No. 09-475

# In the Supreme Court of the United States

MONSANTO COMPANY, ET AL., PETITIONERS

*v.*

GEERTSON SEED FARMS, ET AL.

*ON WRIT OF CERTIORARI*
*TO THE UNITED STATES COURT OF APPEALS*
*FOR THE NINTH CIRCUIT*

**BRIEF FOR THE FEDERAL RESPONDENTS SUPPORTING PETITIONERS**

ELENA KAGAN
*Solicitor General*
*Counsel of Record*
IGNACIA S. MORENO
*Assistant Attorney General*
EDWIN S. KNEEDLER
*Deputy Solicitor General*
SARAH E. HARRINGTON
*Assistant to the Solicitor General*
ANDREW C. MERGEN
ELLEN J. DURKEE
ANNA T. KATSELAS
*Attorneys*
*Department of Justice*
*Washington, D.C. 20530-0001*
*SupremeCtBriefs@usdoj.gov*
*(202) 514-2217*

## QUESTIONS PRESENTED

This case arose out of the decision of the Animal and Plant Health Inspection Service (APHIS) to deregulate a kind of genetically engineered alfalfa, based on APHIS's determination that the alfalfa did not present a plant pest risk. Petitioner Monsanto owns the intellectual property rights to the subject alfalfa and licenses the technology exclusively to co-petitioner Forage Genetics International, LLC. After finding that APHIS had not adequately analyzed the environmental impacts of its deregulation action under the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*, the district court entered, and the court of appeals affirmed, a permanent injunction requiring APHIS to prohibit further planting of the subject alfalfa pending the agency's completion of an Environmental Impact Statement and final decision regarding deregulation. The questions presented are:

1. Whether the court of appeals erred in affirming a permanent nationwide injunction based on a legal standard that presumed irreparable harm.

2. Whether the court of appeals erred in determining that the district court did not abuse its discretion when it declined petitioners' request for an evidentiary hearing on the scope of the permanent injunctive relief.

## TABLE OF CONTENTS



## TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Cases—Continued: Page

Cases—Continued: Page



Statutes and regulations:

Statutes and regulations—Continued: Page

Miscellaneous: Page

# In the Supreme Court of the United States

No. 09-475

MONSANTO COMPANY, ET AL., PETITIONERS

*v.*

GEERTSON SEED FARMS, ET AL.

*ON WRIT OF CERTIORARI*
*TO THE UNITED STATES COURT OF APPEALS*
*FOR THE NINTH CIRCUIT*

**BRIEF FOR THE FEDERAL RESPONDENTS SUPPORTING PETITIONERS**

## OPINIONS BELOW

The amended opinion of the court of appeals (Pet. App. 1a-26a) is reported at 570 F.3d 1130. The opinion of the district court (Pet. App. 60a-79a) is unreported.

## JURISDICTION

The amended judgment of the court of appeals was entered and a petition for rehearing was denied on June 24, 2009 (Pet. App. 104a-107a). The petition for a writ of certiorari was granted on January 15, 2010. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

## STATEMENT

1. The Plant Protection Act (PPA), 7 U.S.C. 7701 *et seq.*, provides a statutory framework for the regulation of plant pests by the Secretary of Agriculture. The PPA

states that "no person shall import, enter, export, or move in interstate commerce any plant pest," unless the action is "authorized under general or specific permit" and is in accordance with regulations issued by the Secretary to prevent the "introduction of plant pests into the United States or the dissemination of plant pests within the United States." 7 U.S.C. 7711(a). Congress enacted the PPA based on its finding that "the smooth movement of enterable plants, plant products, biological control organisms, or other articles into, out of, or within the United States is vital to the United State[s'] economy and should be facilitated to the extent possible." 7 U.S.C. 7701(5). Congress further determined, however, that the Secretary should facilitate such movement "in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests and noxious weeds." 7 U.S.C. 7701(3).

The Secretary of Agriculture has delegated his responsibilities under the PPA to the Animal and Plant Health Inspection Service (APHIS). 7 C.F.R. 2.22(a), 2.80(a)(36). APHIS has promulgated regulations governing, *inter alia*, the introduction (*i.e.*, importation, interstate movement, or release into the environment, see 7 C.F.R. 340.1) of "organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests," 7 C.F.R. 340.0(a)(2) n.1. See 7 C.F.R. Pt. 340. Such items are referred to in the regulations as "regulated article[s]." 7 C.F.R. 340.1.

The regulations provide that a regulated article may be introduced for field testing purposes pursuant to a notification process and subject to specified restrictions to protect against dissemination of the article. See

7 C.F.R. 340.3. The regulations also provide for the issuance of permits for the introduction of a regulated article. See *ibid.* The PPA and its implementing regulations authorize any person to petition APHIS for a determination that an article does not present a plant pest risk and therefore should not be regulated under 7 C.F.R. Pt. 340. 7 U.S.C. 7711(c)(2); 7 C.F.R. 340.6(a). If APHIS determines, "based upon available information," that the regulated article should not be regulated under Part 340, it will approve the petition, either in whole or in part. 7 C.F.R. 340.6(d)(3). The PPA mandates that the Secretary's ultimate decision to approve or deny the petition must be based on "sound science." 7 U.S.C. 7701(4).

2. Congress enacted the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, in order to foster better decisionmaking by agencies and more informed public participation with respect to agency actions that affect humans and the human environment. See 42 U.S.C. 4321; 40 C.F.R. 1501.1(c). NEPA requires that, whenever a federal agency proposes a "major Federal action[] significantly affecting the quality of the human environment," the agency must examine the reasonably foreseeable environmental effects of the proposed action and inform the public about those effects. 42 U.S.C. 4332(2)(C); 40 C.F.R. Pt. 1508; see *BG&E* v. *NRDC*, 462 U.S. 87, 97 (1983). In so doing, the agency must prepare a "detailed statement" of the environmental impact of the proposed action—an "environmental impact statement" (EIS)—the requirements for which are set out in regulations issued by the Council on Environmental Quality (CEQ). 42 U.S.C. 4332(2)(C); 40 C.F.R. Pts. 1502, 1508.

The regulations permit an agency to comply with NEPA by preparing an "environmental assessment" (EA) in lieu of an EIS in certain circumstances. 40 C.F.R. 1501.4. The regulations define an EA as a "concise public document" that briefly describes the need for, alternatives to, and environmental impacts of the proposed federal action. 40 C.F.R. 1508.9. If the agency determines, based on the EA, that the proposed federal action will not significantly affect the quality of the human environment, it then makes a "[f]inding of no significant impact" (FONSI), 40 C.F.R. 1508.13, and it need not prepare an EIS, 40 C.F.R. 1501.3. If the agency determines that the proposed action will significantly affect the quality of the environment, it must prepare an EIS. 40 C.F.R. Pt. 1502; see *DOT* v. *Public Citizen*, 541 U.S. 752, 757-758 (2004).

NEPA "does not mandate particular results, but simply prescribes the necessary process." *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989). NEPA's "mandate to the agencies is essentially procedural" and is designed "to insure a fully informed and well-considered decision" on the part of the federal agency. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 558 (1978).

3. This case concerns "Roundup Ready alfalfa" (RRA), an alfalfa crop that was genetically engineered by petitioner Monsanto Company (Monsanto) to tolerate glyphosate, the active ingredient in the herbicide Roundup. Pet. App. 5a. RRA was genetically engineered to be glyphosate-tolerant by inserting into the alfalfa genome a gene that codes for a particular enzyme. J.A. 348. The gene is from a common soil bacterium (*Agrobacterium* sp. strain CP4), and was introduced via an *Agrobacterium*-mediated transformation

protocol that has been used to introduce specific genes into plant genomes for more than twenty years. *Ibid.* APHIS initially classified RRA as a regulated article under the PPA. Pet. App. 5a.

Alfalfa is a perennial herbaceous legume that is pollinated by insects, usually honeybees or leafcutter bees. J.A. 346-347. Nearly all (99%, see Pet. App. 321a) of the alfalfa grown in this country is grown for consumption by livestock as hay or forage. J.A. 346. Alfalfa is also grown for seed. Most of that seed is used to produce alfalfa plants for hay or forage, although a small amount is grown for human consumption in the form of alfalfa sprouts. J.A. 346-347. More than 22 million acres of alfalfa are harvested in the United States every year. J.A. 446. The States that produce the most alfalfa are located in the Midwest and West, including California, South Dakota, Wisconsin, Idaho, Minnesota, and Iowa. *Ibid.* Alfalfa hay is primarily sold in three major markets: for dairy cattle (the predominant market), beef cattle, and horses. J.A. 447-448. The market for alfalfa seed is far smaller in acreage and more localized in western States. J.A. 447.

