continue regulating the plant. APHIS's lack of jurisdiction over RRA obviated the need for the agency to consult with the FWS under the ESA and to consider alternatives to unconditional deregulation under NEPA. *See Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 665 (2007). The district court thus properly entered summary judgment in favor of the defendants.

I. Regulatory Structure: the Coordinated Framework for Regulation of Biotechnology

Genetically modified plants like RRA are regulated by various agencies pursuant to the Coordinated Framework for Regulation of Biotechnology ("Coordinated Framework"). The Coordinated Framework is a 1986 policy statement from the Office of Science and Technology Policy that "describes the comprehensive regulatory policy for ensuring the safety of biotechnology research and products." Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg.

23,302, 23,302 (June 26, 1986). The goal of this policy statement was to construct a framework that would not impair the competiveness or innovativeness of the United States's biotechnology industry. Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856, 50,856 (proposed Dec. 31, 1984). Pursuant to the Coordinated Framework, regulation of genetically modified plants is divided among three agencies: the Food and Drug Administration ("FDA"), the Environmental Protection Agency ("EPA"), and the USDA, through APHIS. None are required to address the environmental or economic harms with which the plaintiffs are concerned. We deal briefly with the FDA and EPA's regulation of genetically modified plants before turning to the scope of APHIS's regulation under the PPA.

A. FDA Regulation of Genetically Modified Plants

The FDA's regulation of genetically modified plants is derived from its authority to regulate food safety under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301–399. The FDA's authority is limited to removing adulterated food from the national food supply, which could include food from genetically modified plants. The FFDCA, however, does not contain any provisions that specifically address genetically modified plants. In October 2003, Monsanto and Forage Genetics provided the FDA with a summary of information that assessed the safety and nutritional qualities of RRA. After assessing this information, the FDA concluded in early 2004 that RRA and foods derived from it were safe for consumption.

B. EPA Regulation of Genetically Modified Plants

The EPA indirectly regulates genetically modified plants through the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136–136y. FIFRA governs the use, sale, and labeling of herbicides like glyphosate. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 437 (2005). An herbicide must first be "registered" by the EPA before it can be distributed or sold in the United States. 7 U.S.C. §§ 136a(a),136j(a)(2)(F). The EPA registration process starts with the herbicide manufacturer providing the EPA with information about the herbicide. *Id.* § 136a(c)(1)(C), (F). The agency then evaluates the effectiveness of the herbicide and the adverse effects it will have on humans and the environment. *See id.* § 136a(c)(5); *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 530 (9th Cir. 2001). On the basis of this evaluation, the EPA then determines if it will permit the herbicide's use on a given plant, and, if so, how much.

The EPA sets the conditions for the herbicide's use and places them in labeling instructions that a user must comply with. *See* 7 U.S.C. § 136j(a)(2)(G). The EPA reevaluates the herbicide every fifteen years, as part of a "re-registration process" in which the agency determines if it should continue permitting the herbicide's use. *Id.* § 136a(g)(1)(A)(iv). The EPA originally registered glyphosate in 1974. In 2004 and 2005, the EPA approved the application of glyphosate to RRA after determining that the herbicide would not cause any unreasonable environmental risks so long as it was applied in accordance with its labeling instructions. These labeling instructions contain, among other things, prohibitions on glyphosate use near the habitats of threatened or endangered species. The EPA is currently in the process of

"re-registering" glyphosate. The agency is scheduled to complete the re-registration process in 2015.

Because the EPA's FIFRA regulation deals with chemicals, the EPA exercises only limited jurisdiction over genetically modified crops. Such regulation is limited to plants that are modified to produce pesticides. *See* 40 C.F.R. §§ 174.1, 174.3. The EPA therefore does not regulate RRA, because the plant itself does not produce or secrete a pesticide.

