Case No. 13-72346

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

POLLINATOR STEWARDSHIP COUNCIL, AMERICAN HONEY PRODUCERS ASSOCIATION, NATIONAL HONEY BEE ADVISORY BOARD, AMERICAN BEEKEEPING FEDERATION, THOMAS R. SMITH, BRET L. ADEE, and JEFFERY S. ANDERSON,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents,

and

DOW AGROSCIENCES,

Respondent-Intervenor.

On Petition for Review of an Order of the
United States Environmental Protection Agency

PETITIONERS' OPENING BRIEF

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, petitioners Pollinator Stewardship Council, American Honey Producers Association, National Honey Bee Advisory Board and American Beekeeping Federation certify that they have no parent corporations and that no publicly held corporation owns more than 10% of the petitioners.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES **PAGE(S)**

STATUTES

REGULATIONS

LEGISLATIVE HISTORY

INTRODUCTION

In this case, the largest beekeeping organizations in America and three commercial beekeepers (collectively, "Beekeepers") challenge a decision by the U.S. Environmental Protection Agency ("EPA") to approve a new insecticide called sulfoxaflor (sŭl-fŏks-a-flor) under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. Sulfoxaflor belongs to a category of powerful insecticides called neonicotinoids (nēō-nĭkĕtĭnōĭds), and it is classified by EPA as "very highly toxic" to honey bees. The use of sulfoxaflor on millions of acres of farms and orchards nationwide will exacerbate a growing crisis in which about one-third of America's honey bee colonies have collapsed each year since neonicotinoids first became prevalent in the mid-2000s. As a result of this catastrophic die-off, our food security now hangs in the balance.

JURISDICTIONAL STATEMENT

This Court has exclusive jurisdiction to review EPA's May 6, 2013 order approving sulfoxaflor under Section 16(b) of FIFRA, 7 U.S.C. § 136n(b). That section provides, in relevant part:

> In the case of actual controversy as to the validity of any order issued by [EPA] following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part.

7 U.S.C. § 136n(b).

EPA solicited, reviewed, and responded to public comments prior to approving sulfoxaflor. *See* Petitioners' Excerpts of Record ("PER") at 203. This Court has ruled that a public comment process constitutes a "public hearing" within the meaning of Section 16(b) of FIFRA. *See United Farm Workers of Am. v. Envt'l Prot. Agency*, 592 F.3d 1080, 1082-83 (9th Cir. 2010).

Beekeepers were parties to the proceedings before EPA, because they submitted substantive written comments in response to EPA's proposed decision with respect to sulfoxaflor. *See* PER 323 (comments of Pollinator Stewardship Council, American Honey Producers Association, National Honey Bee Advisory Board, American Beekeeping Federation, and Bret L. Adee); PER 318 (comments of Thomas R. Smith); PER 376 (comments of Jeffrey S. Anderson).

Beekeepers include individuals who reside and/or have a place of business within this Circuit. *See* Decl. of Thomas R. Smith at ¶¶ 1, 5 (attesting that he resides and works in Yuma, Arizona); Decl. of Jeffrey S. Anderson at ¶ 3 (attesting he resides and works in Oakdale, California); Decl. or Bret L. Adee at ¶¶ 9-10 (attesting that he works in California, Oregon, and Washington).[1]

Finally, Beekeepers timely filed their petition for review within 60 days of entry of EPA's order approving sulfoxaflor. *See* PER 255 (May 6, 2013 Notice of Registration); July 2, 2013 Petition for Review [DktEntry 2-2].

[1] Declarations establishing this Court's jurisdiction accompany this brief.

STATEMENT OF THE ISSUES

Does substantial evidence in the administrative record support EPA's decision to approve sulfoxaflor under FIFRA, where:

1. EPA lacked required scientific information regarding the risk to bees;

2. EPA improperly relied on voluntary, arbitrary or otherwise inadequate measures to reduce the risk to bees; and

3. EPA skewed its analysis of sulfoxaflor's risks and benefits by ignoring sulfoxaflor's adverse impact on the beekeeping industry and crops that are dependent upon bees for pollination.

Pursuant to Ninth Circuit Rule 28-2.7, all relevant statutes and regulations are included in the addendum that accompanies this brief.

STATEMENT OF THE CASE

Across America, honey bees are dying at rates that are unprecedented and unsustainable. Whether bees ultimately survive and recover is a matter of great consequence not only to professional apiarists, but to all of us. According to EPA:

> An estimated one-third of all food and beverages are made possible by pollination, mainly by honey bees. In the United States, pollination contributes to crop production worth $20-30 billion in agricultural production annually. A decline in managed bee colonies puts great pressure on the sectors of agriculture reliant on commercial pollination services.[2]

[2] News Release, USDA and EPA Release New Report on Honey Bee Health (May 2, 2013), http://www.usda.gov/wps/portal/usda/usdahome?contentid=2013/05/0086.xml.

While the reasons for the honey bee crisis are not yet fully understood, the U.S. Department of Agriculture ("USDA") and EPA agree that "[a]cute and sublethal effects of pesticides on honey bees have been increasingly documented, and are a primary concern."[3]

At issue in this case is EPA's decision to approve a new pesticide that is, by all accounts, "very highly toxic" to honey bees. PER 39. As set forth herein, EPA's conclusion that widespread agricultural use of sulfoxaflor "will not present unreasonable adverse effects against bees," PER 199, is unsupported by – indeed, it is contrary to – substantial evidence in the record, in violation of FIFRA.

The record shows that EPA's own staff scientists concluded that sulfoxaflor poses "a potential for risk to honey bees," based on numerous laboratory toxicity studies. PER 37. EPA staff further determined that the limited studies involving the use of sulfoxaflor under field conditions "were unable to preclude risk to developing brood or long-term colony health . . . due to limitations associated with their design and conduct." *Id*. Consistent with FIFRA and EPA regulations, staff therefore recommended that the agency require adequate field testing prior to approving sulfoxaflor. PER 40.

[3] USDA, Rpt. on the Nat'l Stakeholders Conf. on Honey Bee Health (2013), at vi, *available at* http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf.

In keeping with the conclusions and recommendations of its staff experts, EPA initially proposed to "conditionally register" sulfoxaflor under FIFRA, pending the timely submission of valid field studies demonstrating that use of the pesticide will not pose a risk to bees. PER 170. But less than four months later, having received no additional science and without further public process, EPA suddenly reversed course and registered sulfoxaflor unconditionally. PER 186. In lieu of the requisite science, EPA claimed that a handful of "mitigation measures" would reduce the acknowledged risk to bees. EPA declared that the remaining risk to bees is "outweighed by the benefits of sulfoxaflor registration." PER 199-200.

EPA's decision to register sulfoxaflor unconditionally in the absence of adequate field studies is contrary to both FIFRA and the agency's own regulations. Moreover, there is no evidence that EPA's arbitrary – or, in some cases, entirely voluntary – mitigation measures will address the risk to bees. Nor does the record support EPA's claim that the risk to bees is outweighed by sulfoxaflor's benefits. Instead, the record shows that EPA improperly and artificially constrained its risk-benefit analysis, narrowly considering only sulfoxaflor's purported benefits as an alternative means for killing insect pests. EPA failed entirely to account for the devastating impact that sulfoxaflor will have both on the beekeeping industry and on the multitude of important crops that must be pollinated by bees if they are to bear fruit or seed.