Depending on the needs of the grower and the climate, alfalfa can be planted in the Spring or Fall. Once established, an alfalfa field can be mowed three to four times per year and remain productive for a number of years. J.A. 346-347. Within a field, the plant is often rotated with other crops, both because alfalfa improves the nitrogen content of the soil in which it is planted and because alfalfa exhibits autotoxicity, meaning that alfalfa seeds do not germinate well in established alfalfa fields. J.A. 347.

The management of weeds in alfalfa fields can be expensive, labor intensive, and sometimes complicated.

J.A. 182. Alfalfa growers often use pre-emergent herbicides, which prevent weed seeds from germinating, but a pre-emergent herbicide must be applied in all areas of a field to be effective. *Ibid.* By growing RRA, which is tolerant of glyphosate, growers may instead apply a glyphosate herbicide only after weeds have germinated and only in areas where weeds actually appear. *Ibid.*

APHIS first authorized the field testing of RRA in 1998. J.A. 348. In 1999 and 2000, Monsanto and FGI submitted design protocols to APHIS describing how field trials of RRA would be managed in order to comply with the performance standards that govern all genetically engineered crops authorized by APHIS for field trials. *Ibid.* Those standards require that the genetically engineered plants be confined effectively and that they be discarded after the conclusion of the field trial. *Ibid.* The protocols submitted by Monsanto and FGI included either (1) the maintenance of a buffer zone of at least 900 feet between RRA and other alfalfa, (2) the confinement of flowering plants to cages in order to bar access by pollinators, or (3) the mowing of plantings to prevent the development of flower buds. *Ibid.* In addition, the protocols required the cleaning after use of any farm equipment used on RRA that could have retained its reproductive parts. J.A. 349. The protocols further required that RRA be destroyed with herbicide when the trials ended, and that the plant debris be incorporated into the soil by disking. *Ibid.* Finally, fields planted with RRA were required to be labeled and monitored for one growing season after the termination of the trial. *Ibid.* APHIS ultimately authorized 297 field trials over the course of approximately eight years prior to its decision to deregulate RRA. J.A. 348.

4. In 2004, petitioners submitted to APHIS a petition requesting non-regulated status for RRA under the PPA. Pet. App. 5a. On November 24, 2004, after completing a draft EA, APHIS published a notice in the *Federal Register* (1) informing the public of APHIS's receipt of the petition, (2) making the EA available for public comment, and (3) soliciting public comment on whether RRA presents a plant pest risk. See *id.* at 6a; 69 Fed. Reg. 68,300-68,301.

On June 27, 2005, APHIS published in the *Federal Register* a notice that it had prepared a final EA regarding the proposal to deregulate RRA and had "reached a finding of no significant impact." 70 Fed. Reg. 36,917-36,919. APHIS issued the FONSI after analyzing "data submitted by Monsanto/FGI, a review of other scientific data, field tests of the subject alfalfa, and comments submitted by the public." *Id.* at 36,918. In its deregulation decision, APHIS explained its determinations that RRA: (1) exhibits no plant pathogenic properties; (2) exhibits no characteristics that would cause it to be more weedy than other alfalfa; (3) is unlikely to increase the weediness potential of other species; (4) will not damage raw or processed agricultural commodities; (5) should not damage or harm organisms beneficial to agriculture; and (6) should not reduce the ability to control pests or weeds in alfalfa or other crops. *Id.* at 36,918-36,919. On the basis of its FONSI, APHIS concluded that it did not need to prepare an EIS, and it deregulated RRA. Pet. App. 7a.

5. In February 2006, approximately eight months after APHIS rendered its decision to deregulate RRA, Geertson Seed Farms and others (hereinafter respondents) filed suit against the Secretary of Agriculture and other federal officials (collectively, APHIS) alleging

violations of NEPA, the Endangered Species Act of 1973 (ESA), 16 U.S.C. 1531 *et seq.*, and the PPA. Pet. App. 7a, 27a. Respondents did not seek preliminary injunctive relief prior to the court's determination of the merits of their claims, and RRA therefore was commercially available for planting based on its deregulated status beginning in June 2005. *Id.* at 55a, 58a; J.A. 350.

On cross-motions for summary judgment, the district court held that APHIS had violated NEPA in failing to prepare an EIS. Pet. App. 37a-53a. The court found that APHIS's EA was insufficient in two respects: (1) it did not adequately consider the potential for gene transmission between RRA and non-genetically engineered alfalfa; and (2) it did not adequately consider the potential for the development of glyphosate-resistant weeds. *Id.* at 7a-8a, 32a-53a. The district court declined to reach respondents' ESA and PPA claims. *Id.* at 51a.

Following the district court's decision on the merits, petitioners moved to intervene as defendants on the question of remedy. Pet. App. 8a. The district court granted their motions, agreeing to give them the opportunity "to present evidence to assist the court in fashioning the appropriate scope of whatever relief is granted." *Id.* at 54a (citing *Forest Conservation Council* v. *USFS*, 66 F.3d 1489, 1496 (9th Cir. 1995)). The court received written evidentiary submissions from all parties and heard several hours of oral argument, on the basis of which it issued a preliminary injunction. *Id.* at 63a; see *id.* at 54a-59a.

APHIS proposed a remedy under which it would, in addition to preparing an EIS, impose six restrictions on the planting of RRA and on the handling of RRA seed pending the completion of the EIS. Pet. App. 184a-187a; see J.A. 376-378. APHIS's proposed restric-

tions included: (1) mandatory isolation distances between RRA and conventional or organic alfalfa seed production fields to mitigate any potential pollen flow between the two; (2) mandatory harvesting conditions for RRA fields to minimize cross-pollination in areas where alfalfa seed is produced; (3) a requirement that planting and harvesting equipment be cleaned after contact with RRA prior to its use on non-genetically engineered alfalfa; (4) identification and handling requirements for RRA seed applicable before and after harvest; (5) a prohibition on the use of RRA for livestock grazing purposes or in mixed grass pastures; and (6) a requirement that all RRA seed producers and hay growers be under contract with either Monsanto or FGI and that their contracts require compliance with the first five conditions. See J.A. 439-445. APHIS explained the bases for these conditions in the first and second declarations of Dr. Neil Hoffman, Director of the Environmental Risk Analysis Division of APHIS's Biotechnology Regulatory Services (BRS), and the exhibits attached thereto. J.A. 345-365, 436-542. In setting forth the scientific underpinnings of APHIS's proposed conditions, the Director noted that "BRS has many years of experience regulating [RRA]" and "ha[d] previously granted nonregulated status to other GE [genetically engineered] glyphosate-tolerant crops, including corn, cotton, soybean, canola and sugarbeet." J.A. 347, 348.

Instead of adopting APHIS's suggested limitations, the district court issued a preliminary injunction on March 12, 2007, vacating APHIS's deregulation determination and enjoining all planting of RRA and all sales of RRA seed beginning March 30, 2007. Pet. App. 8a, 54a-59a. The court cited *Idaho Watersheds Project* v. *Hahn*, 307 F.3d 815, 833 (9th Cir. 2002), for the proposi-

tion that, "[i]n the run of the mill NEPA case, the contemplated project, whether it be a new dam or a highway extension, is simply delayed until the NEPA violation is cured," although in "unusual circumstances" an injunction "may be withheld or, more likely, limited in scope." Pet. App. 55a. The court noted that this was not a run of the mill case in certain respects because some alfalfa growers had already purchased and planted RRA in reliance on APHIS's deregulation decision. *Id.* at 8a, 55a. The court did not require those growers to remove or destroy their already-planted RRA; the court also allowed growers who had already purchased RRA seed at the time of its order to plant such seed prior to March 30, 2007. *Id.* at 8a, 55a-58a. In other respects, however, the court concluded that this case was an ordinary NEPA case, and that neither APHIS nor petitioners had identified any "unusual circumstances" that would lead the court to permit an increase in the number of acres planted with RRA while the court considered the appropriate scope of permanent injunctive relief. *Id.* at 56a-57a. The court noted that it would consider "whatever additional evidence [petitioners] wish to provide," allow APHIS the opportunity to present additional evidence, and allow respondents to make their own submission before fashioning permanent injunctive relief. *Id.* at 58a-59a.