C. APHIS's Regulation of Plant Pests and Noxious Weeds Under the Plant Protection Act

1. Regulation of Plant Pests

The PPA's purpose is to prevent the spread of parasitic, diseased, and invasive plants and organisms, and it does so through the regulation of "plant pests" and "noxious weeds." *See* 7 U.S.C. § 7712. The PPA was enacted in 2000 and combined APHIS's prior regulation of plant pests and noxious weeds into a single statute. Previously, plant pests and noxious weeds were regulated by different statutes: The Federal Plant Pest Act of 1957 regulated plant pests while the Federal Noxious Weed Act of 1974 regulated noxious weeds. The PPA made few substantive changes to these statutes. The PPA's definition of "plant pest" is materially the same as the 1957 Federal Plant Pest Act's definition of plant pest. *Compare* Federal Plant Pest Act, § 103(c), 71 Stat. 31, 32 (1957), *with* 7 U.S.C. § 7702(14).

This case turns on the language of the PPA that defines plant pests. APHIS has no jurisdiction to regulate a plant or animal unless the organism is a "plant pest" within the

meaning of the statute. *See* 7 U.S.C. § 7702(14); 7 C.F.R. § 340.2 n.4 ("An[] organism belonging to any taxa [that 7 C.F.R. § 340.2 lists as a plant pest] is only considered to be a plant pest if the organism 'can . . . injure, or cause disease, or damage in any plants or parts thereof. . . .'"). The plaintiffs' principal contention is that RRA is a plant pest under the PPA. They therefore contend that APHIS's conclusion that RRA was not a plant pest was arbitrary and capricious and violative of the PPA and APA.

The PPA defines a plant pest to be:

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

7 U.S.C. § 7702(14).

The PPA states that organisms regulated as "plant pests" must be organisms that cause physical harm to plants through injury, damage, or disease. Neither the statute nor the

regulations indicate that a genetically engineered plant like RRA, which does not itself physically damage plants, can be a plant pest. The regulations echo the statute and define "plant pest" in 7 C.F.R. § 340.1 as "organisms . . . which can directly or indirectly cause diseases or damage."

APHIS regulations do not ignore the introduction of organisms or products altered or produced through genetic engineering, however. *See* 7 C.F.R. § 340.0 n.1. This is because genetically engineered plants are often created using an organism that can itself be a plant pest under APHIS's regulations. Indeed, RRA was created by inserting a glyphosate-resistant gene into the genetic structure of the conventional alfalfa plant using a plant pest. The glyphosate-resistant gene was transferred to the conventional alfalfa plant using a bacterium—Agrobacterium—that APHIS regulations classify as a plant pest. *See* 7 C.F.R. § 340.2. The regulations therefore provide that a genetically modified organism is regulated as a plant pest if it is created using an organism that is itself a plant pest. *Id.* § 340.1 (defining a regulated article under APHIS's plant pest regulations as "[a]ny organism which has been altered or produced through genetic engineering, if the donor organism . . . or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest"). APHIS regulates such a genetically engineered organism, referred to by the parties as a "presumptive plant pest," until the agency concludes on the basis of scientific evidence that the modified plant is not a "plant pest." *See id.* § 340.6.

To discontinue regulating a presumptive plant pest, the regulations spell out that any party may petition APHIS using the petitioning procedures described in 7 C.F.R § 340.6. When such a petition is filed, the agency determines whether

a presumptive plant pest is an actual plant pest within the meaning of the term in the PPA by evaluating data that the petitioning party has included in its petition. *Id.* § 340.6(c). Such evidence is generally provided by the company that engineered the plant, for the regulations require information that is most easily supplied by such a party. The regulation requires information about the presumptive plant pest's biology and any experiments that were conducted on the plant. *Id.* The agency also considers data from field tests in which APHIS permits introduction of the presumptive plant pest into the environment on a limited basis to study how it affects other plants. *Id.* § 340.6(c)(5). On the basis of the information submitted, APHIS examines whether the genetically modified plant presents a greater risk of plant harm than the nonmodified plant. *See id.* § 340.6(c)(4) (requiring that a party petitioning "[d]escribe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived"). If APHIS concludes that the presumptive plant pest does not exhibit any risk of plant pest harm, APHIS must deregulate it since the agency does not have jurisdiction to regulate organisms that are not plant pests.

2. Regulation of Noxious Weeds

The PPA also authorizes APHIS to regulate noxious weeds. 7 U.S.C. § 7712(f). The agency defines noxious weeds as weeds that are "likely to be aggressively invasive, have significant negative impacts, and are extremely difficult to manage or control once established." 76 Fed. Reg. 39,811, 39,811 (July 7, 2011).