Beekeepers ask this Court to set aside EPA's ill-informed and illegal decision to register sulfoxaflor in its entirety and to remand the matter to EPA for reconsideration in accordance with the law. *See* 7 U.S.C. § 136n(b).

STATEMENT OF FACTS

I. Sulfoxaflor

Sulfoxaflor is a powerful insecticide developed by respondent-intervenor Dow AgroSciences LLC ("Dow") that belongs to a class of insecticides called neonicotinoids. PER 42; *see also* PER 363 (study recommending "that sulfoxaflor be considered a neonicotinoid"). Neonicotinoids interfere with a receptor in the central nervous system of insects, causing tremors, paralysis and death at extremely low doses. PER 42.

Like other neonicotinoids, sulfoxaflor is a "systemic" insecticide, meaning that it is absorbed into the treated plant and distributed via the plant's vascular system. PER 42. As a result, spraying a plant with sulfoxaflor not only kills insects that come into direct contact with spray droplets, but also renders the plant itself – including the leaves, stem, flowers, nectar and pollen – highly toxic to insects for weeks thereafter. Hence Dow's oft-touted marketing claim that sulfoxaflor provides both "rapid knockdown" of insects and "from 7 to 21 days of residual control." PER 36.

II. The FIFRA Registration Process

FIFRA, as amended in 1972, reflects "mounting public concern about the safety of pesticides and their effect on the environment." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). The statute "sets forth a comprehensive regulatory scheme for controlling the use, sale, and labeling of pesticides." *Washington Toxics Coal. v. Envt'l Prot. Agency*, 413 F.3d 1024, 1030 (9th Cir. 2005). At its core, FIFRA prohibits the sale or distribution of any pesticide that has not been approved – or "registered" – by EPA. 7 U.S.C. § 136a(a).

Prior to registering a pesticide, EPA has a duty to ensure that it "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). The phrase "unreasonable adverse effects on the environment" is defined 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 [the] pesticide." *Id.*, § 136(bb). Thus, "FIFRA's objective is to protect human health and prevent environmental harm from pesticides through a cost-benefit analysis." *Washington Toxics Coal.*, 413 F.3d at 1032.

So that EPA can evaluate a pesticide's effect on the environment, FIFRA requires the registrant to submit a proposed "label" that sets forth "a statement of all claims to be made for [the pesticide under review], and any directions for its use." 7 U.S.C. § 136a(c)(1)(C). The registrant must also submit "a full description

of the tests made and the results thereof . . .” *Id.* § 136a(c)(1)(F); *see also Thomas v. Union Carbide Agr. Products Co*., 473 U.S. 568, 571 (1985) (“As a precondition for registration of a pesticide, manufacturers must submit research data . . . concerning the product’s health, safety, and environmental effects.”).

If EPA finds that the scientific data submitted by the registrant is insufficient to allow the requisite evaluation of environmental effects, FIFRA authorizes EPA to “conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data.” 7 U.S.C. § 136a(c)(7)(C); *see also Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Cir. 1984) (“Conditional registration is a recognition that less than complete data exists.”). Alternatively, EPA may issue “experimental use permits” for pesticides that are not yet registered if the agency “determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide.” 7 U.S.C. § 136c(a).

III. The Registration Process for Sulfoxaflor

A. Dow’s Registration Application

On December 22, 2010, EPA notified the public that Dow had applied to register under FIFRA the first consumer pesticide formulations (or “products”) that contain sulfoxaflor as their active ingredient. PER 1-3. Marketed under the brand

names "Transform" and "Closer,"[4] Dow's sulfoxaflor formulations are designed for "foliar" use in agriculture, meaning that they are sprayed directly onto the crop's foliage by aircraft or ground equipment. PER 57. Dow's application asked EPA to approve sulfoxaflor for use on an array of different crops (including canola, citrus, cotton, many vegetables, strawberries, melons, tree fruits and nuts, soybeans, and wheat) to kill a number of different insect pests. *Id*.

Depending upon the crop, Dow proposed a "maximum single application rate" of up to 0.133 pounds of active ingredient per acre ("lb a.i./A"), meaning that as much as 0.133 pounds of sulfoxaflor could be applied to a given acre of the crop at one time. PER 57-58. Dow also proposed a "minimum spray interval" of between 5 and 14 days depending on the crop, meaning that a crop sprayed with sulfoxaflor could be sprayed again after the specified interval. *Id*. Finally, Dow proposed a "maximum yearly application rate" of 0.266 pounds per acre for most crops, meaning that as much as 0.266 pounds of sulfoxaflor could be applied to the same acre over the course of a year. *Id*.

[4] Transform is formulated as a water dispersible granule (WG) that contains 50% sulfoxaflor by weight, whereas Closer is formulated as a suspension concentrate (SC) containing 21.8% sulfoxaflor. PER 57. EPA sometimes refers to Transform and Closer by the agency's registration number (62719-625 and 62719-623, respectively) or Dow's formulation code (GF-2372 and GF-2032, respectively) In addition to Transform and Closer, Dow applied to register a third product called "Sulfoxaflor Technical" (62719-631) for non-agricultural use.

B. EPA's Ecological Risk Assessment

On December 19, 2012, the Environmental Fate and Effects Division ("EFED") of EPA's Office of Pesticide Programs released its "Environmental Fate and Ecological Risk Assessment" for sulfoxaflor. PER 29. Based on the studies and data submitted by Dow, the assessment included an evaluation of the risk that the proposed use of sulfoxaflor would pose to "non-target" organisms, including honey bees.

To evaluate the risk to bees, the assessment employed a new process under development by EPA with input from a FIFRA Scientific Advisory Panel. PER 109. As set forth in detail in EPA's "White Paper in Support of the Proposed Risk Assessment Process for Bees," PER 338, the new process is "intended to be iterative and to rely on multiple lines of evidence to further refine and characterize potential risk." PER 424. "Tier 1" of the analysis considers whether individual bees will be exposed to the pesticide at levels that exceed a predetermined "level of concern." PER 110. If so, "Tier 2" considers whether the risk to individual bees extends to the entire colony. *Id*.

As detailed below, EPA's Tier 1 risk assessment for sulfoxaflor identified "*a potential for risk to honey bees*," and the Tier 2 assessment was "*unable to preclude risk to developing brood or long-term colony health*" due to substantial shortcomings in the field studies submitted by Dow. PER 37 (emphasis added).

1. Tier 1 of EPA's Risk Assessment Identified a "Potential for Risk to Honey Bees."

Tier 1 of EPA's risk assessment for bees involved several steps. First, EPA reviewed studies submitted by Dow to determine the "acute median lethal dose" (or "LD_{50}") for bees, which is defined as the single dose that is sufficient to kill half of the individual bees tested. *See* 40 C.F.R. § 152.3. EPA found that Dow's sulfoxaflor formulations have an acute *contact* (or dermal) LD_{50} value of 0.13 micrograms of active ingredient per bee ("μg a.i./bee"), and an acute *oral* (or dietary) LD_{50} value of 0.052 μg a.i./bee.[5] PER 98. In other words, half the bees that come into contact with 0.13 micrograms or more of sulfoxaflor will die, and half the bees that consume more than 0.052 micrograms of sulfoxaflor will die. In light of sulfoxaflor's exceedingly low acute toxicity LD_{50} value, EPA concluded that sulfoxaflor is "*very highly toxic*" to honey bees.[6] PER 39 (emphasis added).

