No. 13-72346

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

POLLINATOR STEWARDSHIP COUNCIL, *et al.*,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY and GINA MCCARTHY, Administrator, U.S. EPA,

Respondents,

DOW AGROSCIENCES LLC,

Respondent-Intervenor

PETITION FOR REVIEW OF AN ORDER OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BRIEF FOR RESPONDENT-INTERVENOR DOW AGROSCIENCES LLC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, counsel for respondent-intervenor Dow AgroSciences LLC ("DAS") submits the following corporate disclosure statement: DAS's only parent corporation is The Dow Chemical Company. The Dow Chemical Company is publicly traded and owns 10% or more of the stock of Dow AgroSciences LLC. No other corporation holds 10% or more of DAS's stock.

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STATEMENT OF JURISDICTION

This is a petition from a final order of the Environmental Protection Agency ("EPA" or "the agency"). This matter arises from an order by EPA registering the new active ingredient sulfoxaflor—an insecticide—pursuant to its authority under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136a(c)(5), for use on multiple commodities, turfgrass, and ornamental plants.

The Court has jurisdiction over this petition under Section 16(b) of FIFRA, 7 U.S.C. § 136n(b). *See United Farm Workers of Am., AFL-CIO v. EPA*, 592 F.3d 1080 (9th Cir. 2010); *see also* Brief for Petitioner ("Pet. Br.") at 1-2; Brief for Respondent ("Resp. Br") at 1. The EPA issued its final order on May 6, 2013; Petitioners filed their petition for review on July 2, 2013. The petition was therefore timely under Section 16(b) of FIFRA, 7 U.S.C. § 136n(b) (granting parties 60 days to file a petition for review).

The Court granted Intervenor Dow AgroSciences LLC's ("DAS") unopposed motion to intervene on August 13, 2013. (Dkt. No. 13).

INTRODUCTION AND SUMMARY OF ARGUMENT

Sulfoxaflor is an innovative insecticide that offers substantial economic and agricultural benefits. First, due to its unique mode of action, sulfoxaflor is effective in controlling certain insects, such as tarnished plant bugs, that have become resistant over time to other insecticides. Second, it is less toxic to bees and other beneficial insects than alternative insecticides, thereby benefitting not only those insects but also those persons whose livelihood is linked to them.

This is not speculation. In 2012, EPA exercised its emergency authority under FIFRA to grant cotton farmers throughout the mid-South access to sulfoxaflor to address an infestation outbreak that other insecticides could not control. Sulfoxaflor helped save the multi-billion cotton industry from potential devastation, with no reports of harm to bees or other pollinators.

Recognizing sulfoxaflor's substantial benefits and proven record of success, and after an exhaustive scientific review, EPA subsequently granted the applications for unconditional registration challenged here, so that this innovative insecticide could be made available to farmers nationwide.[1] As EPA's brief

[1] EPA's approval of the chemical sulfoxaflor as a new active ingredient was embodied in the agency's approval of three product applications filed by DAS. One was for a technical product, which contains a high concentration of sulfoxaflor and is used in formulation of the actual "end-use" products applied by farmers.

thoroughly explains, before doing so the agency determined that sulfoxaflor would not cause "unreasonable adverse effects on the environment." *See* 7 U.S.C. § 136a(c)(5)(D). That decision is unassailable.

Petitioners challenge EPA's registration decisions on three grounds. None has merit.[2]

First, Petitioners argue that EPA's registration decisions were unsupported by substantial evidence because EPA allegedly violated FIFRA and its own implementing regulations by failing to require a "valid" Tier 2 field study. That is little more than an attempt to clothe a substantive scientific challenge in procedural garb. There is no serious dispute that DAS submitted the requisite Tier 2 field studies, so there was no statutory or regulatory violation. Rather, Petitioners' ostensible procedural challenge hinges entirely on their substantive argument that

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The other two applications were for two such end-use products. *See* Petitioners' Excerpts of Record ("PER") 186 (Decision Document Registering Sulfoxaflor ["DD"]). The briefs often use a shorthand reference to registration or approval of sulfoxaflor to refer to what procedurally were approvals of three products.

[2] Petitioners' *amici* largely repeat their arguments on the matters at issue. And to the extent those *amici* raise issues beyond those Petitioners raise, they are beyond the scope of this proceeding. *See Swan v. Peterson*, 6 F.3d 1373, 1383 (9th Cir. 1993); *see also* Brief for Respondent ("Resp. Br.") at 19-20 n.12.

the studies were "invalid." The probative value of the studies, however, is a matter squarely committed to the agency's discretion.

Here, EPA recognized the limits of the studies, and for that reason looked to sources of evidence and modes of analysis beyond those set forth in the agency's Part 158 requirements for registration applications. These included a Pollinator Risk Assessment Framework developed especially to address such situations. It allowed EPA to comprehensively evaluate the risks that sulfoxaflor might pose to beekeepers. Petitioners thus miss the mark by insisting that the agency found that the Tier 2 field studies were unable to "preclude" risk to bees—that is not the statutory standard, and the agency relied on other data, as well as mitigation measures, to evaluate the applications against the actual registration standard and conclude that registration would not pose an *unreasonable* risk to bees.

Second, Petitioners argue that EPA's conclusion that mitigation measures would prevent an unreasonable effect on bees is not supported by substantial evidence. Again, that argument misses the mark. The record evidence supporting sulfoxaflor's registration was very strong. Indeed, EPA probably could have unconditionally registered sulfoxaflor without implementing *any* mitigation measures. The agency's conservative imposition of several additional mitigation

measures illustrates just how attentive it was to the concerns of beekeepers and its duty to manage environmental risk.

Petitioners challenge the efficacy of those mitigation measures, but fail to acknowledge that most of them are mandatory elements of sulfoxaflor's label and that all of them—overall reduction of the application rate, bloom restrictions, increased application intervals, further reduction of application rates for continually blooming and other crops where warranted, and advisory notices for growers and beekeepers to cooperate in order to minimize risk—were recommendations from highly respected scientific sources that are substantially supported in the record. At bottom, EPA's implementation of these mitigation measures eliminates any doubt as to the propriety of its expert determination that the benefits of sulfoxaflor outweigh its risks.

Third, Petitioners argue that EPA did not appropriately balance risks and benefits because it ignored sulfoxaflor's impact on beekeepers and farmers growing crops that depend on bees. But that argument is purely semantic. As the agency recognized, any such impact on third parties is derivative of effect on bees. If there is no unreasonable risk to bees, then by definition there will be no unreasonable risk for these third parties. Petitioners' true complaint is not that

EPA failed to consider the effect on them, but that EPA struck the balance differently than they would have.

Needless to say, however, the fact that Petitioners disagree with the conclusions EPA drew from this sizable record provides no basis for overturning the agency's decision. In evaluating DAS's application, EPA reviewed a long list of scientific studies, a multitude of comments submitted by stakeholders and academics, and real-world evidence from the emergency approval granted to cotton farmers. The agency analyzed the data under the Pollinator Risk Assessment Framework and implemented various mitigation measures recommended by experts in the field. So long as EPA has "substantial evidence" to support its judgment, which it clearly does here, Congress entrusts the expert agency with the authority to weigh the risks and benefits in deciding to register an insecticide. EPA fulfilled its obligation. Its decision should be affirmed.