APHIS regulates noxious weeds and plant pests under different regulatory frameworks. Plant pests are regulated under 7 C.F.R. parts 330 and 340, while noxious weeds are regulated under 7 C.F.R. part 360. Unlike the plant pest framework, which presumes that some genetically modified plants are plant pests, the PPA's noxious weed regulations do not presume that any plant is a noxious weed. Thus, APHIS's classification of a plant as a presumptive plant pest does not trigger any automatic requirement to evaluate it as a noxious weed. Rather, under the PPA's noxious weed regulations, the agency can sua sponte assess the noxious weed properties of the plant. *See* 7 C.F.R. § 360.200. In addition, any party can petition APHIS to list or delist a plant as a noxious weed using a process that is similar to the petition process for deregulating plant pests. *See id.* §§ 360.500, 360.501.

APHIS has never sua sponte evaluated RRA as a noxious weed, and no party has ever petitioned APHIS to list RRA as a noxious weed. APHIS has therefore never designated RRA as a noxious weed.

II. Factual Background, Regulatory History, and Prior Litigation

Grown on over twenty million acres, alfalfa is the United States's fourth most widely grown crop and the third most valuable. Alfalfa is typically grown as hay and is one of the primary food sources for ruminants like cattle, goats, and sheep. Because many conventional herbicides, like Roundup, kill conventional alfalfa plants, Monsanto and Forage Genetics genetically engineered RRA in the 1990s to be resistant to glyphosate. RRA's immunity to glyphosate enables farmers to apply significantly greater amounts of the herbicide than is feasible for conventional alfalfa. This

allows farmers to control weeds in alfalfa fields through glyphosate application and to expand alfalfa production into areas where weed infestations previously made cultivation of the crop difficult.

Monsanto and Forage Genetics market RRA and Roundup together as a single crop system. Use of glyphosate on alfalfa fields is expected to increase dramatically with RRA's introduction; APHIS predicted in its final EIS of RRA that once marketing of RRA takes hold, annual glyphosate usage on alfalfa fields will increase from less than half a million pounds to more than 24 million pounds.

Monsanto and Forage Genetics created RRA by transferring a gene from Agrobacterium, a naturally occurring bacterium, into the genetic structure of conventional alfalfa. APHIS regulations list Agrobacterium as a plant pest. 7 C.F.R. § 340.2. The insertion of this gene changes the genetic structure of the alfalfa plant and makes it resistant to glyphosate. Because APHIS's regulations provide that Agrobacterium can be a "plant pest," APHIS regulated RRA as a presumptive plant pest. *See* 70 Fed. Reg. 36,917, 36,919 (June 27, 2005) (describing APHIS's initial regulation of RRA as a plant pest). So long as RRA was a presumptive plant pest and within APHIS's scope of regulation, farmers could plant the crop only with the agency's consent. *See* 7 C.F.R. § 340.0(a)(2) and n.1.

Seeking to end APHIS's regulation of RRA as a "presumptive plant pest," Monsanto and Forage Genetics invoked the procedures provided in 7 C.F.R. § 340.6 and petitioned the agency in April 2004 for a determination that RRA was not a plant pest. *See* 70 Fed. Reg. 36,917. In response to the petition, APHIS assessed whether RRA

caused any plant pest harms. APHIS considered information submitted by Monsanto and Forage Genetics, including data from RRA field tests, as well as public comments. APHIS, in June 2005, concluded that RRA was not a plant pest and therefore should not be regulated. *Id.* at 36,918-19. APHIS found that RRA presented no greater plant pest harms than conventional alfalfa. *Id.* at 36,918. The agency further found that the plant pest properties of the Agrobacterium used to engineer RRA were "disarmed" and could not injure or damage other plants. *Id.* APHIS stated that the RRA plant would not damage other plants, was not a plant pathogen, should not limit a farmer's ability to control plant pests in alfalfa and other crops, and would not harm threatened or endangered species that were beneficial to agriculture. *Id.* at 36, 918–19.