Second, EPA analyzed the extent to which honey bees would be exposed to sulfoxaflor. Based on modeled conditions, EPA determined that spraying an acre with 0.133 pounds of sulfoxaflor – Dow's proposed maximum single application

[5] For purposes of rough comparison, there are about 454 *million* micrograms in 1 pound. Thus, Dow's proposed maximum single application rate for sulfoxaflor of 0.133 pounds per acre is equivalent to about 60 million micrograms per acre.

[6] Depending on their acute toxicity, EPA classifies pesticides as "practically non-toxic (LD_{50} >11 μg a.i./bee), moderately toxic (LD_{50} is 2-11 μg a.i./bee), or highly toxic to bees (LD_{50} <2 μg a.i./bee)." PER 413-14. With an acute oral LD_{50} value of just 0.052 μg a.i./bee, sulfoxaflor is at the extremely toxic end of the spectrum.

rate – would result in an "estimated environmental concentration" ("EEC") of 4.3 micrograms of sulfoxaflor per bee from consumption of tainted pollen and nectar and 0.36[7] micrograms of sulfoxaflor from direct contact with spray. PER 112.

Third, EPA calculated what it refers to as a "risk quotient" (or "RQ") by dividing the EEC by the LD_{50}. The result was an acute dietary RQ of 83 and an acute contact RQ of 2.8. PER 112. Both RQs *far* exceed EPA's predetermined "level of concern" (or "LOC") for honey bees of 0.4, which reflects the level of exposure at which 10% or more of bees are killed. PER 443.

Because the RQs described above exceeded EPA's level of concern, EPA attempted to "refine" its Tier 1 assessment based on studies submitted by Dow that were intended to measure more precisely the amount of sulfoxaflor that ends up in the pollen and nectar of sprayed pumpkins, cotton, and a flowering plant called *Phacelia*. PER 112-15. However, EPA found that Dow's residue studies had significant "limitations" that could underestimate exposure. PER 138.

> Specifically, the pumpkin residue data reflect systemic transport only and were collected several days after pesticide application. The *Phacelia* residue data are from application rate[s] lower than the proposed U.S. maximum and are very limited for pollen and nectar. The cotton study contains the most extensive residue information available, however, the high variability in sulfoxaflor residues from

[7] Table 40 in EPA's ecological risk assessment contains a mathematical error. 2.7 μg a.i./bee per 1 lb a.i./A is equivalent to 0.359 μg a.i./bee per 0.133 lb a.i./A, not 0.72 μg a.i./bee per 0.133 lb a.i./A, as indicated in Table 40.

> the cotton residue study and the nature of the cotton flowering (*i.e.,* open for only one day) introduces uncertainty in the extrapolation of these residue results to other crops.

PER 138.

In light of the shortcomings in Dow's residue data, EPA concluded that "additional data on the nature and magnitude of sulfoxaflor residues in one or more pollinator-attractive crops would be needed to address this source of uncertainty." PER 138. But even accepting the uncertainty, EPA found that Dow's residue data yielded acute dietary RQs that "range from <0.8 to 5.7 and *exceed the LOC for acute risk (0.4)*." PER 115 (emphasis added). EPA therefore concluded that "*risk to honey bee colonies cannot be precluded* and analysis of effects on the whole hive is warranted (Tier 2)." *Id.* (emphasis added).

2. Tier 2 of EPA's Risk Assessment Was "Unable to Preclude Risk to Developing Brood or Long-Term Colony Health."

Whereas Tier 1 of EPA's honey bee risk assessment is based on laboratory toxicity studies, Tier 2 is based on "semi-field" studies, in which an entire honey bee hive is placed in an outdoor enclosure and the bees are forced to forage on a crop that is sprayed with the pesticide under evaluation. PER 504-05. Because Tier 2 studies subject the whole honey bee colony to the pesticide being tested, they "enable[] the combined impact of lethal and sublethal effects on multiple casts of exposed bees to be ascertained at the hive level (e.g., colony strength, brood development)." PER 507.

Dow submitted a total of six Tier 2 semi-field studies in support of its application to register sulfoxaflor. PER 123. *None* of the six studies conformed to EPA test guidelines. For example, five of the six studies "used application rates that were substantially below the maximum proposed application rate in the US (*i.e.,* below single rate of 0.133 lb ai/A and the yearly maximum rate of 0.266 lb ai/A)." PER 124. Moreover, "[t]he one semi-field study that used maximum US application rates was intended for quantifying residues in plant matrices, and thus, has limited biological effects information." PER 39.

Ultimately, EPA staff scientists determined that the semi-field studies submitted by Dow "were unable to preclude risk to developing brood or long-term colony health from the proposed sulfoxaflor applications due to limitations associated with their design and conduct." PER 37. Staff explained:

> Additional data would be needed to determine the potential effects of sulfoxaflor applications on brood development and long-term colony health at the maximum application rates proposed in the US. Such data would include one or more Tier 2 semi-field tunnel studies conducted according to OECD 75 guidance.[8]

PER 139.

[8] EPA has determined that studies conducted in accordance with Organization for Economic Coordination and Development ("OECD") guidance "can be used to develop data necessary to meet [FIFRA registration] requirements." 40 C.F.R. § 158.70(d)(2). OECD Guidance Document 75 sets forth protocols for a "Honey Bee (*Apis Mellifera L.*) Brood Test Under Semi-Field Conditions." *See* OECD, Guidance No. 75 (2007), *available at* http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono (2007)22&doclanguage=en.

Given the results of the Tier 1 assessment and the myriad problems associated with Dow's Tier 2 field studies, EPA staff reached the following conclusion:

> In considering multiple lines of evidence, including results of Tier 1 risk assessment, the mode of action of sulfoxaflor, the nature of its uptake and persistence in plant tissues, and results (and limitations) of the Tier 2 studies, *the potential impact of the proposed uses of sulfoxaflor at maximum application rates on developing bee brood and colony strength cannot be precluded.*

PER 133 (emphasis added). In short, at the end of their ecological risk assessment, EPA staff scientists had determined that sulfoxaflor is extremely toxic to individual bees – far exceeding the agency's pre-established level of concern – and that the available field studies were scientifically unsound, meaning that EPA could not rule out risks to honey bee colonies.

C. EPA's Proposed Conditional Registration

On January 14, 2013, EPA solicited public comment on a proposed decision to register sulfoxaflor conditionally in accordance with Section 3(c)(7)(C) of FIFRA, 7 U.S.C. § 136a(c)(7)(C). PER 171. As a condition of registration, EPA proposed that Dow be required to submit:

> (1) a Tier 2 semi-field study for assessing impacts on honey bee colony strength and brood development in accordance with OECD-established test guidelines; [and]
>
> (2) an additional residue study to assess the nature and magnitude of sulfoxaflor residues on a pollinator-attractive crop (e.g., canola).

PER 182-83.

Pending the "submission and determined acceptability of the above conditional data," EPA proposed interim label restrictions "to reduce exposure to bees." PER 183. Used in accordance with the interim label restrictions, EPA concluded only that "sulfoxaflor applications will not result in a *catastrophic loss* to brood *during the time required for the conditional studies to be performed and assessed*." *Id.* (emphasis added).