If the Court were to disagree, however, it should not vacate the registrations. Instead, the Court should remand the matter without vacating. Under settled law, vacatur is inappropriate where, as here, the adverse consequences would be severe. As the agency determined, without access to sulfoxaflor, farmers would use insecticides that are less effective and present far greater environmental risks. Taking sulfoxaflor out of the hands of farmers at this point also would be

economically disastrous. In contrast, allowing the product to remain on the market for a limited period of time—especially given EPA's substantial mitigation measures—would have no cognizable adverse effect. Accordingly, vacatur would be inappropriate if the case were remanded to the agency.

ARGUMENT

I. EPA FULLY COMPLIED WITH FIFRA AND ITS IMPLEMENTING REGULATIONS BY REQUIRING THE SUBMISSION OF TIER 2 FIELD STUDIES.

Petitioners first assert that EPA violated "FIFRA and EPA's own implementing regulations" by registering sulfoxaflor "in the absence of valid Tier 2 field studies regarding the risk to honey bee colonies[.]" Pet. Br. at 28; *see generally id.* at 28-31. That argument fundamentally misapprehends how this regulatory regime works. *See* Resp. Br. at 21-24.

Petitioners correctly note that registrants must submit, in accordance with the EPA regulations set forth in Part 158, "sufficient scientific evidence" when applying to register insecticides. Pet. Br. at 28 (citing *Love v. Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988)). No one could seriously suggest, however, that DAS failed to meet its obligations under Part 158. These regulations specify only one required and two conditionally-required studies for honey bees. *See* 40 C.F.R. § 158.630(d). DAS submitted the required acute contact toxicity study, two conditionally-required residue studies, and six conditionally-required field studies.

See 40 C.F.R. 158.630(e) nn. 24, 25 (explaining the triggers for the conditionally required studies); Environmental Fate and Ecological Risk Assessment app. D at 5-14 ("Ecological Risk Assessment") (PER 154-163) (evaluating the residue studies and semi-field studies of sulfoxaflor).[3] Petitioners do not—and could not—dispute these facts.

Whether the Tier 2 studies were "valid" in Petitioners' view has no bearing on DAS's compliance with the requirements imposed under Part 158. *See* Resp. Br. at 23 (explaining that EPA's regulations do "not address the 'validity' or 'invalidity' of pollinator field studies."). Instead, the substance of the Tier 2 field studies bears on whether the record includes the evidence needed to support EPA's decision to register sulfoxaflor products. Contrary to Petitioners' suggestion, *see* Pet. Br. at 29-31, EPA has flexibility in how it "uses [and] evaluates the data and information in its risk assessment and risk management decisions, [and] the regulatory determinations that may be based upon the data." Resp. Br. at 22 (citing 40 C.F.R. § 158.1(b)(3)); *see also* 40 C.F.R. §§ 158.30(a), 158.70(d)(1), 158.80, 158.120. The Part 158 requirements are merely a starting point; they are "the *first*

[3] All references to PER are to Petitioners' Excerpts of Record. DAS is providing its own supplemental excerpts of record ("DAS-ER") and also references EPA's Excerpts of Record ("EPA-ER").

step of EPA's review of applications." 49 Fed. Reg. 30,884, 30,888 (Aug. 1, 1984) (emphasis added). EPA must then "make a *second*, risk/benefit determination" in accordance with its statutory mandate. *Id*. (emphasis added). "Nothing in . . . FIFRA . . . limits the range of data which EPA may consider in making these risk/benefit decisions. . . . EPA may consider any relevant data without regard to who submitted the data, for what purpose, or when the data were submitted . . . ." *Id*.

Accordingly, EPA retained flexibility to determine how best to analyze the Tier 2 field studies and how and whether to consider them in conjunction with other evidence in making its determination with regard to sulfoxaflor. *See* Resp. Br. at 24 (explaining that the regulations allow EPA to "evaluate pollinator field studies on a case-by-case basis").

That is precisely the course EPA followed in this proceeding. The agency "appropriately exercised its technical, professional judgment" in reviewing the Tier 2 field studies and concluding that they included "useful data" that supported DAS's registration application. Resp. Br. at 25. And, as EPA has explained, *see* Resp. Br. at 30-40, the data became even more compelling once it was evaluated within the Pollinator Risk Assessment Framework, which EPA developed with extensive public involvement for the specific purpose of improving assessment of

the effect of insecticides on pollinators. *See* White Paper in Support of the Proposed Risk Assessment Framework for Bees at 27 (Sept. 11, 2012) ("White Paper") (PER 414); Resp. Br. at 24-25.

Petitioners do not challenge EPA's authority under FIFRA and the implementing regulations to evaluate the Tier 2 field studies through this refined framework. Nor could they. *See id.* at 25. "While pesticide manufacturers are required to conduct studies in support of the registration [of pesticides], regulatory authorities are not confined to these studies as the sole source of information regarding the potential for the use of a pesticide to result in adverse effects on the environment." White Paper at 27 (PER 414).

Indeed, the Pollinator Risk Assessment Framework was implemented precisely because of increased concern worldwide with the decline of insect pollinators, in particular the decline of managed honey bee colonies. In light of these concerns, EPA determined that existing risk assessment data requirements under Part 158 might not be adequately protective of honey bees. *See* Interim Guidance on Honey Bee Data Requirements at 1 (Oct. 19, 2011). EPA remedied this deficiency by proposing a formal risk assessment framework in consultation with the FIFRA Scientific Advisory Panel ("SAP"), a body expressly created by

Congress to provide just such advice. *See* 7 U.S.C. § 136w(d).[4] That expert panel was informed, in turn, by the Society of Environmental Toxicology and Chemistry ("SETAC") Pellston Conference on Pesticide Risk Assessment for Pollinators ("Pellston Conference"), as well as other high-quality scientific research from across the globe. *See* Interim Guidance on Honey Bee Data Requirements at 1; White Paper at 24 (PER 411).

The Pollinator Risk Assessment Framework thus was developed with significant input from scientific experts and the public. Notably, the National Honey Bee Advisory Board ("NHBAB")—a petitioner here—commented on the Proposed Risk Assessment, recommending that EPA immediately implement Tier 2 residue studies of pollen and nectar, adopt the goals of the Pellston Conference, and assess pesticide formulations in addition to the active ingredient. *See* National Honey Bee Advisory Board Comments, Dkt. No. EPA-HQ-OPP-2012-0543 (Sept. 11, 2012).[5] EPA implemented these recommendations during the sulfoxaflor

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[4] The FIFRA SAP Panel consists of seven highly regarded expert scientists. *Id.* § 136w(d)(1). In developing the Pollinator Risk Assessment Framework, this panel was further assisted by a ten-member panel of scientific experts across a range of relevant disciplines known as the Science Review Board. *See id.* § 136w(d)(2); Resp. Br. at 11 nn. 6, 7.

[5] *Available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0543-0032.

registration proceeding, incorporating both the SAP recommended scientific approach to risk assessment and the NHBAB recommendations into the testing requirements. *See* Ecological Risk Assessment app. D at 14-19 (PER 163-68) (summarizing results of Tier 2 residue studies in pollen and nectar); *id.* app. D. at 1-3 (PER 150-52) (summarizing acute contact and oral toxicity studies on active ingredient and formulations); White Paper at 43 (PER 430) (incorporating the goals from the Pellston Conference into EPA's risk assessment for bees).