Pursuant to NEPA, APHIS also conducted an "Environmental Assessment." *Id.* NEPA regulations provide that an agency shall conduct an Environmental Assessment to determine if an agency action will significantly affect the environment. 40 C.F.R § 1501.4. If this initial assessment finds that the agency's action may significantly affect the environment, the agency must then prepare an EIS. *Id.* If the agency concludes that its action will not significantly impact the environment, the agency issues a "Finding of No Significant Impact," and the agency can proceed with its proposed action without preparing an EIS. *Id.* In its NEPA Environmental Assessment, APHIS issued a "Finding of No Significant Impact." 70 Fed. Reg. at 36,919. APHIS therefore did not prepare an EIS. On June 14, 2005, APHIS unconditionally deregulated RRA.

A. The *Geertson* Litigation and Related Agency Actions

In early 2006, some of the same farmers and environmental groups who are plaintiffs in this suit responded to APHIS's June 2005 deregulation of RRA by suing the agency in the United States District Court for the Northern District of California. They contended that APHIS's June 2005 deregulation violated the PPA, ESA, and NEPA. With regard to the plaintiffs' NEPA claim, the district court ruled in a February 2007 unpublished decision that APHIS had violated NEPA by failing to prepare an EIS before it deregulated RRA. *Geertson Seed Farms v. Johanns*, No. C06-01075, 2007 WL 518624, at *10-12 (N.D. Cal. Feb. 13, 2007). The district court held that an EIS should have addressed the environmental effects of transgenic contamination and glyphosate-resistant weeds. *Id.* at *12. The district court noted that transgenic contamination could adversely affect the welfare of organic farmers who raise conventional alfalfa. *Id.* Accordingly, the district court issued orders vacating APHIS's deregulation of RRA pending completion of an EIS that addressed those harms, enjoining APHIS from deregulating RRA in any manner while the agency prepared the EIS, and enjoining further planting of RRA. *Geertson Seed Farms v. Johanns*, 2007 WL 776146, at *2-3 (N.D. Cal. Mar. 12, 2007); *Geertson Seed Farms v. Johanns*, 2007 WL 1302981, at *9 (N.D. Cal. May 3, 2007). The district court did not reach the plaintiffs' claims under the PPA or the ESA.

This court affirmed the district court's order. *Geertson Seed Farms v. Johanns*, 570 F.3d 1130, 1133–34 (9th Cir. 2009). The Supreme Court granted certiorari, however, and remanded. *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct.

2743, 2761–62 (2010). The Court held that an injunction that prohibited APHIS from partially deregulating RRA while the agency prepared an EIS was overbroad. *Id.* at 2759–60. It stated that there were situations where APHIS could partially deregulate RRA without causing the plaintiffs irreparable injury. *Id.* The Court noted that the agency could mitigate the dangers of transgenic contamination by limiting the geographic area where farmers could grow RRA or imposing isolation distances between fields of RRA and conventional alfalfa. *Id.* at 2760. For the same reasons, the Court held that the injunction enjoining all RRA planting was overbroad. *Id.* at 2761.

The district court's original decision in *Geertson*, in 2007, had vacated APHIS's deregulation of RRA and that ruling was not challenged in the appellate courts. *Id.* at 2756. The Supreme Court noted that "we assume without deciding that the District Court [in *Geertson*] acted lawfully in vacating [APHIS's] deregulation decision." *Id.* The *Geertson* appellate litigation involved only the scope of the injunction that the district court issued pending APHIS's preparation of an EIS under NEPA. *See id.*; *Geertson Seed Farms*, 570 F.3d at 1133–34.

APHIS released its final EIS in December 2010. The final EIS listed partial deregulation as one of two "preferred" alternatives. The other "preferred" alternative was an action that unconditionally deregulated RRA. The agency was required to choose among these two alternatives while still acting within its jurisdiction under the PPA to regulate plant pests. APHIS concluded that unconditionally deregulating RRA was the alternative consistent with the agency's limited statutory mandate. This conclusion necessarily followed

from APHIS's earlier conclusion in June 2005 that RRA was not a plant pest. *See* 70 Fed. Reg. at 36,919.

While APHIS was preparing the 2010 final EIS, the district court's order in *Geertson*, vacating APHIS's deregulation of RRA, remained in effect. After completing the final EIS in December 2010, the order expired because APHIS had fulfilled its obligations under NEPA by preparing the EIS.