D. EPA's Final Registration Decision

On May 6, 2013, EPA announced its final decision with respect to Dow's application to register sulfoxaflor. PER 185. Despite the agency's proposed decision four months earlier to condition registration on the timely submission of studies showing that sulfoxaflor does not pose a risk to bees, EPA's final decision registered sulfoxaflor unconditionally. PER 197. In so doing, EPA acknowledged that use of sulfoxaflor poses "a potential hazard to bees from exposure." PER 199. However, EPA decided that the risk to bees would be "appropriately mitigated" by "protective statements that limit applications to when bees are not expected to be present." *Id*. Specifically, for crops that bloom continuously – including strawberries, cotton, citrus, and cucurbits[9] – EPA required Dow to revise the labels to include the following "Advisory Pollinator Statement:"

[9] The term "cucurbits" is used to describe cucumbers, summer squash (*e.g.*, zucchini), winter squash (*e.g.*, pumpkins) and melons. PER 307.

> Notifying known beekeepers within 1 mile of the treatment area 48 hours before the product is applied will allow them to take additional steps to protect their bees. Also, limiting application to times when managed bees and native pollinators are least active, e.g., before 7 am or after 7 pm local time or when the temperature is below 55° F at the site of application, will minimize risk to bees.

PER 202. For other crops, EPA required Dow to revise the labels to include the following restriction: "Do not apply this product at anytime between 3 days prior to bloom and until after petal fall." PER 200-01. Finally, EPA reduced the maximum single application rate from 0.133 lbs a.i./A to 0.09 lbs a.i./A and increased the minimum application interval from 7 to 14 days for some crops. *Id.*

"With the inclusion of [these] reduced application rates, increased minimum application intervals, and the pollinator specific labeling mitigation," EPA claimed that "*the remaining eco-risks are outweighed by the benefits of sulfoxaflor registration*." PER 200 (emphasis added).

SUMMARY OF ARGUMENT

EPA's conclusion that its final decision registering sulfoxaflor "will not present adverse effects against bees," PER 200, is unsupported by substantial evidence in the record and violates FIFRA. First, EPA's decision to register sulfoxaflor unconditionally in the absence of adequate field testing for honey bees is contrary to FIFRA and the agency's own regulations. Second, there is no evidence that the inadequate "mitigation measures" EPA adopted will address the acknowledged risk to bees. Third, the record shows that EPA improperly skewed

its analysis of sulfoxaflor's risks and benefits by ignoring adverse impacts to the beekeeping industry and to crops that require bees for pollination. For all these reasons, EPA's decision to register sulfoxaflor must be set aside and remanded for reconsideration.

STANDARD OF REVIEW

EPA's order registering sulfoxaflor may be sustained only if it is "supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). Interpreting equivalent language in other statutes, the Supreme Court has held:

> Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. . . . Accordingly, it must do more than create a suspicion of the existence of the fact to be established.

Universal Camera Corp. v. Nat'l Labor Relations Bd., 340 U.S. 474, 477 (1951). Moreover, "[t]he substantiality of evidence must take into account whatever in the record fairly detracts from its weight." *Id.* at 488. "This is clearly the significance of the requirement . . . that courts consider the whole record." *Id*.

The Supreme Court has indicated that the "substantial evidence" standard of review "affords considerably more generous judicial review than the 'arbitrary and capricious' test" that frequently governs judicial review of final agency actions. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 143 (1967), *overruled on other grounds, Califano v. Sanders,* 430 U.S. 99, 97 (1977); *see also Industrial Union*

Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 705 (1980) (Marshall, J. dissenting) (noting that the substantial evidence standard "represents a legislative judgment that regulatory action should be subject to review more stringent than the traditional 'arbitrary and capricious' standard"). This Court has agreed. *See Union Oil Co. of California v. Federal Power Comm'n* 542 F.2d 1036, 1040-41 (9th Cir. 1976) ("Congress expected greater scrutiny when the enabling statute contains a substantial evidence test.").[10] But any difference between the two standards of review is immaterial in this case, because EPA's decision to register sulfoxaflor satisfies neither standard.

ARGUMENT

I. Beekeepers Have Standing under Article III of the Constitution to Challenge EPA's Decision to Register Sulfoxaflor.

As the outset, Beekeepers have standing under Article III of the Constitution to maintain this action. The Supreme Court has held that an *individual* has Article III standing if he or she "is under threat of suffering 'injury in fact' that is concrete and particularized; the threat must be actual and imminent, not conjectural or

[10] Other circuit courts have split on the issue. *Compare Corrosion Proof Fittings v. Envt'l Prot. Agency*, 947 F.2d 1201, 1214 (5th Cir. 1991) ("Congress put the substantial evidence test in the statute because it wanted the courts to scrutinize [agency] actions more closely than an 'arbitrary and capricious' standard would allow.") *with Association of Data Processing Serv. Organizations v. Board of Governors*, 745 F.2d 677, 683 (D.C. Cir. 1984) ("[I]n their application to the requirement of factual support the substantial evidence test and the arbitrary or capricious test are one and the same.").

hypothetical; it must be fairly traceable to the challenged action of the [respondent]; and it must be likely that a favorable judicial decision will prevent or redress the injury." *Summers v. Earth Island Inst.,* 555 U.S. 488, 493 (2009). An *organization*, in turn, has Article III standing "when its members would otherwise have standing to sue in their own right, the interests it seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Washington State Apple Advertising Comm'n,* 432 U.S. 333, 343 (1977).

As set forth in detail in the declarations that accompany this brief,[11] the petitioners in this case include three individuals who own and operate large-scale commercial beekeeping companies. Petitioner Adee is a co-owner of Adee Honey Farms, currently the largest beekeeping operation in America, with some 90,000 honey bee hives and 50 full-time employees. Decl. of Bret L. Adee ("Adee Dec.") at ¶ 2. Petitioner Smith owns and operates a beekeeping and farming company in Arizona that runs about 3,850 honey bee colonies. Decl. of Thomas R. Smith

[11] This Court may consider Beekeepers' declarations "not in order to supplement the administrative record on the merits, but rather to determine whether petitioners can satisfy a prerequisite to this court's jurisdiction." *Northwest Envt'l Defense Ctr. v. Bonneville Power Admin.*, 117 F.3d 1520, 1528 (9th Cir. 1997); *see also Sierra Club v. Envt'l Prot. Agency*, 292 F.3d 895, 900 (D.C.Cir. 2002) ("A petitioner . . . should establish its standing by the submission of its arguments and any affidavits or other evidence appurtenant thereto at the first appropriate point in the review proceeding.").

("Smith Dec.") at ¶ 3. Petitioner Anderson owns California Minnesota Honey Farms, a migratory beekeeping operation with about 3,000 hives. Decl. of Jeffrey S. Anderson ("Anderson Dec.") at ¶¶ 3, 6.

The petitioners also include four organizations that represent the interests of both professional and amateur beekeepers. Petitioner American Beekeeping Federation ("ABF") has approximately 1,300 members, making it the largest beekeeping organization in the United States. Decl. of George K. Hansen ("Hansen Dec.") at ¶ 4. Petitioner American Honey Producers Association ("AHPA") has about 400 members who make their living from the production of honey. Decl. of Randell C. Verhoek ("Verhoek Dec.") at ¶ 3. All told, approximately "80% of the professional beekeepers in the United States are members of ABF and/or AHPA." Adee Dec. at ¶ 5. The organizational petitioners also include the Pollinator Stewardship Council (formerly called the National Pollinator Defense Fund) and the National Honey Bee Advisory Board, both of which were formed by AHPA specifically to address the adverse impacts that pesticides are having on the beekeeping industry. *Id*. at ¶¶ 4-6.