In short, the Pollinator Risk Assessment Framework reflects the best available science for examining risks to insect pollinators. It uses honey bees as a surrogate species for all pollinators, *see* White Paper at 13, 27 (PER 400, 414), and, because "the functional unit of the honey bee is the colony itself," the Pollinator Risk Assessment Framework "transition[ed] away from data based on individual organisms" to create "a well-defined tiered process" for evaluating colony-level effects on bees, *id*. at 2, 13 (PER 389, 400). In addition, it incorporated into the assessment tests that had not been required under Part 158, such as acute oral toxicity tests, to more realistically reflect the exposure conditions that result from the application of newer pesticides. *See id.* at 32, 107 (PER 419, 494).

EPA intended for the Pollinator Risk Assessment Framework to "improve/expand" its analysis of risk by looking beyond "existing guideline studies" to consider a wider array of data. *Id*. at 57; *see also id*. at 104 ("The ecological risk assessment method proposed in this white paper would expand the current data requirements substantially."). Under this new process, specifically developed to protect pollinators, if Tier 1 studies show that regulatory risk thresholds are exceeded for individual bees, Tier 2 studies are to be used to predict whether any colony-level effects can be observed or are likely to occur (using residue studies in pollen and nectar as well as semi-field studies). *See id*. at 38 box 9a, 9b (PER 425); *id*. at 37 (PER 424) ("[I]f the multiple lines of evidence indicate that unacceptable effects on survival, growth or reproduction of the colony are not likely, then a presumption of minimal risk can be supported."). Where uncertainty remains after refining risk through Tier 1 and Tier 2 testing, EPA refines risk further still using mitigation measures—such as through lower application rates or application timing restrictions—intended to reduce bee exposure to the insecticide. *See id*. at 154 (PER 541). That is exactly what EPA did here. *See* Resp. Br. at 40-52; *infra* at 27-35.

Indeed, sulfoxaflor was the first new active ingredient registered under this robust, iterative, and rigorous risk assessment framework. In order to evaluate

sulfoxaflor under this new process, EPA requested additional data from DAS far exceeding what is required under Part 158. EPA sought this data so that it could, for the first time, assess an insecticide's risks through all routes of exposure (not just contact) and evaluate the insecticide's impact on colonies (instead of only on individual bees). *See* White Paper at 28-29, 56, 74, 104, 108, 110, 117, 119, 129, 152-55 (PER 415-16, 443, 461, 491, 495, 497, 504, 506, 516, 539-42).

In response, DAS submitted 15 bee studies—and 3 other studies to refine the bee studies using residue measurements—to assist EPA's review. *See* V. Kramer et al., *Dow AgroSciences* Position Paper on Sulfoxaflor and Bees: Sulfoxaflor Bee Studies and Risk Assessment at 4, 6, 9, 16-19 (May 7, 2012) (DAS-ER 192, 194, 197, 204-07) ("Position Paper on Bees") (discussing the initial submission of bee studies and EPA's request for additional studies, which DAS subsequently provided). Many of these studies are not described in the Part 158 regulations, but rather were responsive to the expanded data requirements recommended by the Pollinator Risk Assessment Framework. *See* White Paper at 28-29, 56, 74, 104, 108, 110, 117, 119, 129, 152-55 (PER 415-16, 443, 461, 491, 495, 497, 504, 506, 516, 539-42).

Petitioners' claim that EPA did not follow FIFRA and the implementing regulations thus falls flat. DAS submitted complete registration applications in

accordance with FIFRA and Part 158, and EPA then examined a wide array of evidence, including the Tier 2 field studies upon which Petitioners focus, utilizing the sophisticated Pollinator Risk Assessment Framework in evaluating sulfoxaflor. Petitioners have not—and cannot—identify any statutory provision or regulation EPA violated in following this established course.

Nor is there any merit to Petitioners' related argument that "EPA's own scientific analysis confirms that sulfoxaflor poses a potential risk to bees and finds that Dow's Tier 2 field studies were unable to *preclude* risk to developing brood or long-term colony health." Pet. Br. at 31 (emphasis added) (citation and quotations omitted)); *see also id.* at 34 (arguing that "Dow's Tier 2 studies remained unable to *preclude* risk to honey bee colonies" after the application rate was reduced) (emphasis added)). That argument is built on a faulty premise: FIFRA does not require EPA to "preclude" risk to bees to register an insecticide.

FIFRA provides that EPA "shall register a pesticide if," *inter alia*, the agency "determines that … it will perform its intended function without *unreasonable* adverse effects on the environment" and "when used in accordance with widespread and commonly recognized practice it will not generally cause *unreasonable* adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C)-(D) (emphases added). The statute, in turn, expressly defines "unreasonable adverse

effects on the environment" to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide . . . ." 7 U.S.C. § 136(bb). FIFRA thus recognizes that while pesticides almost always pose some risk to the environment, those risks must be balanced against a product's benefits.

The issue that EPA confronted under FIFRA, therefore, was not whether sulfoxaflor poses some conceivable risk to bees. The issue was whether it poses an *unreasonable* risk based on the totality of economic, social, and environmental factors. *See* Resp. Br. at 27, 53, 57-59. Congress has made clear that, given the substantial benefits of pesticides, it intended to allow their use even if they might pose some risk. *See, e.g.*, H.R. Rep. No. 92-511, at 14 (1971) (stating that FIFRA was based on a benefit-risk concept and that "the benefits of using pesticides should be balanced against the risk of using them"); S. Rep. No. 92-970, (1972), reprinted in 1972 U.S.C.C.A.N. 4092, 4095 (stating that FIFRA would "require that EPA make a full weighing of competing interests in making its determinations"). That legislative choice must be respected.

Ninth Circuit case law confirms this understanding. "The FIFRA standard distinctly balances the environmental harm of using a pesticide against its economic, social, and environmental benefits." *Merrell v. Thomas*, 807 F.2d 776,

780 (9th Cir. 1986) (citation omitted); *id.* at 780-81 ("FIFRA's registration standard … reflects the need to balance environmental and agricultural impacts."); *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005) ("FIFRA's objective is to protect human health and prevent environmental harm from pesticides through a cost-benefit analysis of the pesticides."); *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 532 (9th Cir. 2001) ("FIFRA registration is a cost-benefit analysis . . . taking into account the economic, social and environmental costs and benefits of the use of any pesticide.") (emphasis omitted). "This is a compromise adopted by Congress that should not be overturned by judges." *Merrell*, 807 F.2d at 781; *see also* Resp. Br. at 20-21.

At the end of the day, therefore, Petitioners' attack on the Tier 2 field studies misses the point. EPA fully complied with the law by requiring DAS to submit those studies, and gave them the probative weight to which the agency determined they were entitled. Petitioners' assertion that the studies—by themselves—did not "preclude risk" to bees has no bearing on the validity of the agency's conclusion that sulfoxaflor products do not present an unreasonable risk to bees.