APHIS then issued, in January 2011, the ROD, unconditionally deregulating RRA. The ROD relied on APHIS's June 2005 assessment of RRA's plant pest properties conducted in response to Monsanto and Forage Genetics's 2004 deregulation petition in which the agency had concluded that RRA was not a plant pest. The 2011 ROD noted that although RRA was created using a plant pest (the Agrobacterium), the genetically modified plant did not present any direct or indirect plant pest risks and therefore should be granted "nonregulated status." The ROD stated that because RRA will not damage or injure other plants, it does not present a greater plant pest risk than conventional alfalfa.

APHIS noted in the ROD that its final EIS had recognized that continued regulation of RRA was the environmentally preferred option, but APHIS concluded that, as a matter of law, neither the PPA nor the regulations permitted it to continue regulating RRA once it concluded that RRA was not a plant pest within the regulatory scope of the statute. The agency stated that "it would be inconsistent with the PPA, the regulation codified at 7 C.F.R. part 340, and the biotechnology regulatory policies in the Coordinated Framework, to prevent the commercial release of [RRA]."

B. This Litigation

Almost immediately after the issuance of APHIS's 2011 ROD deregulating RRA, the plaintiffs filed this action in the district court. The district court held that the dangers of transgenic contamination and increased glyphosate usage are not plant pest harms under the PPA. *Ctr. for Food Safety*, 844 F. Supp. at 1017. It also ruled that the PPA's separate regulatory frameworks for plant pests and noxious weeds did not require APHIS to evaluate whether RRA was a noxious weed at the time the agency considered whether RRA was a plant pest. *Id.* at 1015. The district court also noted that APHIS's deregulation of RRA was not inconsistent with the Supreme Court's decision in *Monsanto*, *id.* at 1018, in which the Supreme Court expressly stated that it was not deciding if APHIS acted lawfully when it deregulated RRA, *see Monsanto*, 130 S. Ct. at 2756.

The district court rejected the plaintiffs' other theories as well. Citing *National Association of Home Builders v. Defenders of Wildlife*, 551 U.S. 644 (2007), it held that once APHIS correctly concluded that it no longer had jurisdiction to regulate RRA, the deregulation of RRA was a nondiscretionary act that did not obligate the agency to consult with the FWS under the ESA concerning further action. *Ctr. for Food Safety*, 844 F. Supp. 2d at 1020–21. The district court further held that APHIS's EIS satisfied NEPA's procedural requirements. *Id.* at 1024. Accordingly, the district court entered summary judgment in favor of the defendants on all claims. *Id.* at 1024–25.

In this appeal, the plaintiffs argue that the district court misinterpreted the PPA in multiple ways when it upheld APHIS's decision to deregulate RRA. They contend

fundamentally that the district court erred in concluding that transgenic contamination and the harms associated with increased herbicide use are not plant pest harms under the PPA, and that RRA was therefore not a "plant pest" within the agency's regulatory jurisdiction.

This appeal thus turns on whether the agency properly determined that RRA is not a "plant pest" under the PPA. If RRA is not a "plant pest," the agency was without jurisdiction to regulate the plant, and was required to order deregulation, thus obviating the need to consult with the FWS or consider other options involving continued regulation of RRA.

DISCUSSION

I. Whether RRA is a "Plant Pest" and Thus Within the Scope of APHIS's Regulatory Authority

The primary issue we must determine is whether APHIS has interpreted the meaning of "plant pest" in the PPA too narrowly. The plaintiffs maintain that it has, and that the term includes all genetically engineered plants and organisms that have an environmentally adverse effect on plants. According to the plaintiffs, APHIS has discretion under the PPA to regulate RRA, which, if correct, would require the agency, pursuant to the ESA, to consult with the FWS about the crop's effects on endangered plant and animal species. 16 U.S.C. § 1536(a)(2); *see Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1020 (9th Cir. 2012) (en banc).

The parties all agree that under the PPA, APHIS regulates organisms that are "plant pests." The PPA defines a "plant pest" as any "living stage" of a list of organisms, or articles

"similar to or allied with" 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). While neither the statute nor the regulations further define the type of "injury," "damage," or "disease" a plant pest must cause, all of the organisms that APHIS lists as plant pests can cause widespread physical damage or destruction of plants.