The interests at stake in this lawsuit – honey bee survival and health – are clearly germane to the organizational petitioners' purposes, and Beekeepers' claims under FIFRA and request for prospective equitable relief do not require the participation of individual members. *See United Food & Comm. Workers Union*

Local 751 v. Brown Group, Inc., 517 U.S. 544, 546 (1996) ("[I]ndividual participation is not normally necessary when an association seeks prospective or injunctive relief for its members."). As set forth below, Beekeepers also satisfy the remaining criteria for standing.

A. Sulfoxaflor Poses an Actual and Imminent Threat to Beekeepers' Economic Livelihood.

To appreciate the extent to which EPA's decision to register sulfoxaflor poses an actual and imminent threat to Beekeepers, it is important to bear in mind the magnitude of the existing honey bee crisis. According to EPA:

> In 2006, some commercial beekeepers reported losses of 30-90% of their hives during wintering months. A portion (approximately 50%) of these declines were characterized by the disappearance of adult worker bees with few or no dead bees in the colony, the presence of capped brood with a small cluster of nurse bees, the queen, and the presence of intact honey and pollen stores; this syndrome has been termed Colony Collapse Disorder.

PER 404.

Prior to 2006, commercial apiarists could anticipate losing up to 10 or 15 percent of their bees each year, mostly over the course of the winter. Exh. A to Hansen Dec. at 1. Losses of that magnitude were sustainable, in that they could be recovered by dividing hives and pooling resources. *See* Anderson Dec. at ¶ 5. Since 2006, however, annual overwinter losses have risen dramatically. Surveys conducted by USDA show that 28 to 33 percent of total U.S. honey bee colonies died each winter from 2007 to 2011. Exh. A to Hansen Dec. at 1. Total winter

losses dipped to 22 percent in 2012, but preliminary results of the 2013 survey indicate that 31 percent of colonies died last winter. Hansen Dec. at ¶ 7.

Compounding these unsustainable overwinter losses is a marked increase in the incidence of "significant *summer* mortality – a time when bee populations should be healthy due to warm weather, long days, and food abundance." Anderson Dec. at ¶ 7. All told, according to USDA: "*Since 2006 an estimated 10 million bee hives at an approximate current value of $200 each have been lost, and the total replacement costs of $2 billion dollars has been borne by the beekeepers alone*." Exh. A to Hansen Dec. at 2 (emphasis added).

Petitioners and their members have suffered greatly at the front lines of this honey bee crisis. According to petitioner Adee:

> Prior to 2005, we would expect to lose between 3-8% of our colonies over the course of the winter. Now, we consider it a good year if we lose only 20%. In 2012, we lost 42% of our hives over winter, but by the time we came around to pollinate almonds in the early spring, our losses were at 55%.

Adee Dec. at ¶ 12; *see also* Anderson Dec. at ¶ 6 ("In 2012 . . . I had 3,150 hives in April, but by February 2013, I was down to just 998 hives, meaning I lost almost 70% of my hives just in the last year."); Verhoek Dec. at ¶ 6 ("[O]ur annual loses have increased to as much as 50% per year . . ."); Smith Dec. at ¶ 7("[I]n January 2008, 6,000 of 7,280 hives – over 80% of our honeybee business – failed over the course of just 45 days.").

The nationwide collapse of honey bee colonies is not only a crisis for commercial beekeepers; it is also a direct and dire threat to America's food supply. Scientists estimate that one-third of the food we eat – and an even greater proportion of our overall nutrition – comes from crops that will not make fruit or seed unless they are first pollinated by a bee. PER 332; Exh. A to Adee Dec. As summarized by USDA:

> It is imperative that we increase honey bee survival both to make beekeeping profitable but more importantly to meet the demands of U.S. agriculture for pollination and thus ensure [our] food security. . . . Currently, the survivorship of honey bee colonies is too low for us to be confident in our ability to meet the pollination demands of U.S. agricultural crops.

Exh. A to Hansen Dec. at 5. Unless current trends are reversed, a prominent USDA researcher has warned that "*[w]e are one poor weather event or high winter bee loss away from a pollination disaster*." *Id.* (emphasis added).

In the midst of all of this, EPA's unlawful decision to register sulfoxaflor threatens to turn crisis into catastrophe. EPA does not contest the "properties of sulfoxaflor that render it a potential concern to bees: high acute oral toxicity, foliar spray application on pollinator attractive crops, and systemic uptake in plants." PER 204. Nor does EPA dispute "that bees may potentially be exposed to sulfoxaflor in numerous crops." PER 239. Indeed, EPA's own analysis details at least three reasons why managed honey bees are all but certain to be exposed to sulfoxaflor.

First, "[s]ulfoxaflor is proposed to be widely used in the U.S. to control or suppress a wide range of insect pests," meaning that "*[t]he spatial extent of usage areas is expected to cover large acreages of the proposed crop land in the U.S.*" PER 57 (emphasis added). Second, most commercial beekeeping operations are migratory in nature, and "[e]xposure to multiple insecticides and/or multiple exposures to a single insecticide is inherent for mobile bee populations as hives are relocated throughout the country." PER 239. Third, because honey bees can forage up to five miles from the hive, "the spatial scale of potential pesticide exposure can be much larger than typical sizes of fields planted in crops and may encompass multiple cropped and noncropped areas at any given time." PER 410.

For these same reasons, Beekeepers' hives are and will be exposed to sulfoxaflor. For example, petitioner Smith attests that "sulfoxaflor is already being applied on crops – including cotton – near Yuma where my bees forage and where I provide commercial pollination services." Smith Dec. at ¶ 9. Petitioner Anderson states that because sulfoxaflor has been registered for use on soybeans, a dominant Midwestern crop, his bees "will now be exposed to sulfoxaflor just about anywhere I place them in Minnesota." Anderson Dec. at ¶ 4. Petitioner Adee explains that his bees "risk exposure to pesticides in general, and sulfoxaflor in particular, at just about every point during the year." Adee Dec. at ¶ 7.

Ultimately, exposure to sulfoxaflor will translate directly into further economic losses for Beekeepers. *See, e.g.,* Smith Dec. at ¶ 11 ("I will likely have even higher costs to provide minimal protections as a result of this new exposure to [sulfoxaflor]."); Anderson Dec. at ¶ 19 ("[S]ulfoxaflor could be the final nail in the coffin for my business."). These economic injuries are "clearly a sufficient basis for standing." *San Diego County Gun Rights Comm. v. Reno,* 98 F.3d 1121, 1130 (9th Cir. 1996); *see also Sierra Club v. Morton,* 405 U.S. 727, 733-34 (1972) ("[P]alpable economic injuries have long been recognized as sufficient to lay the basis for standing").

B The Threat Posed by Sulfoxaflor Is Traceable to EPA's Decision to Approve the Pesticide; a Judicial Order Setting Aside EPA's Approval Would Provide Redress.

Having demonstrated that they are injured by sulfoxaflor, Beekeepers need only show that the injury is "fairly traceable" to EPA's registration decision at issue herein, and that a "favorable judicial decision will prevent or redress the injury." *Summers,* 555 U.S. at 493. The Supreme Court has characterized the "fairly traceable" and "redressability" components of the standing inquiry as essentially "two facets of a single causation requirement." *Allen v. Wright*, 468 U.S. 737, 753 n. 19 (1984).