II. EPA'S REGISTRATION OF SULFOXAFLOR WITH MITIGATION MEASURES IS SUPPORTED BY "SUBSTANTIAL EVIDENCE."

Petitioners next argue that sulfoxaflor products' risks outweigh their benefits notwithstanding EPA's mitigation measures. *See* Pet. Br. at 31-36. Again, that argument lacks merit.

A. EPA Correctly Found That Sulfoxaflor's Agricultural Benefits Are Substantial And That It Does Not Pose An Unreasonable Risk To Bees.

EPA relied upon substantial evidence to conclude that sulfoxaflor's potential risk to bee colonies is "outweighed by the benefits of sulfoxaflor." PER 200; *see also* Resp. Br. at 28-40. Although Petitioners completely ignore them, the benefits of sulfoxaflor to farmers are undeniable. *See* Resp. Br. at 54-58. As EPA has thoroughly explained, sulfoxaflor's agricultural benefits are abundantly clear from both the FIFRA Section 18 emergency exemption granted to cotton farmers in the mid-South in order to save their crop from tarnished plant bug, which had become resistant to other insecticides, *see id.* at 55-56, and for many other reasons, as discussed below.

But it is important first to underscore the significance of the first of these reasons: the dire economic conditions facing cotton farmers that justified the emergency exemption in the first place. In 2012, EPA concluded that "significant economic loss"—defined as loss exceeding 20% of gross revenue from decreased

cotton yields—would be likely in Arkansas, Louisiana, Mississippi, and Tennessee without sulfoxaflor. *See* Biological and Economic Analysis Division's (BEAD) Review of Benefits (Nov. 19, 2012) ("BEAD Review") at 17 (PER 20); BEAD Review of a Second Amendment from the State of Mississippi and Louisiana to the Emergency Exemption Request at 6-7 (June 29, 2011) (DAS-ER 101-102). Some states estimated that farmers would forfeit up to 49% of revenue from cotton farming unless they could use a pesticide with a novel mode of action that could control tarnished plant bug, which had developed resistance to other pesticides on the market. *See, e.g.*, La. Dep't of Agric. & Forestry, Additional Clarification of Information and Responses to Queries for a Section 18 Application at 10-11 (June 5, 2011) (DAS-ER 112-13). In Louisiana alone, economic loss from the tarnished plant bug pest was estimated at $4.1 million. *Id.* at 11 (DAS-ER 113).

EPA's knowledge from this experience—that sulfoxaflor had demonstrated the capacity to prevent this "significant economic loss," 40 C.F.R. § 166.2(a)(1), for those states granted the emergency exemption—alone would have provided the substantial evidence of "economic . . . benefits," 7 U.S.C. § 136(bb), needed to justify EPA's decision to make this important insecticide unconditionally available to farmers nationwide. But the administrative record here actually included ample additional evidence supporting this finding. For example, when public comment

was solicited on the proposed unconditional registrations, crop farmers growing a wide range of agricultural products expressed a critical need for sulfoxaflor to control target pests, and that other insecticides were unable to control these target pests.[6]

Collectively, these commenters represented thousands of farmers and growers. As an example, the Florida Fruit and Vegetable Association commented

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[6] *See* National Cotton Council of America Comments, Dkt. No. EPA-HQ-OPP-2010-0889-0001 (Jan. 14, 2011); Florida Fruit & Vegetable Ass'n Comments, Dkt. No. OPP-2010-0889 (Jan. 17, 2011); Washington State Potato Commission Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Jan. 25, 2013); U.S. Canola Ass'n Comments, Dkt. No. EPA-OPP-2010-0889 (Feb. 7, 2013); American Soybean Ass'n Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 8, 2013); National Sunflower Ass'n Comments, Dkt. No. EPA-OPP-2010-0889 (Feb. 8, 2013); California Citrus Mutual Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (2013); California Grape & Tree Fruit League Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 9, 2013); California Specialty Crops Council Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 10, 2013); National Cotton Council of America Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 12, 2013); California Citrus Quality Control Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 11, 2013); California Strawberry Commission Comments, Dkt. No. OPP-2010-0889 (Feb. 12, 2013); Western Growers Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 12, 2013); Florida Fruit & Vegetable Ass'n Comments, Dkt. No. OPP-2010-0889 (Feb. 12, 2013); United Fresh Produce Ass'n Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 12, 2013) (DAS-ER 38-45, 50-89) (representing the Florida Fruit and Vegetable Association, Washington State Potato Commission, US Canola Association, the American Soybean Association, the National Sunflower Association, the California Grape and Fruit Trade, the California Specialty Crops Council, the National Cotton Council, the California Strawberry Commission and the United Fresh Product Association).

that sulfoxaflor was superior in many situations to other registered alternatives in controlling the Asian citrus psyllid pest, which is "considered the most significant threat overall to the state's $9 billion citrus industry." Florida Fruit & Vegetable Ass'n Comments at 2, Dkt. No. OPP-2010-0889 (Feb. 12, 2013) (DAS-ER 81-86); *see also* National Cotton Council of America Comments at 4, Dkt. No. EPA-HQ-OPP-2010-0999-0001 (Jan. 14, 2011) (DAS-ER 38-40) (noting necessity of sulfoxaflor to effectively control tarnished plant bug to protect the $120 billion U.S. cotton industry). The farming community's overwhelming support for sulfoxaflor's unconditional registration in the proceeding below is a crucial aspect of the administrative record that Petitioners have simply ignored.

In determining that sulfoxaflor products offered significant benefits, EPA also relied on substantial evidence that sulfoxaflor is more effective and less toxic than a wide range of other insecticides and that, if registered, it would replace many of these insecticides in a competitive marketplace. *See* Resp. Br. at 54-55. Indeed, it is worth emphasizing just how much less toxic sulfoxaflor is than competing insecticides and how much less of it would be needed to achieve farmers' pest management goals. For example, the alternatives—such as dicrotophos, imidacloprid, lambda-cyhalothrin, and thiamethoxam—are from 5 to 97 times *more* toxic to bees than sulfoxaflor. *See* J.E. Nelson et al., Public Interest

Document Supporting the Registration of Sulfoxaflor at 76 tbl. 14, 79 tbl. 16 (July 31, 2010) (DAS-ER 312, 315) ("Public Interest Document"); *see also* Response to Comments ("RTC") at 26 (PER 228) ("Sulfoxaflor use will primarily displace use of existing less effective insecticides which have an activity profile which is similar to or worse than sulfoxaflor against honey bees and non-targets."). Moreover, the only other insecticide available to address the pests of concern that has a lower toxicity was ineffective for many uses because it led to outbreaks of secondary pests. *See* Public Interest Document at 76 tbl. 14, 79 tbl. 16 (DAS-ER 312, 315); RTC at 36 (PER 238).[7]

These findings strongly support EPA's decision. EPA was aware of study projections showing that, because of its effectiveness, low use-rate, and lower toxicity profile, sulfoxaflor likely would displace from the U.S. insecticide marketplace altogether more toxic insecticide such as organophosphates, which have long been a major EPA and Congressional concern. *See* Public Interest

[7] "Secondary pests" are insects that are not controlled by a particular insecticide, and whose threats to crops may increase if that insecticide kills off their predators or competitors, or simply fails to control them. *See* RTC at 9, 36 (PER 211, 238).