The parties then submitted evidence, including declarations, concerning the appropriate scope of permanent injunctive relief. Pet. App. 9a, 64a. The court entered a permanent injunction on May 3, 2007. *Id.* at 60a-79a. The court ordered APHIS to prepare an EIS and enjoined all planting of RRA from March 30, 2007, until the completion of the EIS. *Id.* at 79a. In its order, the court acknowledged that petitioners had "requested

an evidentiary hearing, apparently so the Court can assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed, as well as to resolve disputes with plaintiffs' witnesses." *Id.* at 67a. The court denied that request, reasoning that to make the findings requested by petitioners would be tantamount "to engag[ing] in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS." *Id.* at 68a; see *id.* at 68a-69a.

The district court also noted that APHIS had not submitted evidence concerning whether, and to what extent, its proposed interim conditions would be followed. Pet. App. 69a-70a. The court criticized the efficacy of particular proposed restrictions in eliminating the possibility of gene flow, noting that weather conditions might prevent farmers from always harvesting as contemplated by APHIS's proposal. *Id.* at 70a-71a. The court stated that it had explained in its ruling on the merits of the NEPA issue that "contamination of organic and conventional alfalfa crops with the genetically engineered gene has occurred and defendants acknowledge as much. Such contamination is irreparable environmental harm." *Id.* at 71a; see *id.* at 70a-71a. The court concluded that the harm to "farmers and consumers who do not want to purchase genetically engineered alfalfa or animals fed with such alfalfa outweighs the economic harm to Monsanto, Forage Genetics and those farmers who desire to switch to Roundup Ready alfalfa." *Id.* at 71a.

6. a. APHIS and petitioners appealed on the ground that the permanent injunction was overly broad. Pet. App. 10a. Petitioners further argued that the district court erred by denying their request for an evidentiary hearing. *Id.* at 16a. No appellant challenged the

district court's merits determination that APHIS's NEPA analysis was insufficient. *Id.* at 5a.

The court of appeals initially affirmed entry of the permanent injunction in an opinion dated September 2, 2008. Pet. App. 82a-103a. Following the filing of a petition for rehearing and rehearing en banc by petitioners, the court issued an amended opinion on June 24, 2009, *id.* at 1a-26a, and simultaneously denied the petition for rehearing en banc, *id.* at 104a-107a.

The court of appeals rejected the contention that the district court had erred in issuing the permanent injunction because it had improperly presumed irreparable injury to respondents. Pet. App. 10a-16a. In the court of appeals' view, "the record demonstrates that the district court applied the traditional four-factor test" for the issuance of an injunction, as "required by" *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006). Pet. App. 13a; *id.* at 10a-16a. The court noted that the district court had found that gene contamination of organic and conventional alfalfa had occurred while petitioners had contractual obligations in place that were similar to the mitigation measures proposed by APHIS, and that such contamination constituted irreparable harm because contamination cannot be reversed and farmers cannot replant alfalfa for two to four years after contaminated alfalfa has been removed. *Id.* at 13a-14a. The court also concluded that the district court adequately considered the interests of both petitioners and the public. *Id.* at 14a-15a. In upholding the scope of the injunction, the court of appeals rejected the government's argument that the district court should have deferred to APHIS's proposed interim measures. *Id.* at 15a-16a.

Finally, the court rejected petitioners' argument that the district court erred in declining to hold an evi-

dentiary hearing involving live testimony before issuing the permanent injunction. Pet. App. 16a-20a. The court stated that a district court should generally hold such a hearing absent waiver by the adverse party. *Id.* at 17a. But the court of appeals explained that the district court in this case "did not believe defendants had established any material issues of fact that were in dispute in the case before the court," but rather "viewed the disputed matters to be issues to be more properly addressed by the agency in the preparation of an EIS." *Id*. at 17a-18a.

The court of appeals observed in this regard that the injunction at issue was similar to the one in *Idaho Watersheds*—which the court of appeals also upheld without an evidentiary hearing, 307 F.3d at 830-831—because the injunction will be in effect only until APHIS completes an EIS and provides the parties with an opportunity to participate in further proceedings regarding the scope of permanent measures. Pet. App. 17a-19a. The court noted as well that the government did not contend that an evidentiary hearing was required, perhaps to avoid the duplicative inquiries by the district court and the agency of the sort the court of appeals had described in *Idaho Watersheds*. *Id.* at 19a. Finally, the court disagreed with the dissent on the antecedent issue of whether the district court had failed to hold any evidentiary hearing at all, noting that the court had held one hearing on the NEPA violation, held two hearings on the scope of injunctive relief (which included some questioning by the court of petitioner Forage Genetics' president), and reviewed extensive documentary submissions. *Id*. at 19a-20a.

b. Judge Smith dissented on the issue of whether the district court should have conducted an evidentiary

hearing before issuing the permanent injunction. Pet. App. 20a-26a. He would have held that, under Federal Rule of Civil Procedure 65, a district court must hold an evidentiary hearing unless the material facts are undisputed or the adverse party waives its right to such a hearing. Pet. App. 20a-21a (citing *Charlton* v. *Estate of Charlton*, 841 F.2d 988, 989 (9th Cir. 1988)). Judge Smith found that neither exception applied, and dismissed as insignificant APHIS's failure to request an evidentiary hearing given that petitioners had requested one. *Id.* at 21a-22a.

7. Pursuant to the district court's order, APHIS has been preparing an EIS related to the petition to deregulate RRA. On December 14, 2009, APHIS announced the availability for public review of a nearly 200-page draft EIS, which addresses, *inter alia*, the potential for gene flow from RRA to conventional and organic alfalfa, as well as the potential for an increase in glyphosate-resistant weeds. USDA, *Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status Draft Environmental Impact Statement* (Nov. 2009), http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa_deis.pdf (draft EIS); *USDA Seeks Public Comment on Draft Environmental Impact Statement for Genetically Engineered Alfalfa* (Dec. 14, 2009), http://www.aphis.usda.gov/newsroom/content/2009/12/ printable/alfalfa_brs.pdf (press release). APHIS extended the initial 60-day comment period, which commenced on December 18, 2009, the date of publication of the notice of availability of the draft EIS in the *Federal Register*. 74 Fed. Reg. 67,206. The comment period will now close on March 3, 2010. 75 Fed. Reg. 8299-8300 (2010).

## SUMMARY OF ARGUMENT

The issuance of a permanent injunction in this case was improper. The district court failed to find either that respondents had suffered or were likely to suffer irreparable harm or that legal remedies would be inadequate to compensate any harm respondents might suffer. Instead, the district court presumed that irreparable injury had resulted or would result from APHIS's failure to comply with the procedural requirements of NEPA. But this Court has repeatedly held that the mere fact of a statutory violation by a government agency does not establish irreparable injury. The Court has emphasized that plaintiffs challenging administrative action must satisfy the traditional four-factor test before a district court may enter an injunction.

As a result of the lower courts' error, there is a nationwide injunction in place that is not supported by the equities of this case. The injunction eliminates a choice for growers and consumers nationwide and intrudes on APHIS's regulatory role. APHIS deregulated RRA in furtherance of its mission under the PPA, and the district court did not find a substantive violation of the PPA. Nor did respondents submit any evidence that their alfalfa crops had been cross-pollinated by the RRA gene, or that APHIS's proposed interim measures would be insufficient to prevent any such harm in the future. The interim measures proposed by APHIS would have satisfied its obligation under NEPA to refrain from activities that would have an adverse environmental impact or would limit the choice of reasonable alternatives pending completion of an EIS. The district court ignored traditional principles governing review of administrative action in refusing to defer to the interim measures APHIS proposed based on its scientific exper-

tise. The court substituted its own judgment about the measures needed to prevent gene flow from RRA fields to non-RRA alfalfa fields while APHIS prepares the EIS.