It is well established that "the causation requirement for constitutional standing is met when a [petitioner] demonstrates that the challenged agency action

authorizes the conduct that allegedly caused the [petitioner]'s injuries, if that conduct would allegedly be illegal otherwise." *Animal Legal Defense Fund, Inc. v. Glickman*, 154 F.3d 426, 440 (D.C. Cir. 1998) (en banc); *see also Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 967 (9th Cir. 2006) (holding that injury from a mining project is caused by the federal government, where the project could not proceed without federal approval).

In this case, *but for* EPA's decision to register sulfoxaflor under FIFRA, the pesticide would not threaten Beekeepers, because under FIFRA "no person in any State may distribute or sell to any person any pesticide that is not registered." 7 U.S.C. § 136a(a); *see also Natural Res. Defense Council v. Envt'l Prot. Agency*, ___ F.3d ___, 2013 WL 5943409, *3 (9th Cir., Nov. 7, 2013) (finding that "there is roughly no chance" of exposure to a pesticide absent EPA registration under FIFRA). A favorable ruling on the merits would result in EPA's registration decision being "set aside," thereby providing Beekeepers with redress. *See* 7 U.S.C. § 136n(b). For all these reasons, Beekeepers have Article III standing to maintain this lawsuit.

II. EPA's Conclusion that Sulfoxaflor Will Have No Unreasonable Adverse Environmental Effects Is Unsupported by Substantial Evidence.

A. EPA Lacked Valid Tier 2 Field Studies Regarding Risks to Honey Bee Colonies, in Violation of FIFRA and Applicable Regulations.

The record in this case shows that EPA registered sulfoxaflor in the absence of valid Tier 2 field studies regarding the risk to honey bee colonies, in violation of FIFRA and EPA's own implementing regulations.

As discussed previously, FIFRA authorizes EPA to register a pesticide only if use of the pesticide "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). It is well established that "[t]he burden of persuasion that a pesticide product is entitled to registration . . . is always on the proponent(s) of registration." 40 C.F.R. § 154.5. Thus, this Court has held that the registrant – here, Dow – must "demonstrate with sufficient scientific evidence that . . . the pesticide will not generally cause unreasonable adverse effects on the environment." *Love v. Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988).

FIFRA directs EPA to "publish guidelines specifying the kinds of information which will be *required* to support the registration of a pesticide . . ." 7 U.S.C. § 136a(c)(2)(A) (emphasis added). To this end, regulations promulgated by EPA and codified in Title 40, Part 158 or the Code of Federal Regulations set forth "the kinds of data and information EPA *requires* in order to make regulatory judgments under FIFRA . . . about the risks and benefits of pesticide products." 40 C.F.R.

§ 158.1(a) (emphasis added). Consistent with FIFRA, EPA's regulations confirm that the agency "*will not approve an application* unless there are available to EPA for its review *all* data that are necessary to make the required risk/benefit finding under FIFRA." 40 C.F.R. § 152.85(e) (emphasis added).

Among other things, EPA's regulations provide that the registrant must submit specified studies regarding a pesticide's effect on "terrestrial and aquatic non-target organisms." 40 C.F.R. § 158.630. Of particular relevance here "*field testing for pollinators*" is "conditionally required" whenever "data from other sources (Experimental Use Permit program, university research, registrant submittals, etc.) indicate potential adverse effects on [honey bee] colonies . . ." *Id.*, § 158.630(d) and (e) n.25.[12] EPA has determined that the requirement in 40 C.F.R. § 158.630 for pollinator field testing is general and can be satisfied by valid Tier 2 semi-field studies conducted in accordance with EPA guidelines. PER 504.

In this case, EPA found that the Tier 1 toxicity information submitted by Dow "*indicates that risk to honey bee colonies cannot be precluded* and analysis of

[12] The tables in Part 158 "use the descriptors R (required), CR (conditionally required), and NR (not required) as a general indication of the applicability of a data requirement." 40 C.F.R § 158.110. The regulations explain:

> Data designated as ''conditionally required'' (CR) for products with a given use pattern are required by EPA to evaluate the risks or benefits of a product having that use pattern if the product meets the conditions specified in the notes accompanying the requirement.

Id., § 158.110(b).

effects at the whole hive level is warranted (Tier 2)." PER 115 (emphasis added). Thus, because the Tier 1 data "indicate potential adverse effects on colonies," EPA's regulations required the submission of pollinator field testing. *See* 40 C.F.R § 158.630, n.25. However, the record shows that the pollinator field studies submitted by Dow did not satisfy EPA test guidelines and were otherwise inadequate.

EPA found that the available field studies were all inadequate in one or more ways: all but one involved application rates substantially below the maximum proposed rate, several had inadequate controls, most were of inadequate length or did not assess effects within the proper time interval, and one was a pesticide residue study that was not designed to assess biological effects at all. PER 123-27. EPA concluded:

> *[T]he results from the available semi-field tunnel studies are insufficient for concluding whether sulfoxaflor applications adversely impact brood development*, even at the lower application rates used. Additional data would be needed to determine the potential effects of sulfoxaflor applications on brood development and long-term colony health at the maximum application rates proposed in the US. Such data would include one or more Tier 2 semi-field tunnel studies conducted according to OECD 75[13] guidance.

PER 139 (emphasis added).

[13] *See* footnote 8, *supra,* discussing OECD 75 guidance.

A court should not defer to an agency's decision where, as here, the agency fails to adhere to its own regulations. *See, e.g., Western States Petroleum Ass'n v. Envt'l Prot. Agency*, 87 F.3d 280, 283 (9th Cir. 1996) (citing *Oil, Chem., & Atomic Workers Int'l Union Local 1-547 v. National Labor Relations Bd.*, 842 F.2d 1141, 1143, n. 1 (9th Cir. 1988)). The record in this case shows that EPA registered sulfoxaflor unconditionally in the absence of a single valid Tier 2 field study required by the agency's own implementing regulations to assess the risk to honey bee colonies. In the absence of the requisite scientific data, EPA's conclusion that sulfoxaflor "will not present unreasonable adverse effects against bees," PER 199, is unsupported by substantial evidence in the record. Instead, EPA's own scientific analysis confirms that sulfoxaflor poses "a potential for 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." PER 37.

B. EPA Improperly Relied on Voluntary, Arbitrary or Otherwise Inadequate Mitigation Measures to Reduce the Risk to Bees.

Rather than require Dow to submit a valid Tier 2 field study regarding the risk to honey bees, EPA decided to rely on essentially three "mitigation measures" to paper over the data gaps and "address" the risk to bees. First, for crops that bloom continuously, EPA required Dow to revise the sulfoxaflor labels to include the following "Advisory Pollinator Statement:"

> Notifying known beekeepers within 1 mile of the treatment area 48 hours before the product is applied will allow them to take additional steps to protect their bees. Also, limiting application to times when managed bees and native pollinators are least active, e.g., before 7 am or after 7 pm local time or when the temperature is below 55° F at the site of application, will minimize risk to bees.[14]

PER 202. Second, for those crops that do not bloom continuously, EPA directed Dow to revise the labels to prohibit spraying during bloom. PER 200-01. Finally, EPA required Dow to reduce the maximum single application rate for most crops to 0.09 pounds of active ingredient per acre and increase the minimum spray interval to 14 days. PER 200-02.