Document at 75 (DAS-ER 311).[8] In support of its sulfoxaflor registrations, DAS submitted studies showing that their approval would reduce the total environmental load of more toxic insecticides by slashing organophosphate use by 2.8 million pounds in the first two years after registration. *See id.* at 5 (DAS-ER 241); RTC at 37 (PER 239); Position Paper on Bees at 5 (DAS-ER 193). Based on the most recent estimates published by EPA, beginning in the third year after registration the annual reduction in organophosphate use would represent over 6.3% of total U.S. organophosphate sales. *See* Public Interest Document at 75 tbl. 13 (DAS-ER 311); Arthur Grube et al., EPA, *Pesticides Industry Sales and Usage, 2006 and 2007*

[8] Organophosphate insecticides attack insect nervous systems but also present challenges to worker and consumer health that Congress and EPA have long sought to minimize. *See, e.g.*, Food Quality Protection Act of 1996, Pub. L. No. 104-70, § 250, 110 Stat. 1489, 1510-11 (1996) (amending FIFRA to fast-track registration of pesticides that reduce risks to human health); Organophosphate Pesticides; Reassessment of Diazinon Non-Contributor Tolerances, 67 Fed. Reg. 56,557, 56,558 (Sept. 4, 2002) (noting that the Food Quality Protection Act instructed EPA to review the pesticides posing "the greatest risk to public health," which led EPA to identify organophosphate pesticides as a "high priority" for review). On the basis of this "increasing regulatory scrutiny," farmers commented during the sulfoxaflor public comment period that they were "keenly interested in finding replacement products" that could serve as an "alternative to many organophosphate insecticides." *See* California Specialty Crops Council Comments at 2, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 10, 2013) (DAS-ER 64-66).

Market Estimates at 16-17 (2007).[9] There thus can be no doubt as to sulfoxaflor's significant environmental benefits.

EPA then carefully studied any potential harm to bees that would result from sulfoxaflor's registration. *See* Resp. Br. at 28-36. But far from indicating that there would be an increased risk to bees, the record demonstrated that sulfoxaflor would provide significant *benefits to bees* and other pollinators by replacing insecticides far more harmful to that population.[10] EPA also received and reviewed comments from university researchers reaching the same conclusion: bees would better off with sulfoxaflor available nationwide than they would be if DAS's application were denied. *See* RTC at 11-12 (PER 213-14).

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[9] *Available at* http://www.epa.gov/opp00001/pestsales/07pestsales/market_estimates2007.pdf.

[10] *See* U.S. Canola Ass'n Comments, Dkt. No. EPA-OPP-2010-0889 (Feb. 7, 2013); National Sunflower Ass'n Comments, Dkt. No. EPA-OPP-2010-0889 (Feb. 8, 2013); California Specialty Crops Council Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 10, 2013); California Strawberry Commission Comments, Dkt. No. OPP-2010-0889 (Feb. 12, 2013); Florida Fruit & Vegetable Ass'n Comments, Dkt. No. OPP-2010-0889 (Feb. 12, 2013) (DAS-ER 52-53, 56-57, 64-66, 75-77, 81-86) (representing canola, strawberry, sunflower, various fruit and vegetable farmers); *see also* DD at 16-18 (PER 200-02) (characterizing all of these crops as mildly to highly attractive to bees).

Importantly, EPA bolstered this determination with real-world evidence, drawn from the experiences of farmers and regulators in several states covered by the FIFRA Section 18 emergency exemption for sulfoxaflor. *See* Resp. Br. at 50. States receiving emergency exemptions pursuant to FIFRA Section 18 must report "[a]ny unexpected adverse effects resulting from . . . use of [the] pesticide." 40 C.F.R. § 166.32(a). During and after the emergency exemption period for sulfoxaflor, EPA received no reports of adverse effects on bees. *See* RTC at 14-15 (PER 216-217). To the contrary, EPA received numerous positive reports, including from university entomologists who monitored field use of sulfoxaflor. These entomologists reported to EPA that sulfoxaflor had positive effects on bees based on its comparative toxicity to other insecticides.[11] EPA correctly concluded, therefore, that the Section 18 exemption period supported its final decision in favor of sulfoxaflor's registration. *See* RTC at 14-15 (PER 216-17).

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[11] *See* D. Kerns, Ph.D., LSU AgCenter Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Jan. 29, 2013); G. Lorenz, Ph.D., University of Arkansas Comments, Dkt. No. EPA-HQ-OPP-2010-0889-0010 (Feb. 6, 2013); E. Beers, Professor of Entomology, Washington State University Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 1, 2013); L. Godfrey, Ph.D., University of California, Davis Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 6, 2013); J. Gore, Mississippi State University Comments, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 1, 2013); P. Ellsworth, Ph.D., University of Arizona, Dkt. No. EPA-HQ-OPP-2010-0889 (Feb. 1, 2013) (EPA-ER 135-37, 146-47, 148-50, 151-53; DAS-ER 46-48, 90-95).

Finally, sulfoxaflor has now been on the market as a registered pesticide since May 2013 and, just as with the Section 18 emergency exemption period, entomologists and agricultural experts note sulfoxaflor's critical importance for controlling harmful pests and replacing more toxic insecticides. Because of its diverse use on multiple crops, sulfoxaflor is estimated to meet the needs of an annual $2 billion market segment that no currently-registered pesticide meets. *See* Antonio Galindez, President and Chief Executive Officer, Dow AgroSciences, Presentation at Goldman Sachs Agricultural Biotech Forum, *Science Serving the Needs of a Growing World* at 9 (Mar. 7, 2012).[12] Since its registration, many leading crop publications and university researchers continue to recommend its use to control target pests and to reduce use of pesticides more toxic to beneficial, non-target insects such as bees. *See* Thomas Orton et al., Rutgers Univ. N.J. Agric. Experiment Station, *2014 Commercial Vegetable Production Recommendations for New Jersey* (Feb. 2014) (recommending sulfoxaflor for pest control in various vegetable crops);[13] Hembree Brandon, Delta Farm Press, *Plant Bug Control Plan*

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[12] *Available at* http://www.dow.com/investors/presentations/pdfs/Goldman_Sachs_March_2012_03052012_FINAL.pdf.

[13] *Available at* http://plant-pest-advisory.rutgers.edu/wp-content/uploads/2014/02/2014-NJ-Commercial-Vegetable-Production-Recommendations-Complete.pdf.

Essential for Late Mississippi Cotton Crop (July 18, 2013);[14] Mark Bolda et al., *Field Efficacy of the Experimental Insecticides Sulfoxaflor, Tolfenpyrad and Flonicamid for Lygus Bugs in Strawberry* (Feb. 28, 2013) (conducting field trials on strawberries that showed sulfoxaflor use resulted in "significantly higher amounts of marketable fruit" and greater reduction of pests than alternative insecticides);[15] Dominic Reisig, North Carolina State University, *2013 Early-Season Plant Bug Insecticide Results* (July 18, 2013).[16] This confirms what was already evident from the record: sulfoxaflor provides substantial benefits to farmers and beekeepers alike.

B. EPA Implemented Mitigation Measures To Minimize Potential Risk To Bees.

In light of the substantial record evidence, EPA probably would have been well within its rights to register sulfoxaflor without taking additional steps to mitigate any potential risk to bee colonies. But EPA, taking a cautious approach, adopted a series of mitigation measures to guard against any potential risk to bees.