This Court need not decide whether the district court was required to hold an evidentiary hearing including live witness testimony prior to entering the permanent injunction because the existing record makes clear that the injunction is overly broad. The error committed by the district court was not a failure to obtain necessary evidence, but a failure to apply the correct legal standard to the facts in the existing record, which show that the possibility of gene flow is *de minimis*. If the Court reaches the issue, however, it should not adopt a rule that invariably requires a district court to hear live testimony in an Administrative Procedure Act (APA) case before deciding whether to enter permanent injunctive relief. Although a district court may need to receive additional evidence to assess the appropriateness of equitable relief, the court should be permitted to exercise its discretion in deciding how to do so, including through written submissions.

## ARGUMENT

The district court held that APHIS violated NEPA by preparing an EA instead of an EIS in conjunction with petitioner's request to have RRA deregulated, and the court ordered APHIS to prepare an EIS. Neither APHIS nor petitioners appealed those rulings. But this Court has made clear that the finding of a statutory violation by a government agency does not necessarily justify the entry of an injunction barring the proposed action. *Weinberger* v. *Romero-Barcelo*, 456 U.S. 305, 311, 313 (1982). On the contrary, the entry of an injunction

may be awarded only upon a separate showing that the plaintiff is entitled to such relief. *Winter* v. *NRDC*, 129 S. Ct. 365, 375-376 (2008).

Moreover, even when injunctive relief is found appropriate, that relief must be tailored to address the statutory violation, taking into account the respective harms to the parties, measures that can be taken to mitigate those harms, and the public interest. See, *e.g.*, *Winter*, 129 S. Ct. at 376-381. The essence of a court's equity jurisdiction is the power to mold each injunction "to the necessities of the particular case." *Romero-Barcelo*, 456 U.S. at 312; see also *Lewis* v. *Casey*, 518 U.S. 343, 359-360 (1996) (citing cases); *Califano* v. *Yamasaki*, 442 U.S. 682, 702 (1979).

The federal parties do not challenge the propriety of some injunctive relief in this case to cure the violation of NEPA found by the district court and to minimize the prospect of environmental harm while APHIS prepares an EIS. The courts below erred, however, in rejecting APHIS's proposed interim measures, which were carefully tailored to accomplish those purposes, and instead imposing a broad injunction barring all future sales and planting of RRA.

The district court in this case applied the wrong legal standard, effectively presuming that the NEPA violation caused irreparable injury and justified the entry of a broad injunction. And the court of appeals erred in upholding that injunction, which is not tailored to the circumstances of the case and cannot be supported by a proper balancing of equities.

## I. THE DISTRICT COURT APPLIED THE WRONG STANDARD IN ISSUING THE PERMANENT INJUNCTION

This Court has frequently articulated the standard a plaintiff must meet to justify a district court's entry of a permanent injunction. As this Court reiterated in *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006):

> According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

See also *Romero-Barcelo*, 456 U.S. at 312 ("The Court has repeatedly held that the basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies."); *Winter*, 129 U.S. at 374, 381.

Contrary to this clear mandate, the district court enjoined—first preliminarily and then permanently—all commercial planting of RRA, without requiring respondents to demonstrate that they had suffered or likely would suffer irreparable harm in the absence of such an injunction, that remedies at law would be inadequate to compensate them for any injury, and that the balance of harms warranted more than the measures submitted by APHIS. Pet. App. 54a-59a, 60a-79a. Although the court of appeals recited the appropriate legal standard, see *id.*

at 11a, its determination that the district court correctly applied that standard cannot be squared with the course of proceedings in this case.

### A. The District Court Entered The Permanent Injunction Based On An Erroneous Presumption That An Injunction Should Be Entered Except In Unusual Circumstances

1. Under traditional principles of equity, "the scope of injunctive relief is dictated by the extent of the violation established." *Yamasaki*, 442 U.S. at 702. In this case, the district court found a single statutory violation: APHIS's failure to prepare an EIS under NEPA before deregulating RRA. Specifically, the court concluded that APHIS did not adequately study the potential for gene flow from RRA to conventional and organic alfalfa and the potential for the development of glyphosate-resistant weeds. Pet. App. 35a-47a. APHIS did not appeal the portion of the permanent injunction that ordered "the government to prepare an EIS before it makes a decision on Monsanto's deregulation." *Id.* at 79a. But in ordering a halt to all commercial planting of RRA pending completion of the EIS, rather than approving APHIS's proposed conditions on planting, the district court incorrectly exercised its equitable jurisdiction.

NEPA imposes procedural requirements on federal agencies, but does not require an agency to choose any particular substantive result. *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989). An agency's failure to conduct the "hard look" required by NEPA before undertaking a particular action, see *Winter*, 129 S. Ct. at 376 (quoting *Methow Valley Citizens Council*, 490 U.S. at 352), does not, in itself, constitute

irreparable injury to the plaintiff. *Summers* v. *Earth Island Inst.*, 129 S. Ct. 1142, 1151 (2009). As in any case seeking to enjoin government action, an injunction in a NEPA case must be based, *inter alia*, on a finding that the action at issue has caused or is likely to cause irreparable injury to the plaintiff.

As a matter of practical experience, cases involving claims of significant harm to the environment may result in injunctive relief more often than private litigation involving economic or other interests. As this Court observed in *Amoco Production Co.* v. *Village of Gambell*, 480 U.S. 531 (1987), certain types of injury cannot be undone. "Environmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, *i.e.*, irreparable. If such injury is sufficiently likely, therefore, the balance of harms will usually favor the issuance of an injunction to protect the environment." 480 U.S. at 545.

But the Court in *Amoco Production Co.* explicitly rejected a standard under which, in the absence of "unusual circumstances," "[i]rreparable damage is presumed when an agency fails to evaluate thoroughly the environmental impact of a proposed action." 480 U.S. at 541, 544-545 (quoting *People of the Vill. of Gambell* v. *Hodel*, 774 F.2d 1414, 1423 (9th Cir. 1985), rev'd in part and vacated in part, 480 U.S. 531 (1987)). Such a "presumption," the Court held, "is contrary to traditional equitable principles." *Id.* at 544-545. Rather, in every NEPA case (as in every other kind of case), a plaintiff must demonstrate that it has suffered or is likely to suffer irreparable injury to obtain an injunction. Not every NEPA plaintiff will be able to make that showing, and respondents did not do so here.

Ignoring *Amoco*, the district court in this case relied on Ninth Circuit cases holding that, "in the run of the mill NEPA case," an injunction should issue delaying the agency action in question, and that such an injunction should be denied only in "unusual circumstances." Pet. App. 65a-66a (quoting *Idaho Watersheds Project* v. *Hahn*, 307 F.3d 815, 833 (9th Cir. 2002), and citing *National Parks & Conservation Ass'n* v. *Babbitt*, 241 F.3d 722, 737 (9th Cir. 2001), cert. denied, 534 U.S. 1104 (2002)); see also *id.* at 55a. Although the courts below gave lip service to the proposition that an injunction does not automatically issue upon the finding of a NEPA violation (see *id.* at 65a; *id.* at 11a), they effectively flouted the bedrock principle of equity that an injunction must be based on a likelihood of irreparable harm.

APHIS's decision to deregulate RRA without the appropriate EIS does not itself establish or create a presumption of irreparable harm to respondents or the environment. In *Romero-Barcelo*, this Court explained that, "[u]nless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied." 456 U.S. at 313 (quoting *Porter* v. *Warner Holding Co.*, 328 U.S. 395, 398 (1946)). NEPA does not restrict the equity jurisdiction of federal courts, either explicitly or implicitly, and "nowhere specifies the consequences of a failure" by agency officials to prepare an EIS. See *Brock* v. *Pierce County*, 476 U.S. 253, 259 (1986). Neither do the applicable NEPA regulations require cessation of all agency actions or activities during the course of the NEPA process. See 40 C.F.R. 1506.1(a); see also *National Audubon Soc'y* v. *Department of the Navy*, 422 F.3d 174, 203 (4th Cir. 2005) ("The CEQ regulations and our own

caselaw make clear that agency action prior to completing a sufficient environmental study violates NEPA only when it actually damages the environment or 'limit[s] the choice of reasonable alternatives.'") (citation omitted). The district court's determination in this APA suit that APHIS had violated NEPA's procedural requirements therefore was not itself sufficient to support the district court's broad injunction.[1]