The problem for EPA is that the record does not support the agency's hope-and-prayer "belief" that this "additional labeling mitigation will reduce exposure to bees and therefore the potential for downstream effects would be minimized." PER 238. First, there is no evidence that EPA's "Advisory Pollinator Statement" will address the risk to bees, because compliance with EPA's advice is entirely voluntary. In its response to comments on this issue, EPA acknowledged candidly that the advisory statements are not mandatory or legally enforceable, but are intended only to "inform growers of additional steps they can take to minimize exposure to foraging bees." PER 252. Despite the agency's explicit reliance on

[14] Only the first sentence of the Advisory Pollinator Statement (recommending 48-hour notification) applies to cotton, the most prominent of the continuously flowering crops. PER 202. The additional recommendation against daytime spraying applies to citrus, strawberries, cucurbits, and ornamentals, but it does not apply to cotton. *Id.*

this measure in its final registration decision, EPA's response to comments ultimately admits that "notification is not a mitigation measure." *Id*.

EPA's reliance on bloom restrictions is similarly unfounded, because the restrictions do not apply to crops that bloom continuously, including cucurbits, strawberries, citrus, and cotton. By EPA's own estimates, these continuously flowering crops are grown on *over 11 million acres* in the United States. PER 6. Moreover, unlike many of the crops for which the bloom restriction applies, EPA admits that the continuously blooming crops excluded from the bloom restriction are "moderately" to "highly" attractive to honey bees. PER 202. In short, substantial evidence does not support EPA's conclusion that the bloom restriction will protect bees, because it simply does not apply to millions of acres of crops that will be sprayed with sulfoxaflor and will attract bees.

EPA relies primarily on its third mitigation measure – reducing the maximum single application rate from 0.133 pounds of active ingredient per acre to 0.09 lbs a.i./A – to address the documented risk to bees. But the record does not support EPA's conclusion that this 32% reduction in the maximum single application rate is sufficient. Instead, at rates ranging from just 0.023 lbs a.i./A to 0.086 lbs a.i./A – *i.e.,* at rates *still below* EPA's reduced application rate – EPA's final registration decision concedes that "[a]cute contact RQ values range from 0.5 to 1.8," respectively, "*which exceeds the acute risk level of concern for bees (0.4)*."

PER 195 (emphasis added). Similarly, at 0.086 lbs a.i./A – even accepting Dow's flawed cotton residue study – EPA's final registration decision concedes that "the oral acute RQs for the highest exposed castes of honey bees *do exceed the acute risk [level of concern]*." PER 196 (emphasis added). In short, at levels *below* EPA's reduced rate of 0.09 lbs a.i./A, EPA's final registration decision confirms that, "*acute risk to honey bee colonies cannot be precluded* and analysis of effects at the whole hive level is warranted (Tier 2)." PER 196.

Along the same lines, even at EPA's reduced application rate of 0.09 lbs a.i./A, the record shows that Dow's Tier 2 studies remained unable to preclude risk to honey bee colonies. Four of the six Tier 2 studies (*i.e.,* Schmitzer 2010 and Schmitzer 2011a, b and c) analyzed application rates of just *0.043 lbs a.i./A* – still less than half of EPA's reduced application rate of 0.09 lbs a.i./A. PER 129. The remaining Tier 2 studies (Ythier 2012 and Hecht-Rost 2009) used EPA's reduced application rate, but Ythier 2012 "was intended to measure sulfoxaflor in plant tissues, not biological effects."[15] PER 125. Hecht-Rost 2009, in turn, not only lacked an adequate control group, PER 131, but also "evaluated brood after only 7

[15] Ythier 2012 was intended to "refine" the Tier 1 risk assessment by measuring the amount of sulfoxaflor residue in cotton pollen and nectar; it "was not designed to provide a comprehensive evaluation of biological effects" for purposes of a Tier 2 assessment. PER 126. As discussed previously, EPA staff scientists questioned the validity and value of Ythier 2012 even as a Tier 1 residue study, and they recommended that EPA require "additional data on the nature and magnitude of sulfoxaflor residues in one or more pollinator-attractive crops." PER 138.

and 9 days exposure, which is far short of the recommended duration of semi-field studies by OECD Guideline 75." PER 125. Hence, EPA's response to comments concedes that "long-term observations of colonies following sulfoxaflor application in tunnels were not available at the current maximum application rate of 0.086 lb a.i./A." PER 228.

Not surprisingly, EPA staff scientists concluded that "the results from the available semi-field tunnel studies are *insufficient* for concluding whether sulfoxaflor applications adversely impact brood development, *even at the lower application rates used*" in those studies. PER 139 (emphasis added). The record therefore confirms that EPA registered sulfoxaflor in the absence of a single valid Tier 2 study analyzing the impact that sulfoxaflor will have on honey bee colonies at EPA's "mitigation measure" reduced application rate of 0.09 lbs a.i./A.

"With its delicate balance of thorough record scrutiny and deference to agency expertise, judicial review can occur only when agencies explain their decisions with precision." *American Lung Ass'n v. Envt'l Prot. Agency*, 134 F.3d 388, 392 (D.C. Cir. 1998); *see also Natural Res. Defense Council v. Envt'l Prot. Agency*, 966 F.2d 1292, 1306 (9th Cir. 1992) ("Without data supporting [EPA's decision], we owe no deference to EPA's line-drawing."). Here, had EPA reduced the application rate sufficiently so that resulting RQs did not exceed the agency's level of concern, or had EPA adopted an application rate that had been analyzed

and demonstrated to be safe by at even one Tier 2 field study, then EPA's reliance on that reduced rate might be rational. But the record not only fails to explain why EPA believed that reducing the application rate to 0.09 lbs a.i./A would mitigate the risk to bees, EPA's own analysis shows that sulfoxaflor *remains* a threat to bees at 0.09 lbs a.i./A. In short, the agency selected the 0.09 lbs a.i./A application rate arbitrarily, in violation of FIFRA and the basic tenant of administrative law that agencies articulate a rational basis for their decisions that is founded on substantial evidence in the record. *See, e.g., Humane Soc'y v. Locke*, 626 F.3d 1040, 1052-53 (9th Cir. 2010) (rejecting the agency's conclusion that a sea lion predation rate of 1% would have an adverse impact on salmon, where the agency arrived at the 1% threshold arbitrarily).

C. EPA Improperly Skewed Its Weighing of Sulfoxaflor's Risks and Benefits in Favor of Registration.

In the final analysis, even with the "mitigation measures" discussed above, EPA's final registration decision concedes that sulfoxaflor "may present potential risk to bees." PER 200. Determined to approve the pesticide nevertheless, EPA declared that the risk to bees is "outweighed by the benefits of sulfoxaflor registration." *Id*. But contrary to FIFRA, the record shows that EPA improperly tipped the scales in favor of registration by considering only sulfoxaflor's purported benefits, while ignoring adverse impacts to the beekeeping industry and crops that are dependent upon honey bees for pollination.