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[14] *Available at* http://deltafarmpress.com/cotton/plant-bug-control-plan-essential-late-mississippi-cotton-crop.

[15] *Available at* http://ucanr.edu/blogs/blogcore/postdetail.cfm?postnum=9379.

[16] *Available at* http://www.nccrops.com/2013/07/18/2013-early-season-plant-bug-insecticide results/.

EPA's implementation of a conservative application rate, bloom restrictions, and other measures remove any doubt as to the propriety of its decision to register sulfoxaflor unconditionally. Petitioners' attacks on these mitigation measures as insufficient to minimize harm to bees all miss the mark.

Petitioners claim that the reduced application rate was "unable to preclude risk to honey bee colonies." Pet. Br. at 34. But, as explained above, that is not the pertinent inquiry under FIFRA. *See supra* at 15-17. EPA reduced the application rates to mitigate any risk to bees in order to be doubly sure that sulfoxaflor would not pose an *unreasonable* risk to the environment. The agency employed a cautious approach in this proceeding that renders its decision to register sulfoxaflor unassailable.

Specifically, the administrative record shows that once the application rate was lowered, EPA appropriately refined its risk assessment in reliance on the Tier 2 studies. *See* Resp. Br. at 51-52. That is precisely what the agency had said it would do. *See* White Paper at 154 (PER 541) (explaining that EPA may "employ risk mitigation measures [which] seek to limit bee exposure via the use of label restrictions. Where mitigation measures result in reduced loading (*i.e.*, lower application rates or number of applications), the effect of reduced loading . . . should be re-evaluated . . . ."); *see also* Guidelines for Ecological Risk Assessment

at 123 (1998) (same).[17] But EPA did not rely exclusively on these studies. It also relied on additional studies that allowed it to limit any remaining uncertainty in its risk analysis. *See supra* at 13-15.

Thus, EPA concluded in its data evaluation reports that the semi-field studies, including those conducted using the lower, approved application rate, supported unconditional registrations in three ways: (1) they showed low mortality in brood and colony relative to controls; (2) they showed rapid decline of residues in pollen and nectar[18] and that degradates were not toxic to bees; and (3) they

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[17] EPA can reconsider the risks of sulfoxaflor if registered unconditionally at a lower application rate instead of conditionally registering it at a higher application rate. *See* Resp. Br. at 28-40; *see also Nat'l Ass'n. of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658-59 (2007); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514-17 (2009). Petitioners do not contend otherwise. Nor do they dispute that EPA could reassess risk at that lower rate without new data. *See* Pet. Br. at 35-36; *see also* White Paper at 13, 32 (PER 400, 419); Guidelines for Ecological Risk Assessment at 123 (1998).

[18] The rapid decline in pesticide residues shown in the tunnel studies was also supported by two studies measuring sulfoxaflor residues in alfalfa foliage. From these studies, EPA concluded that sulfoxaflor did not display extended toxicity of residues in pollen and nectar. To the contrary, the studies showed that the toxicity of residues to bees was only short-term. *See* Ecological Risk Assessment at 11 (PER 39); Position Paper on Bees at 23 (DAS-ER 211). The Pollinator Risk Assessment Framework endorsed use of these residue studies conducted according to Guideline 850.3030 to qualitatively refine the risk assessment, *see* White Paper at 107 (PER 494), and EPA used them for this purpose in the final registration, *see* RTC at 24 (PER 226) ("[T]he available information on sulfoxaflor residues in

distinguished sulfoxaflor from insecticides with known adverse effects. *See* Annex B at 33, 46-47, 62, 81, 96, 105-06, 118 (EPA-ER 41, 54-55, 70, 89, 104, 113-14, 126). In evaluating and responding to public comments, EPA explained how these conclusions supported its decision to unconditionally register sulfoxaflor products. *See* RTC at 19-20, 27, 42, (PER 221-22, 229, 244). Indeed, no colony-level harm was observed in two tunnel studies conducted at the lower application rate, and these observations were supported with data showing that adverse effects on brood and colony were not likely. *See* Resp. Br. at 38-40. Refining risk and reducing uncertainty accords with the Pollinator Risk Assessment Framework, which properly does not seek to assure the complete absence of risk but only to assure that "unacceptable effects" are "not likely" to occur. *See* White Paper at 37 (PER 424).

Petitioners' assertion that EPA's other mitigation measures are a "hope-and-prayer" approach, Pet. Br. at 32, is equally meritless. As an initial matter, while Petitioners emphasize that advisory statements are not "mandatory," *id*. at 32, that criticism does not extend to the vast majority of the mitigation measures EPA implemented: prohibiting application during bloom, limiting maximum application

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pollen and nectar indicates it dissipates relatively rapidly, with the vast majority of pollen and nectar DT50 values determined to be 3 days or less.").

rates during bloom, and increasing the number of days between applications. Those measures are mandated on sulfoxaflor's label, and FIFRA makes it unlawful to use a pesticide in a manner inconsistent with its labeling. *See* 7 U.S.C. § 136j(a)(2)(G); *see also* Resp. Br. at 44-45. Pursuant to FIFRA, EPA has delegated authority to States to enforce such labeling requirements on applicators, dealers, and businesses. *See* 7 U.S.C. §§ 136u, 136w-1, 136w-2.

Petitioners' general suggestion that these measures are scientifically unreliable is similarly unfounded. *See* Pet. Br. at 32-33. The Pollinator Risk Assessment Framework cites two important sources of guidance that provide the scientific and technical support for the mitigation measures EPA chose to include on the final sulfoxaflor labels to protect bees. The first, a report from the Pellston Conference ("Pellston Report"), resulted from a meeting of 48 premier experts from a wide variety of disciplines who came together in 2011 to discuss issues in pollinator risk assessments. *See* Pellston Report at 5-6 (DAS-ER 120-21). The Pellston Report is discussed throughout the White Paper as a significant source of guidance for the risk assessment framework. *See* White Paper at 24-25, 32, 114, 175 (PER 411-12, 419, 501, 562); *see also* Interim Guidance on Honey Bee Data Requirements 1 ("A formal process for quantifying potential risks of pesticides to honey bees and non-Apis bees is evolving and will be informed by the [Pellston

Conference].”). The second, a study by Ph.D. entomologist Helmut Riedl and several other scientists and regulators, is cited specifically in the record as a source of guidance for regulators to design effective mitigation measures based on its recommendations. *See* Helmut Riedl *et al.*, *How to Reduce Bee Poisoning from Pesticides* 1 (2006) (DAS-ER 163) (“Riedl Guidance”); Ecological Risk Assessment at 82 (PER 110); White Paper at 37 (PER 424). The mandatory mitigation measures closely trace the recommendations made by the Pellston Report and Riedl Guidance.

Petitioners’ specific attacks on these measures fail as well. With regard to EPA’s decision to prohibit use of sulfoxaflor products when certain crops are in bloom, Petitioners have almost nothing to say. That is not surprising given the substantial record evidence demonstrating this measure’s capacity to effectively minimize risk to bees. *See* Resp. Br. at 43-48. The Riedl Guidance informs growers and applicators that most incidents of bee mortality occur “when insecticides are applied to bee-pollinated crops during the bloom period.” Riedl Guidance at 2-4 (DAS-ER 164-66). Similarly, the Pellston Report explained that bloom restrictions are an effective method of mitigation. *See* Pellston Report at 38 (DAS-ER153). Accordingly, EPA’s decision to impose a bloom restriction to

reduce bee exposure clearly reduces any potential risk to that population. *See* Resp. Br. at 46.