The district court purported to find the necessary irreparable injury in respondents' assertion that they faced a risk of "contamination of organic and conventional alfalfa crops with the genetically engineered gene" in RRA. Pet. App. 71a. As an initial matter, a plaintiff must demonstrate more than a mere possibility of irreparable harm in order to be entitled to injunctive relief. In the context of a preliminary injunction, this Court made clear in *Winter* that a plaintiff must "demonstrate that irreparable injury is *likely* in the absence of an injunction." 129 S. Ct. at 375. The same considerations apply in determining whether a permanent injunction is appropriate. See *id.* at 381. Indeed, this Court stated in *eBay* that a plaintiff must demonstrate

---

[1] In authorizing review of agency action in a suit for declaratory or injunctive relief, see 5 U.S.C. 703, the APA suggests no departure from the well-established rule that the party seeking an injunction bears the burden of establishing that such relief is necessary. See, *e.g.*, *eBay*, 547 U.S. at 391. Indeed, the APA's very authorization of "declaratory judgments," 5 U.S.C. 703, indicates that the APA does not compel an injunction when agency action is found unlawful. See H.R. Rep. No. 1980, 79th Cong., 2d Sess. 42 (1946) (referring to possibility of suits for declaratory relief to "determine the validity or application of a rule or order"); see also S. Rep. No. 752, 79th Cong., 1st Sess. 26 (1945). Thus, under the APA, a party challenging agency action must demonstrate that a declaratory judgment would be inadequate and that the further relief of an injunction is necessary.

"that it *has suffered* an irreparable injury," 547 U.S. at 391 (emphasis added), to qualify for a permanent injunction, a standard that cannot be satisfied by unsupported assertion of a potential future harm. There was no showing that RRA had significantly affected conventional or organic alfalfa crops, or that any such effect was imminent or likely. That omission properly required the district court to adopt APHIS's proposed safeguards and reject respondents' request for nationwide injunctive relief barring all sales and commercial planting of RRA until an EIS is completed.[2]

In sum, the district court predicated the injunction it imposed on the NEPA violation alone, effectively pre-

[2] In support of their motion for permanent injunctive relief, respondents submitted declarations of growers of non-genetically engineered alfalfa expressing their fears that their crops would be affected by RRA and that they accordingly would suffer economic loss. See, *e.g.*, J.A. 380, Geertson Decl. ¶ 6 (stating that allowing the planting of RRA is "threatening" to non-RRA crops); J.A. 400-401, Asumendi Decl. ¶¶ 3-6 (relating company's fear that it will be unable to choose to grow conventional alfalfa, and will lose money); J.A. 404, Holtz Decl. ¶ 5 (stating that he is "very concerned" about the release of RRA); J.A. 409, Gauntt Decl. ¶ 5 (concerned that widespread planting of RRA will threaten overseas business); J.A. 666, Baxter Decl. ¶ 6 ("While I have not been contaminated yet, I believe it is only a matter of time."). However, respondents did not claim that any of them had actually experienced such an impact or consequent economic loss. One declarant claimed to have abandoned his organic alfalfa operation because of a fear of liability if his seed acquired the RRA gene and affected another farmer's organic seed, but did not state that such an effect had actually occurred. J.A. 398-399, Schmaltz Decl. ¶¶ 10-11. Similarly, other declarants claimed to have heard second-hand reports of RRA gene flow. J.A. 663-664, Nichols Decl. ¶¶ 6-8; J.A. 1008-1009, Briggs Decl. ¶¶ 13-15. Respondents also speculated, based on a pollen flow study that had documented the RRA gene in feral alfalfa located 1.7 miles from an RRA seed field, that some gene flow could occur. E.R. 441, Pl. Mot. 8 n.4; J.A. 380-381, Geertson Decl. ¶¶ 8-10.

suming the existence of irreparable injury (and other prerequisites to an injunction) in the absence of "unusual circumstances," rather than actually finding harm. Pet. App. 65a-66a. In entering its injunction, the district court stated that it had already found in its initial memorandum and order finding the NEPA violation that cross-pollination had occurred. See *Id.* at 71a. But the district court's reliance on its earlier order exposes its error, because the discussion there addressed only whether APHIS had adequately considered the potential for infiltration of conventional alfalfa crops by RRA, not whether such infiltration had actually occurred. *Id.* at 35a-45a.[3] Without a finding that harm from such infiltration had occurred or is likely to occur, the district court's injunction cannot stand.[4]

2. Even if respondents had demonstrated a significant risk that RRA would enter some fields of conventional and organic alfalfa crops through cross-pollination, that showing would not have supported the broad

---

[3] Although the district court purported to find that some cross-pollination had already occurred, it relied on hearsay evidence submitted by respondents, none of which in fact showed that a meaningful level of cross-pollination had occurred under conditions similar to those proposed by APHIS. Pet. App. 404a-407a. One alleged incident involved the discovery of the RR gene in a non-RRA seed lot. *Id.* at 404a. But petitioners demonstrated that any intermingling of RRA in that grower's seeds was likely caused by the grower's own use of RRA or was a false positive due to lab contamination. *Id.* at 405a.

[4] The district court elsewhere appeared to acknowledge that it had not adequately assessed the risk that adverse effects would result if RRA cross-pollinated some conventional or organic alfalfa fields. Indeed, the court declined even to engage in that analysis because doing so would, in the district court's view, "require th[e] Court to engage in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS." Pet. App. 68a.

permanent injunction the district court entered. Respondents did not show—and the district court did not find—that such an effect would cause irreparable harm.

a. As an initial matter, there is no evidence in the record that gene flow from RRA would destroy other types of alfalfa, even if left completely unchecked rather than subjected to the safeguards embodied in the APHIS conditions. The glyphosate-resistant gene in RRA is not contagious; it will not transform a non-RRA alfalfa plant into RRA upon mere contact. See Pet. App. 232a, 386a; J.A. 355. If RRA plants were to cross-pollinate with conventional or organic alfalfa, the pollinated non-RRA plant might produce seeds with the RRA gene. But the original non-RRA plant would not be transformed into an RRA plant. And the likelihood that such an RRA-affected seed would be produced—and then would grow into a mature RRA plant—is small and dependent on the occurrence of a series of unlikely events.

*First*, an RRA field must be permitted to flower and, therefore, produce pollen. J.A. 438; Pet. App. 230a. Farmers who grow RRA for hay and forage—as 99% of alfalfa farmers do, Pet. App. 321a—do not generally permit their fields to flower in any significant degree because flowering decreases the nutritional value of the plant, which also reduces its economic value. Pet. App. 128a, 279a; J.A. 346-347, 355, 483-484, 565.

*Second*, assuming a field flowers more than the grower intended (because, for example, of weather-related delays in mowing, see Pet. App. 70a), pollinating bees must transfer the pollen from those flowers to another field. J.A. 438; Pet. App. 230a. In fields grown for hay and forage, farmers do not stock their crops with pollinators because they do not intend to permit the

plants to flower. J.A. 438; Pet. App. 230a-231a, 279a. Thus, pollination could occur only through feral bees; but feral bees are unlikely to be attracted to RRA fields grown for hay or forage because such fields generally produce few flowers. J.A. 356; Pet. App. 128a-130a, 231a.

*Third*, a pollinator would have to travel to a non-RRA alfalfa field that was flowering simultaneously—an unlikely event given that different varieties of alfalfa flower at different times—and to pollinate one or more of those flowers. J.A. 438.

*Fourth*, the grower of the non-RRA alfalfa would have to allow his crop to produce seeds, which generally occurs at least a month after the crop flowers. Only if plants in the non-RRA crop that have been fertilized with pollen from an RRA plant produce seeds might an RRA plant grow in a non-RRA alfalfa field. J.A. 438; Pet. App. 231a. But the grower with a non-RRA hay field is unlikely to postpone cutting for that long, because, as explained above, the alfalfa would lose nutritional and economic value.