With respect to genetically engineered plants, the regulations specifically define the term "regulated article" as a genetically engineered organism that is created using an organism that is itself a plant pest. 7 C.F.R. § 340.1. The regulations go on to specify that, as such, the "regulated article" must injure plants. 7 C.F.R. § 340.2 n.4 ("An[] organism belonging to any taxa [that 7 C.F.R. § 340.1 lists as a plant pest] is only considered to be a plant pest if the organism 'can . . . injure, or cause disease, or damage in any plants or parts thereof. . . .'").

The plaintiffs' concern is with two types of harm genetically modified RRA can cause: transgenic contamination of conventional alfalfa and increased herbicide use. These alleged harms may well be adverse environmental and economic effects. APHIS contends, however, they do not constitute plant disease, injury, or damage, which are the harms that the statute requires. The agency therefore concludes that RRA is not a "plant pest."

In support of its position, APHIS points out that, as a matter of historical practice, it has previously assessed the plant pest properties of genetically modified crops such as cotton, corn, and soybeans. In conducting these plant pest assessments, APHIS does not consider whether the genetically modified plant could cross-pollinate with and alter

the genetic structure of other plants. This policy is consistent with APHIS's classification of other plants that could cross-pollinate and destroy the crop value in the process (such as canola with other types of rapeseed, and field with sweet corn). The agency has never classified a plant as a "plant pest" based on such cross-pollination effects. APHIS explains this is because it does not consider such alteration to be a plant pest harm within the meaning of the statute. The agency has similarly never considered the possible consequences associated with increased herbicide use, including creation of herbicide resistant weeds, to be "plant pest" injuries. APHIS explains such harms do not constitute physical damage or injury to other plants. APHIS's consistent interpretation, which is also the best interpretation of this particular statutory language, must be taken into account. *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) ("consistency" of agency interpretations with "earlier and later pronouncements" is a factor to consider in deciding whether to defer to agency interpretation); *United States v. Mead Corp.*, 533 U.S. 218, 219 (2001).

The plaintiffs nevertheless argue that APHIS's interpretation of the meaning of plant pest is too narrow. They contend that we should hold that RRA is a plant pest because the RRA plant results from the transfer of genetic material from the Agrobacterium. Since the statute in 7 U.S.C. § 7702(14)(H) defines a plant pest to be "[a]ny article similar to or allied with any of the articles specified," the plaintiffs assert that the RRA plant is "allied with" the Agrobacterium. Thus, the plaintiffs' theory is that transgenic contamination and increased glyphosate use are harms caused by the Agrobacterium, and therefore must also be "plant pest" harms under the PPA.

The plaintiffs' logic is a stretch because it fails to deal with the language of the statute defining plant pest harm as injury, disease, or damage to other plants. *See* 7 U.S.C. § 7702(14). Although the regulations classify Agrobacterium itself as a plant pest, the Agrobacterium's plant pest properties are "disarmed" and can no longer injure other plants once the bacterium's genetic material is inserted into the genetic structure of conventional alfalfa. 70 Fed. Reg. at 36,918 ("APHIS determined that the vectors and other elements [of the Agrobacterium] were disarmed [in the RRA plant] . . . ."). RRA is thus no more likely to injure or damage other plants than is conventional, nonmodified alfalfa. *Id.*

We do not suggest that the genetic engineering is without possible economic consequences. APHIS's final EIS noted that transgenic contamination could economically hurt farmers who raise conventional alfalfa and market their crop as organic. The contamination of conventional alfalfa with the glyphosate-resistant gene could close foreign markets to U.S.-grown alfalfa. It could also force farmers of conventional alfalfa to incur additional costs testing and certifying that their alfalfa is not contaminated with the glyphosate-resistant gene. These concerns, however, are not the result of plant pest harms as defined under the PPA. APHIS thus has no power to regulate the adverse economic effects that could follow RRA's deregulation.