As set forth previously, FIFRA defines the phrase "unreasonable adverse effects on the environment" to include "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) (emphasis added). Thus, "[o]nce [EPA] has found that a risk inheres in the use of a pesticide, [the agency] has an obligation to explain how the benefits of . . . use outweigh that risk." *Envt'l Defense Fund v. Envt'l Prot. Agency*, 548 F.2d 998, 1012 (D.C. Cir. 1976); *see also* S. Rep. 970, 92d Cong. 2d Sess., *reprinted in* 1972 U.S.C.C.A.N. 4092, 4095 ("[A]ny adverse effect ought not to be tolerated unless there are overriding benefits from the use of a pesticide.").

Moreover, EPA must "make a *full weighing* of competing interests in making its determinations." *Id.* (emphasis added). The legislative history explains:

> [T]he balancing of benefit against risk is supposed to take every relevant factor that the [EPA] Administrator can conceive into account. The question he must decide is "Is it better for man and the environment to register this pesticide, or is it better that this pesticide be banned?" He must consider hazards to farmworkers, hazards to birds and animals and children yet unborn. He must consider the need for food and clothing and forest products, forest and grassland cover to keep the rain when it falls, prevent floods, provide clear water. He must consider aesthetic values, the beauty and inspiration of nature, the comfort and health of man. All these factors he must consider, giving each its due. No one should be given undue consideration, no one should be singled out for special mention, no one should be considered a "vital" criterion.

S. Rep. 838, 92d Cong. 2d Sess., *reprinted in* 1972 U.S.C.C.A.N. 3993, 4032-33.

In this case, because EPA found that the use of sulfoxaflor presents "risks to honey bees," the agency instructed its Biological and Economic Analysis Division ("BEAD") "to conduct an assessment on four of the crop groups (fruiting vegetables, cucurbit vegetables, citrus, and cotton) to determine benefits which would be associated with the registration of sulfoxaflor." PER 5. "Due to ongoing concerns for honey bees," BEAD also considered "the importance of honey bees as crop pollinators *for the assessed crop groups*." PER 5. However, BEAD quickly dismissed this latter issue, concluding that "honey bees are only essential to the production of cucurbit vegetables." PER 24.

Missing from BEAD's analysis – and the rest of the administrative record – is any assessment of the "importance" of honey bees to (1) the beekeeping industry and (2) the agricultural industry, to the extent that the latter involves the multitude of other crops that are dependent upon bees for pollination. This despite the fact that Beekeepers and others specifically urged EPA to consider and weigh the substantial economic impact that further honey bee declines will have on these industries. Regarding the impact on the beekeeping industry, for example, Beekeepers' comments on the proposed registration decision explained:

> For a representative beekeeper with 3,000 hives and a conservative estimate of income of $300/hive over the course of a year, a 45% loss represents $405,000. For the beekeeping industry as a whole, with 2.5 million hives, the loss is $337.5 million.

PER 323.

More broadly, Beekeepers discussed at length the interdependent relationship between honey bees and many important crops. PER 323-24. Because most commercial beekeeping operations migrate across the country over the course of the year following periods of bloom, Beekeepers pointed out that "the bees that may be exposed to sulfoxaflor in cotton, tomato, citrus and cucurbit fields are the same bees that are absolutely critical for pollinating almonds, cherries, apples, pears, cranberries, blueberries, and more." PER 327. Petitioner Smith elaborated on this issue in his comments:

> The [BEAD] assessment lacks the understanding of the relationship between managed honeybees and production agriculture. Managed honeybee colonies are moved through[out] the nation to meet the demands of crops requiring pollination. . . . If a colony is damaged due to exposure on cotton to the level where it cannot be utilized to commercially pollinate crops, those crops are at risk of an inadequate supply of available pollinators and/or the additional costs of supply and demand.

PER 318.

To give one clear example of this agricultural interdependence, Beekeepers' comments attached a report showing that almond trees in California are almost entirely dependent upon managed honey bees that are brought in from out of state. The report explains:

> Probably the most remarkable example of the relation between the intensification of agriculture and the dependence on the honey bee is the US almond industry in California's Central Valley. . . . [W]ith a total of over 275,000 hectares and more than 60 million trees, the area accounts for more than half of global almond production.

> While the almond industry grew impressively throughout the past decades, the number of managed bee colonies in the US more than halved. . . . The further the number of available colonies and the number of required colonies converge, the greater the risk that future colony losses will have an economic impact on the almond industry.

PER 334; *see also* PER 336 (scientists warning that further pollinator declines "could seriously threaten the continued production of insect pollinated crops").

Despite such comments, EPA refused to assess or consider the substantial costs associated with further bee declines due to sulfoxaflor. Instead, EPA admitted candidly in its response to comments that it had focused exclusively on sulfoxaflor's purported benefits:

> BEAD's role in the assessment process is to examine whether the new pesticide meets a need that is not being met by currently registered pesticides or non-chemical alternatives and determines [sic] if the benefits from the new pesticide are greater than those from currently registered pesticides or non-chemical pest control measures. *As such, BEAD only assesses the benefits of registration.*

PER 233 (emphasis added). EPA went on to confirm that BEAD had considered *only* whether a subset of crops that could be sprayed with sulfoxaflor (*i.e.,* fruiting vegetables, cucurbits, citrus, and cotton) benefit from bees. Thus, the agency stated:

> The [BEAD] impact assessment provides information relative to the importance of honey bees to cotton production. Based solely on the reproductive biology of cotton, EPA concluded that honey bee pollination can increase yields but is not essential for cotton production.

PER 234. BEAD *did not* consider, however, whether other crops that may not be sprayed with sulfoxaflor –*e.g.*, almonds, apples, plums, pears, cherries, blueberries and more – are nevertheless dependent upon the very same bees for pollination.

EPA's approach to this issue does not satisfy FIFRA. When, as in this case, EPA finds that a pesticide poses a risk to the environment, FIFRA prohibits EPA from registering the pesticide unless – after carefully assessing and weighing *both* the benefits *and* the costs – EPA finds "overriding" benefits from the pesticide's use. *See* 1972 U.S.C.C.A.N. at 4095. EPA's decision to ignore sulfoxaflor's economic impact on beekeepers and bee-dependent crops violates FIFRA's plain direction to take into account *all* "costs and benefits." 7 U.S.C. § 136(bb). As this Court has held in another case involving FIFRA's cost-benefit standard, "[w]ithout any investigation of those economic effects . . . EPA could not do even a rough and ready balancing." *Love*, 858 F.2d at 1361-62.

CONCLUSION AND RELIEF REQUESTED

At its heart, this case raises fundamental questions about whether a starkly toxic and insufficiently studied pesticide will inflict catastrophic damage on bees, the beekeeping industry, and all of us who rely on bees to pollinate much of the food we eat. Because EPA's decision to register sulfoxaflor runs counter to the scientific evidence in the record, Beekeepers respectfully request that this Court set aside EPA's decision in whole and remand the matter for reconsideration in accordance with FIFRA. *See* 7 U.S.C. § 136n(b).

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STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, petitioners Pollinator Stewardship Council *et al.* state that they are unaware of any related case.

CERTIFICATE OF COMPLIANCE

I certify that pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and Ninth Circuit Rule 32-1, the foregoing opening brief is proportionately spaced, has a typeface of 14 points, and contains 10,133 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

Dated: December 6, 2013

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CERTIFICATE OF SERVICE

I hereby certify that 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 on December 6, 2013. 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.

In addition, I certify that I served by Priority Mail, postage prepaid, one paper copy of Petitioners' Excerpts of Record on the persons listed below:

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