*Finally*, the seed would have to actually grow into an RRA plant. But that is unlikely if the seed simply drops to the ground in that field because alfalfa exhibits autotoxicity, meaning that alfalfa seeds do not germinate well in established alfalfa fields. J.A. 347, 438; Pet. App. 232a-233a.[5]

Given this necessary chain of improbable events, the chance that RRA would infiltrate and germinate in any alfalfa field grown for hay or forage is exceedingly low. And the interim safeguards APHIS submitted to the

[5] In addition, alfalfa seeds are relatively heavy and therefore unlikely to be carried by the wind outside of that field. Pet. App. 130a. Nor does alfalfa shed pollen to the wind. *Id.* at 230a.

district court would further protect against that possibility.

b. Even if some RRA were to take root in a conventional alfalfa hay or seed field, the economic harm to the grower of the affected crop is compensable with money damages. That harm, as an initial matter, is not likely to be significant. The grower might lose some potential buyers, but could continue to sell the affected alfalfa in markets not sensitive to the presence of genetically modified plants.[6] And if the grower preferred to rid its field of the crop containing some RRA plants, it could do so by using common techniques of clearing the field and then replanting with non-RRA alfalfa seed within one

---

[6] Indeed, the infiltration of RRA into a conventional alfalfa field would not necessarily cause an organic grower to lose its USDA organic certifications. The USDA National Organic Program (NOP) was established in 1990 to create uniform standards governing the marketing of organic crops. See Organic Foods Production Act of 1990, 7 U.S.C. 6501 *et seq.* The process-based NOP "requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances, such as modified genes, from adjoining land that is not under organic management." Pet. App. 37a (citation omitted). But the NOP regulations do not prohibit the sale of a crop as organic merely because it has been affected by genetic drift from a crop that has been genetically engineered. 65 Fed. Reg. 80,556 (2000) ("The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation."). Indeed, the issue of genetic drift was raised during the rulemaking process for the NOP, and USDA rejected suggestions that restrictions should be placed on the growers of genetically engineered crops to protect against genetic drift. See *ibid.* Instead, USDA explained that, "[a]s long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation." *Ibid.*

growing cycle. Pet. App. 387a, 397a, 409a-410a.[7] In any event, this economic harm is fully compensable by money damages from the responsible private party, assuming a court were to find that a legal injury had occurred. Because traditional legal remedies would suffice to cure economic harm from gene flow, that harm cannot support the permanent injunction. *E.g.*, *Romero-Barcelo*, 456 U.S. at 312.

c. The case would be different if the district court had found irreparable harm to a plant species, but no evidence of such harm exists. It is a great leap from a finding of cross-pollination (assuming that were justified) to a finding of significant harm to any species of conventional alfalfa. With respect to animal species, the "loss of only one [animal] is [not a] sufficient injury to warrant a preliminary injunction"; a plaintiff "must demonstrate 'a substantial likelihood of * * * irreparable harm'" to his own interests resulting from some form of "irretrievabl[e] damage [to] the species." *Fund for Animals* v. *Frizzell*, 530 F.2d 982, 986-987 (D.C. Cir. 1975) (citation omitted); accord *Water Keeper Alliance* v. *United States DoD*, 271 F.3d 21, 34 (1st Cir. 2001) (death of a "single member of an endangered species" does not qualify as irreparable harm absent showing of how "probable deaths * * * may impact the species"). The same analysis should apply for a plant species. An adverse effect on plants in one or several fields of a crop as widely grown as alfalfa is not irreparable injury to the species. Hence, this case differs markedly from NEPA cases in which irreparable environmental harm

[7] In addition, a grower of non-RRA alfalfa can engage in self-help to prevent the possibility of RRA's infiltrating his field by mowing it before the crop produces seeds—a practice that is in his economic interest in any case. See p. 36, *supra*.

will result from the statutory violation. Here, at most economic harm, and not any irreparable harm to a species, is a plausible consequence of declining to enter an injunction.

3. Finally, the district court erred in balancing the equities in this case. RRA was commercially available for nearly two years during the pendency of the merits phase of the litigation, during which time respondents did not seek a preliminary injunction. In that period, more than 3000 growers in 48 states planted approximately 220,000 acres of RRA, in reliance on APHIS's deregulation decision. See J.A. 350. While the permanent injunction does not require the destruction of any RRA for which seed was purchased before March 12, 2007, and which was planted before March 30, 2007, it removes RRA as a future option for both growers and consumers. The injunction also prevents petitioners from continuing to market their product. The district court dismissed that harm as the mere "loss of anticipated revenue"—without acknowledging that that is the same type of harm respondents would suffer if cross-pollination were to occur in their fields. Pet. App. 71a-72a. The district court did not explain why potential economic harm to the farmers represented by respondents outweighed acknowledged and substantial economic harm to Monsanto and FGI, as well as harm to growers and consumers who prefer RRA.

### B. The District Court's Injunction Was Not Tailored To Cure The NEPA Violation

The district court erred in entering its permanent injunction for an additional reason: the injunction was not appropriately tailored to curing the NEPA violation. The goal of injunctive relief is to arrive at a "'nice ad-

justment and reconciliation' between the [parties'] competing claims" of injury resulting from "the granting or withholding of the injunction," by "balanc[ing] the conveniences of the parties and possible injuries to them" and "mould[ing] each decree to the necessities of the particular case." *Romero-Barcelo*, 456 U.S. at 312 (citations omitted). The district court's broad injunction failed to meet that standard.

1. As a general matter, the exercise of equitable discretion should be informed by the purposes and policies of the statute to be enforced. See, *e.g.*, *Hecht Co.* v. *Bowles*, 321 U.S. 321, 331 (1944) (equity jurisdiction must be exercised in light of the objectives of the relevant statute); *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496-498 & n.9 (2001). If the relevant statute does not mandate an immediate prohibitory injunction for every violation, courts have the discretion to fashion more tailored relief to secure prompt compliance with the statute while taking account of other factors in the equitable calculus. In *Romero-Barcelo*, for example, the Court held that, instead of enjoining the challenged activity because of a violation of the Clean Water Act, a court could "order that relief it considers necessary to secure prompt compliance with the Act" by directing the agency to apply for a permit for the activity at issue. 456 U.S. at 320. The Court took a similar approach in *Amoco Production Co.*, see 480 U.S. at 541-546, noting that the district court's decision not to enjoin all oil exploration activities until the Interior Department completed a study of potential impacts on subsistence uses under the relevant statute "did not undermine" the policy of that statute. *Id.* at 544-546; see *Oakland Cannabis Buyers' Coop.*, 532 U.S. at 498 n.9.

A similar approach is warranted in appropriate circumstances under NEPA. The failure to prepare an EIS does not necessarily require an injunction forbidding all action that would be addressed by the EIS while the agency undertakes its preparation. In a similar situation in *Winter*, for example, the Court noted that "[a] court concluding that the Navy is required to prepare an EIS has many remedial tools at its disposal, including declaratory relief or an injunction tailored to the preparation of an EIS rather than the Navy's training in the interim." 129 S. Ct. at 381.

As the Court has noted, the purpose of NEPA is to "ensure[] that [a federal] agency will not act on incomplete information, only to regret its decision after it is too late to correct." *Marsh* v. *Oregon Natural Res. Council*, 490 U.S. 360, 371 (1989); see *Winter*, 129 S. Ct. at 376; *Methow Valley Citizens Council*, 490 U.S. at 349; *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 558 (1978). That purpose is reflected in the CEQ regulations implementing NEPA, which impose limits on agency action pending completion of the NEPA process. Specifically, during the preparation of an EIS, an agency may not take any action in connection with the implicated activity that would "[h]ave an adverse environmental impact" or would "[l]imit the choice of reasonable alternatives." 40 C.F.R. 1506.1(a).

Consistent with these regulations, a court should not enter a broad injunction if an agency can show that the actions it will take pending preparation of an EIS will not materially harm the environment and will leave open a reasonable range of alternatives for final agency decision. And in determining whether the agency has satisfied this standard, the court should take into account whether there is "little if any information about pro-

spective environmental harms" in the case, or whether, even though an EIS has not yet been prepared, there already is a body of data and experience relating to the environmental and other consequences of the governmental action. *Winter*, 129 S. Ct. at 376.

2. a. In this case, the district court found that APHIS erred in deregulating RRA without preparing an EIS on the effects of RRA's cross-pollination (if any) of conventional and organic alfalfa. But the court's injunction was not properly tailored to curing that NEPA violation. The district court appropriately ordered APHIS to prepare an EIS regarding the deregulation. The contested question relates to the standards that should govern RRA while APHIS is preparing the EIS. In addressing that question, the district court was not limited either to allowing the deregulation to proceed (notwithstanding the NEPA violation), or to prohibiting all sale or commercial planting of RRA until the EIS is complete. The court instead should have adopted the agency's proposal for reasonable interim measures.