The most Petitioners are willing to say is that the bloom restrictions are insufficient because do not apply to crops blooming continuously. Pet. Br. at 33. But the Pellston Report recognized (as EPA did in registering sulfoxaflor) that many insecticides (including, of course, those used on crops that bloom continuously) must be used during bloom periods, and at rates sufficient for pest control. The Pellston Report therefore concluded that when an insecticide must be used during bloom, EPA should consider other mitigation methods in an effort "to manage exposure and limit risk." Pellston Report at 38 (DAS-ER 153). Petitioners ignore that EPA heeded this advice by imposing mandatory measures that reduced the number and frequency of applications. Specifically, for certain crops that must be sprayed while they are in bloom, EPA increased mandatory intervals between applications and limited the number of applications during bloom. *See* DD 16-18 (PER 200-02).

Petitioners likewise ignore that, in order to further limit bee exposure during bloom, EPA imposed mandatory measures lowering the application rate for specific crops. The application rates for continuously blooming crops such as cotton, cucurbits, fruiting vegetables, and strawberries were all lowered below the

rate that could be used for crops that did not continuously bloom. *See* DD at 18 (PER 202). For other crops, such as ornamentals (which are attractive to honey bees but do not continuously bloom), EPA set a lower application rate during bloom to protect pollinators, but allowed a higher rate prior to bloom. (That decision was also supported by the fact that data showed that the higher, pre-bloom rate was necessary for pest control.) *See* EPA, Registration Jacket, EPA Reg. No. 62719-623 (Vol. 1) at 89-90, 99-100 (DAS-ER 23-24, 33-34). This fine-tuned approach, which imposes mandatory restrictions based on the specific crop characteristics, shows just how attentive EPA was to its duty to maximize sulfoxaflor's effectiveness while also minimizing its potential impact on pollinators.

Finally, Petitioners' attack on those mitigation measures that are not mandatory, *see* Pet. Br. at 31-33, inappropriately discounts the well-developed scientific evidence showing that advisory statements on the sulfoxaflor label—regarding beekeeper notification and limits on application times—effectively mitigate risk to bees. EPA's further recommendation—on top of the mandatory measures imposed by product label—that growers notify beekeepers of their use of sulfoxaflor, for example, is consistent from expert analysis concluding that beekeeper-grower cooperation "is the most effective way to reduce bee poisoning."

Riedl Guidance at 3-4 (DAS-ER 165-66); *see also* Pellston Report at 38 ("In the case of honey bees, communication and cooperation among growers, applicators, and beekeepers is perhaps the most important tool to reduce risk and to ensure that the needs to all parties are met."). Better information does make a difference: "the underlying cause of most bee poisoning incidents is a lack of awareness, rather than an intent to do harm." Riedl Guidance at 3 (DAS-ER 165).[19]

III. EPA DID NOT IGNORE BEEKEEPERS OR THE AGRICULTURAL PRODUCTS DEPENDING ON POLLINATORS IN WEIGHING THE RISKS AND BENEFITS OF SULFOXAFLOR.

Petitioners finally argue that EPA "ignor[ed] adverse impacts to the beekeeping industry and crops that are dependent upon honey bees for pollination." Pet. Br. at 36; *see also id.* at 36-41. That is simply untrue. *See* Resp. Br. at 53-57. After evaluating the entire record, including numerous comments from beekeepers and pollinator-dependent crop farming organizations, EPA found that sulfoxaflor would not pose an unreasonable risk to bee colonies and, in fact, would provide them with substantial benefits as compared to other insecticides on the market. *See supra* at 21-24. As a consequence, EPA correctly concluded that

[19] The other advisory mitigation measure, which recommended limiting application times based on the time of day and temperature, was also supported by highly credible expert analysis. *See* Riedl Guidance at 4 (DAS-ER 166); Pellston Report at 37 (DAS-ER 152).

unconditionally registering sulfoxaflor products would not have the detrimental "downstream effects" on beekeepers and honey-bee dependent crops that might warrant denial of DAS's applications. Resp. Br. at 53; *see also id.* ("EPA explained that it believed the labeling mitigation required for sulfoxaflor would minimize the potential downstream effects on beekeepers and the agricultural economy.") (citing RTC at 36 (PER 238)). EPA thus clearly considered the issue. It just concluded that there was substantial evidence in the administrative record showing that sulfoxaflor's benefits outweigh its risks, especially in light of the measures taken to mitigate any potential harm to bees.

Petitioners clearly disagree with how EPA struck the balance. But that is not a basis for granting the relief they seek. This is the type of complex, scientific judgment that an expert agency such as EPA is specially equipped to make. *See, e.g.*, *Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997) ("As we have said, we review scientific judgments of the agency 'not as the chemist, biologist, or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.'"); *Nat'l Oilseed Processors Ass'n v. Browner*, 924 F. Supp. 1193, 1201 (D.D.C. 1996) ("The EPA rulemaking involves consideration of complex scientific data and sophisticated analysis fit primarily for

those tutored in the field."); *Am. Trucking Ass'ns, Inc. v. EPA*, 283 F.3d 355, 362 (D.C. Cir. 2002) ("It is not our function to resolve disagreement among the experts or to judge the merits of competing expert views."); *Allied Local & Reg'l Mfrs. Caucus v. EPA.*, 215 F.3d 61, 73 (D.C. Cir. 2000) ("Our role, of course, is to determine neither whether EPA's approach was 'ideal,' nor whether it was the 'most appropriate,' but only whether it was reasonable.").

Not surprisingly, therefore, federal courts have long recognized that EPA is tasked with the responsibility for determining whether a pesticide's substantial benefits warrant its registration even when there is some degree of uncertainty as to the precise risk it poses to the environment. *See* Resp. Br. at 44-45. "[R]egulators entrusted with the enforcement of . . . laws" such as FIFRA "have not thereby been endowed with a prescience that removes all doubt from their decisionmaking." *Ethyl Corp. v. EPA*, 541 F.2d 1, 24 (D.C. Cir. 1976); *see also Or. Natural Res. Council Fund v. Brong*, 492 F.3d 1120, 1134 (9th Cir. 2007) (noting that when a statute "requires an agency to predict future conditions, uncertainty is an inherent part of the process"). Hence, "[w]here [EPA] regulations turn on . . . an assessment of risks, or on predictions dealing with matters on the frontiers of scientific knowledge, [courts] will demand adequate reasons and explanations, but not 'findings' of the sort familiar from the world of adjudication." *Ethyl Corp.*,

541 F.2d at 23; *see also Forest Guardians v. U.S. Forest Serv.*, 329 F.3d 1089, 1099 (9th Cir. 2003) ("An agency's actions need not be perfect[.]"). EPA has met these tests here.