The plaintiffs also maintain that because RRA results in more use of the herbicide glyphosate, the harms associated with increased glyphosate usage are plant pest harms under the PPA. We recognize, of course, that deregulating RRA is expected to result in increased use of herbicides. Indeed, RRA was developed so farmers could apply significantly greater amounts of herbicides to alfalfa fields. The increased

use of herbicides can be potentially damaging to the environment. But the PPA addresses only the harms caused by plant pests to other plants and APHIS can regulate RRA only if it causes plant pest harms. *See* 7 U.S.C. § 7702(14). The environmental harms the plaintiffs cite are not plant pest harms. Moreover, the RRA plant itself does not cause the harm produced by herbicides. It is the application of herbicides to fields of RRA, not the RRA plant, that results in such harm.

APHIS stresses it has no authority to regulate the use of herbicides like glyphosate. The Coordinated Framework tasks the EPA, under FIFRA, with regulating herbicide use, and it does so through labeling instructions that the herbicide user must comply with. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991–92 (1984) (noting that amendments to FIFRA in 1972 "transformed FIFRA from a labeling law into a comprehensive regulatory statute . . . [that] regulated the use, as well as the sale and labeling, of pesticides" (citation omitted)); Coordinated Framework, 51 Fed. Reg. at 23,302. The PPA was enacted to protect plants, but not to control the burgeoning use of chemicals in crop production.

For these reasons, we cannot interpret the language of the PPA, which Congress has not materially amended since 1957, to address the alleged harms that may result from the modification of a plant's genome. The job of updating Title 7 of the United States Code to address the potential harms caused by genetic modification (including transgenic contamination and increased herbicide use) is a job for Congress, not this court, to undertake. Pursuant to the language of the statute, we must rule that RRA is not a plant pest under the meaning of the term in the PPA and the regulations.

II. APHIS's Unconditional Deregulation of RRA Violated Neither the ESA nor NEPA.

The plaintiffs argue that before APHIS decided to deregulate RRA, the agency should have consulted with the Fish and Wildlife Service ("FWS") about the adverse environmental effects that RRA's deregulation may have on endangered and threatened plants and animals. The Endangered Species Act ("ESA") imposes a duty on an agency to consult with the FWS or the National Oceanic and Atmospheric Administration Fisheries Service when an agency action may adversely affect a listed species or its critical habitat. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a); *see Karuk*, 681 F.3d at 1011.

The ESA's consultation duty is triggered, however, only when the agency has authority to take action and discretion to decide what action to take. There is no point in consulting if the agency has no choices. The Supreme Court recognized the principle in *National Association of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 655 (2007), when it said that "the ESA's requirements would come into play only when an action results from an exercise of agency discretion." *See Karuk*, 681 F.3d at 1021 (recognizing that *Home Builders* "harmonizes the ESA consultation requirement with other statutory mandates that leave an agency no discretion to consider the protection of listed species" (citation omitted)). In *Home Builders*, the Supreme Court held that once the EPA had determined that Arizona met the statutory requirements under the Clean Water Act for the transfer of regulatory authority over the state's National Pollution Discharge Elimination System permitting program, the EPA had no duty to consult because the transfer was a nondiscretionary act. *Home Builders*, 551 U.S. at 655.

Here, once APHIS concluded that RRA was not a plant pest because it did not cause plant pest injury to plants, the agency had no jurisdiction to continue regulating the crop. The agency's deregulation of RRA was thus a nondiscretionary act that did not trigger the agency's duty to consult under the ESA. Accordingly, the district court correctly ruled that APHIS's deregulation of RRA did not violate the ESA.

Nor did the district court err in entering summary judgment in favor of the defendants on the plaintiffs' NEPA claim. That claim rested on the contention that APHIS should have considered partial deregulation as an alternative to full deregulation. NEPA requires that an agency take a "hard look" at the environmental effects of a proposed action that could significantly affect the environment by evaluating all reasonable alternatives to the proposed action. *See* 40 C.F.R. § 1502.14(a); *Earth Island Inst. v. U.S. Forest Serv.*, 442 F.3d 1147, 1159 (9th Cir. 2006) (internal quotation marks omitted), *abrogated on other grounds by Winter v. Nat'l Res. Def. Council, Inc.*, 555 U.S. 7, 21 (2008). Here, there were no reasonable alternatives to deregulation because the agency lacks jurisdiction to regulate RRA. APHIS was not required to look at alternatives to the unconditional deregulation of RRA absent any jurisdiction to adopt them. *See S. Coast Air Quality Mgmt. Dist. v. FERC*, 621 F.3d 1085, 1092 (9th Cir. 2010) ("[NEPA] does not expand the jurisdiction of an agency beyond that set forth in its organic statute . . . .") (internal quotation marks omitted) (alterations in original).