The determination of what interim measures should govern in such a case is appropriately based on scientific expertise informed by APHIS's considered judgment and experience in administering the PPA. APHIS is the agency charged by Congress with developing the relevant expertise and exercising the relevant judgment under the PPA—and also with implementing NEPA in connection with those responsibilities. APHIS accordingly submitted proposed interim measures to the district court. As explained below, the measures APHIS proposed were carefully tailored to address the statutory violation, prevent environmental injury, and address the other relevant equitable considerations during that interim period. Those measures also left open the

full range of reasonable alternatives available to APHIS at the completion of its EIS. The agency thus demonstrated the appropriateness of a tailored remedy.

b. Based on its extensive expertise with RRA and other genetically engineered plants, APHIS proposed that the district court include in its injunctive order six science-based conditions on RRA introduced between the date of the court's judgment and the completion of the EIS. Those proposed conditions specified: (1) isolation distances between RRA fields and conventional alfalfa seed production fields to mitigate potential cross-pollination;[8] (2) harvesting requirements to minimize potential cross-pollination; (3) cleaning requirements for farm equipment used in RRA production; (4) handling and identification requirements to minimize commingling of RRA and conventional or organic alfalfa after harvest; (5) a ban on RRA for livestock grazing purposes or in mixed-grass pastures; and (6) a requirement that all RRA seed producers and hay growers enter into contracts with petitioners promising compliance with these conditions. Pet. App. 185a-187a; see J.A. 439-445. APHIS explained the details and scientific basis for each of the proposed conditions in two declarations of the Director of the Environmental Risk Analysis Division for APHIS's Biotechnology Regulatory Services

[8] The proposed measures would have required that RRA crops grown for hay be located at least 165 feet from any alfalfa field used for certified seed production. Pet. App. 186a. For RRA crops grown for seed production, the proposed measures would have required isolation distances of at least 1500 feet when leafcutter bees are used to pollinate the field and three miles when honey bees are used as pollinators. *Ibid.*

(BRS).[9] See J.A. 345-365 (Decl. of Neil Hoffman); J.A. 436-542 (Second Decl. of Neil Hoffman and exhibits).[10]

Those declarations explain that the potential for gene flow between RRA fields and conventional or organic alfalfa fields used for hay or forage is negligible. J.A. 438; J.A. 355-358. The Director based that expert judgment on scientific evidence that (1) there is no potential for gene flow in fields that do not produce seeds, even when pollen is present, J.A. 355; (2) gene flow cannot occur unless flowering in proximate fields is simultaneous, which is unlikely given the number of alfalfa varieties that are grown, J.A. 355, 438; (3) gene flow requires the presence of sufficient pollinators as well as significant movement by pollinators among fields, which is unlikely because growers do not stock alfalfa fields grown for hay or forage with pollinating bees, *ibid.*; and (4) successful gene flow would require fertile embryos to mature, fall to the ground, and germinate in spite of the effects of autotoxicity and competition from mature plants, *ibid.*; see pp. 25-27, *supra*. The Director also explained the scientific basis for his proposed isolation distance requirement. J.A. 439-441.[11]

---

[9] BRS is the division of APHIS that is responsible for regulation of the importation, interstate movement, and release into the environment of genetically engineered plants. J.A. 345.

[10] The Director based his conclusions on various scientific studies of the potential for gene flow from RRA to other types of alfalfa. Those sources, which were submitted to the district court, are included at J.A. 446-542.

[11] The Director relied on scientific evidence that: (1) an isolation distance of 165 feet between an RRA hay field at 20%-50% bloom (a considerably higher level of bloom than APHIS's proposed interim measures would have permitted) and a seed field was found to reduce pollen-mitigated gene flow to under 0.2% for leaf cutter bees and 0.3% for honey bees; and (2) isolation distances of 1500 feet for leaf cutter

c. It is well established that courts should defer to the conclusions of agency officials that are based on expertise and scientific evidence. *E.g.*, *Oregon Natural Res. Council*, 490 U.S. at 376-377; *BG&E*, 462 U.S. at 103. That deference is due even when an agency has initially failed to comply with procedural requirements established by statute. See *Brock* v. *Pierce County*, 476 U.S. 253, 260 (1986) (the Court "would be most reluctant to conclude that every failure of an agency to observe a procedural requirement voids subsequent agency action, especially when important public rights are at stake"); *Barnhart* v. *Peabody Coal Co.*, 537 U.S. 149, 157-163 (2003). The district court here concluded that APHIS erred in failing to prepare an EIS regarding deregulation of RRA. Pet. App. 33a-47a. But that determination did not excuse the court from according appropriate deference to the agency's subsequent determination, based on scientific and regulatory judgment and expertise, of the interim measures appropriate pending the EIS's completion.

This Court has held:

> If the record before the agency does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation. The reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being re-

---

bees and three miles for honey bees between RRA grown for seed production and other alfalfa fields used for seed production were found to reduce pollen-mediated gene flow to under 0.1%. J.A. 439-440.

> viewed and to reach its own conclusions based on such an inquiry.

*Florida Power & Light Co.* v. *Lorion*, 470 U.S. 729, 744 (1985); see *Camp* v. *Pitts*, 411 U.S. 138, 143 (1973). Under these principles, if a court orders a remand after finding that an administrative agency has failed to support its decision not to prepare an EIS, the agency typically will have substantial discretion about how best to respond to the court's order. As an initial matter, the agency can choose whether to develop a more complete EA and explanation, to prepare an EIS, or to abandon the proposed action altogether. See, *e.g.*, *Center for Biological Diversity* v. *National Highway Traffic Safety Admin.*, 538 F.3d 1172, 1226-1227 (9th Cir. 2008); *O'Reilly* v. *United States Army Corps of Eng'rs*, 477 F.3d 225, 239-240 (5th Cir. 2007); *San Luis Obispo Mothers for Peace* v. *NRC*, 449 F.3d 1016, 1035 (9th Cir. 2006), cert. denied, 549 U.S. 1166 (2007). And if the agency decides to prepare an EIS, it can determine the appropriate way to meet environmental concerns, including the adoption of interim measures mitigating environmental impact, while preparation of the EIS is ongoing. Cf. *Motor Vehicles Mfrs. Ass'n of the United States, Inc.* v. *State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 57 & n.21 (1983).

In this case, APHIS did not request that the court remand to allow it to consider that full range of options. But that difference should not so dramatically affect the outcome as it did in this case. Here, the Director of APHIS's BRS expressed his expert judgment in a submission filed with the court, rather than in an administrative proceeding following a formal remand. In that submission, he proposed conditions that the PPA would have allowed APHIS to adopt on remand as interim

measures. Just as a court would have deferred to the agency's decision on an administrative remand, so too the district court should have deferred to the Director's submission. That submission was no less based on scientific and technical expertise in implementing the PPA, as well as on the agency's responsibility to take into account the requirements of NEPA. See, *e.g.*, 7 U.S.C. 7701(3) ("it is the responsibility of the Secretary to facilitate * * * interstate commerce in agricultural products * * * that pose a risk of harboring plant pests * * * in ways that will reduce, to the extent practicable, *as determined by the Secretary*, the risk of dissemination of plant pests") (emphasis added). Cf. *Bell* v. *Wolfish*, 441 U.S. 520, 547 (1979) (noting deference accorded remedies proposed by government officials in institutional reform litigation); *Pell* v. *Procunier*, 417 U.S. 817, 827 (1974) (same).

The district court therefore erred in rejecting APHIS's proposed interim measures and instead prohibiting all planting of RRA. APHIS adequately explained, by reference to scientific evidence, the basis for its proposed measures, which would have subjected RRA to significant regulation pending completion of an EIS. The proper role of the district court in reviewing the agency submission was not to determine whether it would have reached the same conclusion about the risk and consequences of cross-pollination. *Oregon Natural Res. Council*, 490 U.S. at 378, 385. Respect for APHIS's "substantial agency expertise," *id.* at 376, in assessing the effect of plant products on the environment called for deference by the court to "the reasonable opinions of [APHIS's] own qualified experts even if, as an original matter, [the] court might [have found] contrary views more persuasive." *Id.* at 378. In declining to adopt

APHIS's proposed interim measures pending completion of an EIS, and instead imposing its own broad prohibitory injunction, the district court failed to respect the domain that Congress has set aside for the administrative agency, *SEC* v. *Chenery Corp.*, 332 U.S. 194, 196 (1947), and "exercise[d] an essentially administrative function," *FPC* v. *Transcontinental Gas Pipe Line Corp.*, 423 U.S. 326, 334 (1976) (*Transcontinental Gas*) (quoting *FPC* v. *Idaho Power Co.*, 344 U.S. 17, 21 (1952)).