IV. REMAND IS THE APPROPRIATE REMEDY IF PETITIONERS PREVAIL IN THIS PETITION FOR REVIEW.

For the reasons set forth above and in the EPA's brief, the sulfoxaflor product registrations should be affirmed. But if the Court disagrees, it should not vacate the sulfoxaflor registrations. *See* Resp. Br. at 59. "A flawed rule need not be vacated." *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) ("*CCAT*"). Rather, it "'can be left in place while the agency follows the necessary procedures' to correct its actions." *Id.* (quoting *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)). That is the appropriate course here.

First and foremost, "'the disruptive consequences of an interim change that may itself be changed'" make vacatur inappropriate. *CCAT*, 688 F.3d at 992 (quoting *Allied-Signal, Inc.*, 988 F.2d at 150-51); *see also Int'l Union, United Mine Workers v. Fed. Mine & Safety Health Admin.*, 920 F.2d 960, 967 (D.C. Cir. 1990); *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1049 (D.C. Cir. 2002); *W. Oil & Gas Ass'n v. EPA*, 633 F.2d 803, 813 (9th Cir. 1980). There will be significant harm and disruption to farmers if the Court vacates the registration decisions. That disruption must be avoided.

As noted above, cotton farmers need sulfoxaflor to help prevent "near total crop loss" because cotton's primary pest, the tarnished plant bug, has become resistant to existing insecticides. *See* National Cotton Council of America Comments at 1, Dkt. No. EPA-HQ-OPP-2010-0889-0001 (filed Jan. 14, 2011) ("Cotton Comments") (DAS-ER 39); RTC at 11-12 (PER 213-14). For the cotton industry alone, vacatur will negatively affect $120 billion in yearly commerce and over 200,000 U.S. jobs. *See* Cotton Comments at 1 (DAS-ER 39). Sulfoxaflor is also needed in Florida to combat new, invasive pests that threaten its $9 billion citrus industry. Florida Fruit & Vegetable Ass'n Comments at 3-4, Dkt. No. EPA-HQ-OPP-2010-0889-0001 (Jan 17, 2011) (DAS-ER 44). Without sulfoxaflor or an equivalent, citrus farmers will face catastrophic losses due to the spread of an incurable disease to the state's citrus trees. *See id.* Arizona strawberry and melon farmers would face the same harsh consequences. *See* Comments of Western Growers at 1-2, Docket No. EPA-HQ-OPP-2010-0889-0362 (Feb. 12, 2013) (DAS-ER 79-80). These and similar concerns of growers in other states alone make vacatur inappropriate.

Vacatur also would undermine and disrupt DAS's significant investment in sulfoxaflor. *See CCAT*, 688 F.3d at 994 (holding that vacatur "would also be economically disastrous" as "[t]his is a billion-dollar venture employing 350

workers"). While DAS's precise investment in the product is not in the record, it is a matter of public record that the cost to bring a new pesticide to market can exceed $180 million. *See* Fred Whitford, et al., *The Pesticide Marketplace: Discovering and Developing New Products*, PPP-71, at 11 (2009); CropLife America, *The Cost of New Agrochemical Product Discovery, Development & Registration and Research & Development Predictions for the Future* at 3 (Jan. 2010) (finding that the average cost of bringing a new pesticide to market was $256 million in 2008). Vacating sulfoxaflor's registrations will undoubtedly impair DAS's ability to recoup its investment and continue its innovations in the crop production market.

In contrast, avoiding vacatur would not have negative consequences for beekeepers or the environment. *See supra* at 21-27. Indeed, the slow pace at which Petitioners have pursued their claims undermines any suggestion that sulfoxaflor will cause them immediate harm if the matter is remanded to EPA without vacatur. The Court's original schedule set briefing to conclude October 21, 2013. (Dkt. No. 2-1). The Court has extended that schedule twice without objection from any party. (Dkt. Nos. 14, 15, 17, 18). Briefing is now set to conclude on March 28, 2014, almost nine months after Petitioners filed their petition for review. Any alleged harm that has occurred during that time

apparently was not damaging enough for Petitioners to pursue interim relief or an expedited briefing schedule, or even to insist on a normal one. In any event, the Court can alleviate any alleged harm by imposing time limits on EPA. *See*, *e.g.*, *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995) (setting a 90-day time limit on remand); *MCI Telecomms. Corp. v. FCC*, 143 F.3d 606, 609 (D.C. Cir. 1998) (six months).

Vacatur also would be inappropriate because this is not a scenario where "fundamental flaws 'foreclose EPA from promulgating the same standards on remand.'" *North Carolina v. EPA*, 531 F.3d 896, 929 (D.C. Cir. 2008) (citation omitted). Rather, because it is "conceivable that the [EPA] may be able" to fix the deficiencies identified by this Court, *Allied-Signal* 988 F.2d at 1451, it should be given the opportunity to do so, *see Black Oak Energy, LLC v. FERC*, 725 F.3d 230, 244 (D.C. Cir. 2013) (remanding without vacatur because the court found "it plausible that [the agency] can redress its failure of explanation on remand while reaching the same result."). *See*, *e.g.*, *United Mine Workers*, 920 F.2d at 967 (remanding without vacatur when the agency failed "to give an adequate treatment of certain issues, *i.e.*, show[ed] a want of reasoned decisionmaking, with some possibility that substantial evidence may be missing on some points"); *Nat'l Lime Ass'n v. EPA*, 233 F.3d 625, 635 (D.C. Cir. 2000) (remanding without vacatur to

give EPA the chance to consider evidence not adequately addressed); *A.L. Pharma*, 62 F.3d at 1492 (remanding without vacatur to give the agency an opportunity to articulate its reasoning more clearly).

Finally, this is an especially easy case for remand because the bottom-line remedial question—whether EPA could still make a determination that sulfoxaflor should be on the market—could be answered by EPA by conditionally registering sulfoxaflor, even if there were current deficiencies in the supporting science. In other words, even if the Court were to conclude there is not even a possibility that EPA could accumulate substantial evidence justifying unconditional registration in a remand proceeding, which should not remotely be the case, EPA can easily satisfy conditional registration's lower bar while further studies are conducted. *See Natural Res. Def. Council v. EPA*, 735 F.3d 873, 876 (9th Cir. 2013) ("FIFRA permits EPA to conditionally register a pesticide . . . until the agency receives sufficient data from an applicant . . . to decide whether to issue an unconditional registration."). Vacatur would be inappropriate for this reason alone.

CONCLUSION

For all of these reasons, the Court should deny the Petition for Review and affirm EPA's decision.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify the following:

This brief complies with the type-volume limitation of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure and 9th Circuit Rule 32-1 because this brief contains 10,437 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure.

This brief complies with the typeface requirements of Rule 32(a)(5) of the Federal Rules of Appellate Procedure and the type style requirements of Rule 32(a)(6) of the Federal Rules of Appellate Procedure because this brief has been prepared in a proportionally spaced typeface using the 2010 version of Microsoft Word in 14 point Times New Roman.

/s/ David B. Weinberg
David B. Weinberg

STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, counsel for Respondent Intervenor are unaware of any related cases pending in this Court.

SUPPLEMENTAL STATUTORY ADDENDUM

All pertinent statutes and regulations are contained in Petitioners' Addendum of Statutory and Regulatory Authority. *See* Dkt. 20-3 (Dec. 6, 2013).

CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2014, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ David B. Weinberg
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