III. Consistency with *Monsanto v. Geertson Farms*

The plaintiffs nevertheless contend that the district court's decision upholding APHIS's unconditional deregulation of RRA conflicts with the Supreme Court's *Monsanto* decision, where the Court looked at alternatives to deregulation. The two decisions, however, concern different issues. In *Monsanto*, the Court's decision went only to the scope of the injunction enjoining the planting and deregulation of RRA pending preparation of the EIS. *Monsanto*, 130 S. Ct. at 2756. The Court assumed, without deciding, that APHIS had jurisdiction to regulate RRA. *Id*. In this appeal, the issue is whether APHIS correctly determined that RRA is not a plant pest, thereby compelling unconditional deregulation of RRA. The Supreme Court in *Monsanto* expressly noted that it was not addressing that issue. *Id.* ("[W]e assume without deciding that the District Court [in *Geertson*] acted lawfully in vacating [APHIS's] deregulation decision."). *Monsanto* is therefore not on point, and thus the district court's decision before us is not inconsistent with *Monsanto*.

IV. Noxious Weed Risk

The plaintiffs contend that APHIS violated the PPA by not evaluating whether RRA was a "noxious weed" under 7 U.S.C. § 7712(f). According to the plaintiffs, when Monsanto and Forage Genetics petitioned APHIS for a determination that RRA was not a "plant pest," the statute compelled the agency to evaluate whether RRA should be regulated as a noxious weed. The plaintiffs' theory is that RRA is a noxious weed under the PPA because it will "indirectly injure . . . agricultural interests" by creating glyphosate-resistant weeds. *See* 7 U.S.C. § 7702(10) (defining a "noxious weed" as "any plant or plant product that

can directly or indirectly injure or cause damage to crops . . . or other interests of agriculture").

Neither the PPA nor APHIS's regulations, however, require APHIS to conduct a separate noxious weed analysis in response to a party's petition to deregulate a plant under 7 C.F.R. § 340.6. Plant pests and noxious weeds are regulated under separate regulatory frameworks. Regulations for plant pests are contained in 7 C.F.R. parts 330 and 340 while the regulations governing noxious weeds are contained in 7 C.F.R. part 360. The procedures under 7 C.F.R. § 340.6 provide for deregulating a presumptive plant pest. A party seeking to list or delist a plant as a noxious weed must invoke procedures set forth in 7 C.F.R. § 360.500 and § 360.501. The separate regulatory frameworks for plant pests and noxious weeds are consistent with standards of the statute treating plant pests and noxious weeds separately. Indeed, the PPA kept in place the separate regulatory frameworks for plant pests and noxious weeds that were originally promulgated under the Federal Plant Pest Act and the Federal Noxious Weed Act. *See* 7 U.S.C. § 7758(c) ("Regulations issued under the authority of [the Federal Plant Pest Act and Federal Noxious Weed Act] shall remain in effect . . . .").

While APHIS has proposed amending its regulations to consider noxious weed harms and plant pest harms together, it has not yet adopted those regulations. *See* Proposed Rule, 73 Fed. Reg. 60,008, 60,011 (Oct. 9, 2008). Therefore, the regulations have no effect on APHIS's analysis of RRA. This is because proposed regulations have no legal effect. *Henry v. Champlain Enters., Inc.*, 445 F.3d 610, 619 (2d Cir. 2006); *see also Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 883, 845 (1986).

Because no party petitioned APHIS to list RRA as a noxious weed, the agency did not violate the PPA by not evaluating RRA's noxious weed properties when it deregulated RRA. The district court thus correctly ruled that APHIS did not violate the PPA by not considering, sua sponte, whether RRA was a noxious weed.

CONCLUSION

The district court's judgment in favor of the Appellees is **AFFIRMED**.