## II. THE DISTRICT COURT WAS NOT REQUIRED TO HOLD A FULL EVIDENTIARY HEARING WITH LIVE-WITNESS TESTIMONY AND CROSS-EXAMINATION ON THE SCOPE OF INJUNCTIVE RELIEF

1. Petitioners urged this Court to grant certiorari in part because the district court presumed irreparable harm without holding a hearing that included live-witness testimony and cross-examination. See Pet. 18-28. There is no need for this Court to address the hearing issue. The error committed by the district court, and condoned by the court of appeals, was not the failure to receive additional evidence in a different format. As discussed above, the district court erred in presuming that irreparable injury would result from APHIS's action unaccompanied by an EIS, and compounded that error in refusing to accord the requisite deference to APHIS's judgment concerning the appropriate interim measures pending completion of an EIS. Those errors, either alone or in combination, are sufficient to warrant vacating the injunction the district court entered and replacing it with APHIS's proposed interim measures without any need to consider the hearing issue. Indeed, in the court of appeals, petitioners agreed with APHIS

that the district court could have adopted APHIS's proposed interim measures in an injunctive order without first holding an evidentiary hearing. See Monsanto C.A. Br. 47-48.

2. If the Court should nonetheless decide to consider the hearing issue, it should hold that the district court did not err in declining to conduct a trial-type hearing in the circumstances of this case. A federal court plays a different role in an equitable suit challenging agency action under the APA than in a suit between private parties, and accordingly may take a different approach to addressing such factual issues.

If a district court needs to consider evidence beyond the administrative record in determining whether to enter an injunction in an APA case, the court may ordinarily do so through means other than a live evidentiary hearing. Petitioners are correct that, as a general matter, a litigant is entitled to have material factual disputes resolved by a district court based on evidence from the parties. But it does not follow that a district court is required to receive that evidence in a trial-type proceeding in an equitable action for review of agency action under the APA.

The court in such a case instead may consider the parties' competing views by holding a "paper hearing" involving the review of written submissions. That is what happened, for example, in the preliminary injunction proceedings in *Winter*. In that case, the Navy adopted certain interim measures to protect the environment while it prepared an EIS and the district court imposed several more; based on its consideration of declarations, the EA, and other material that the parties submitted, this Court then determined whether the scope of the injunctive relief entered was appropriate

based on that record. See 129 S. Ct. at 371-373, 376-378. Similarly, in *United States* v. *B&O R.R.*, 225 U.S. 306, 323 (1912), this Court held that the Commerce Court, in considering whether to grant a preliminary injunction against enforcement of an order of the Interstate Commerce Commission, should apply "general principles of equity" to determine the propriety of issuing such an injunction "on the face of the papers presented."[12]

The permissibility of that approach follows from the nature of the administrative process that precedes judicial review under the APA. The APA provides for an agency hearing with presentation of live testimony in rulemaking or adjudicatory proceedings only when required by another statute. See 5 U.S.C. 553, 554, 556(a). A trial-like evidentiary hearing "is neither a required, nor even the most effective, method of decisionmaking in all circumstances." *Mathews* v. *Eldridge*, 424 U.S. 319, 348 (1976). Even in the context of individualized determinations, factual disputes may be resolved on written submissions—*i.e.*, without an oral hearing—when their resolution is unlikely to involve credibility determinations. *Yamasaki*, 442 U.S. at 696. And an agency may freely exclude from individual evidentiary hearings, and instead resolve in a more general proceeding, any predictive or legislative-type issues affecting

[12] The Hobbs Judicial Review Act, 28 U.S.C. 2341 *et seq.*, now vests jurisdiction in the courts of appeals to review certain administrative actions, and grants the courts authority to enjoin enforcement of such orders pending review based on "evidence submitted to the court of appeals." 28 U.S.C. 2349(b). There is no requirement for an evidentiary hearing. In immigration cases, which are subject to judicial review under the Hobbs Judicial Review Act, see 8 U.S.C. 1252(a)(1), courts of appeals routinely dispose of requests for stays in immigration cases based on written submissions, without holding an evidentiary hearing.

numerous persons. See *Mobil Oil Exploration & Producing Se., Inc.* v. *United Distribution Cos.*, 498 U.S. 211, 228 (1991); *United States* v. *Florida E. Coast Ry.*, 410 U.S. 224, 239-240 (1973); see also Henry J. Friendly, *Some Kind of Hearing*, 123 U. Pa. L. Rev. 1267, 1302-1303, 1307 (1975) (*Some Kind of Hearing*). A trial-type administrative hearing may be especially unwarranted when an agency's decision is based on scientific or other expert evidence. *Mathews*, 424 U.S. at 344-346; *Some Kind of Hearing* 1284-1285 (noting that, in cases dealing with "recondite scientific or economic subjects[,] * * * the main effect of cross-examination is delay"). Determinations of this kind typically are legislative or regulatory in nature, rather than dependent on the adjudication of historical or personal facts.[13]

In administrative proceedings under the PPA, parties are not entitled to a trial-like hearing to air their views about whether a regulated article should be prohibited or deregulated in whole or in part.[14] Nothing in

---

[13] Although some courts of appeals have found error in a district court's failure to hold an evidentiary hearing prior to entry of an injunction, those cases are predominantly non-APA cases or cases in which the court is called upon to resolve historical facts particular to the litigants before it. That was the case, for example, in *United States* v. *Microsoft Corp.*, 253 F.3d 34, 101-103 (D.C. Cir.), cert. denied, 534 U.S. 952 (2001), in which the court of appeals held that the district court should have held an evidentiary hearing on the propriety and scope of the remedy before ordering Microsoft to submit a plan for divestiture.

[14] Under APHIS regulations, when the agency receives a deregulation petition, it must publish in the *Federal Register* a notice of such petition and shall specify that any interested person may submit written comments regarding the petition to APHIS for a period of at least 60 days. 7 C.F.R. 340.6(d)(2). The regulations also provide that, if a petition for deregulation is denied, there is an opportunity for an appeal on the basis of written submissions, although the Administrator

the PPA or its implementing regulations requires such a hearing. Nor are parties entitled to such a hearing as part of APHIS's NEPA process. If petitioners would not have a right to a trial-type hearing on such issues before the agency—either in the first instance or if the court had remanded the case to APHIS—it is hard to see why they should gain that right by intervening in the part of an APA action regarding the same issues.[15] And nothing in the nature of those issues suggests the need for an individualized hearing. In the NEPA context, the propriety of equitable relief is likely to turn on legislative-type judgments involving scientific or economic data, rather than on adjudicative assessments of the credibility or accuracy of fact witnesses to historical events. Accordingly, a court considering such relief may do so by evaluating the agency's and other parties' written submissions.

---

may, at his discretion, provide an informal hearing. See 7 C.F.R. 340.6(f).

[15] In addition, in-court evidentiary hearings that would require the testimony of agency officials responsible for administering a federal program impose significant costs on the government. *United States* v. *Morgan*, 313 U.S. 409, 422 (1941) (quoting *Morgan* v. *United States*, 304 U.S. 1, 18 (1938)) (noting that courts reviewing agency action should not "probe the mental processes" of the agency's decisionmaker).

## CONCLUSION

The judgment of the court of appeals should be reversed, and the case should be remanded with instructions to vacate the permanent injunction entered by the district court.

Respectfully submitted.

ELENA KAGAN
*Solicitor General*
IGNACIA S. MORENO
*Assistant Attorney General*
EDWIN S. KNEEDLER
*Deputy Solicitor General*
SARAH E. HARRINGTON
*Assistant to the Solicitor General*
ANDREW C. MERGEN
ELLEN J. DURKEE
ANNA T. KATSELAS
*Attorneys*

MARCH 2010