Nos. 19-72109 & 19-72280

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY, et al.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

On Petition for Review of Final Agency Action of the
United States Environmental Protection Agency

BRIEF OF THE ENVIRONMENTAL PROTECTION AGENCY

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GLOSSARY

Endangered Species Act ..... ESA

U.S. Environmental Protection Agency ..... EPA

Federal Insecticide, Fungicide, and Rodenticide Act ..... FIFRA

U.S. Department of Agriculture ..... USDA

INTRODUCTION

Sulfoxaflor is a highly selective pesticide that targets a range of piercing and sucking insects. It has become an indispensable form of pest control for growers as numerous crops have become resistant to older pesticides. Further, sulfoxaflor is generally less toxic, has lower application rates and requires fewer applications than many older, widely used pesticides. It also dissipates quickly in pollen and nectar, thereby posing less risk to pollinator species than other widely-used alternatives.

Petitioners here challenge the U.S. Environmental Protection Agency's (EPA) 2019 issuance of amendments to the registration of sulfoxaflor under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[1] One of the consolidated petitions for review also advances claims under the Endangered Species Act (ESA). EPA recognizes that the Agency failed to comply with the ESA's requirement of issuing an effects determination prior to issuing the 2019 registration amendments

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[1] The actions challenged in this case are amendments to the registrations that were first issued in 2019. *See* July 12, 2019 PRIA Label Amendment – Closer SG, PSCER000031; July 12, 2019 PRIA Label Amendment – Transform WG, PSCER000111. The earlier registrations of sulfoxaflor in 2016 are not at issue in this case.

for sulfoxaflor. EPA further recognizes that the Agency's rationale describing why the amendments satisfy the FIFRA standard could be more robust, particularly in light of the recent decision in *Nat'l Family Farm Coal. v. EPA*, 960 F.3d 1120, 1127 (9th Cir. 2020). Accordingly, EPA respectfully requests that this Court remand the challenged registration amendments to the Agency to allow EPA to correct the ESA error and also to provide additional detail on why the FIFRA standard is satisfied on this record. It is well established that remand is proper in the circumstances here—namely, where EPA acknowledges a legal error and also where an intervening court decision requires further examination by the Agency.

EPA further seeks that the remand be granted without vacatur. The ESA error may be remedied through further Agency action on remand, and EPA can—at the same time—provide additional explanation as to why the registration amendments satisfy the FIFRA standard. Vacatur would be inequitable because it would render sale and distribution of sulfoxaflor for the uses permitted in the 2019 amendments unlawful under FIFRA, thereby removing a pesticide with reduced toxicity from the market and very likely increasing the use of

older, generally more toxic alternatives. In fact, increased use of these alternatives could pose greater risk to the very species that Petitioners seek to protect as well as to other species and humans. This environmental harm, along with the clear adverse economic consequences that would result from vacatur, establishes that remand without vacatur is proper.

STATEMENT OF JURISDICTION

This court has jurisdiction over the consolidated petitions for review under 7 U.S.C. § 136n(b), which provides for judicial review in the courts of appeals "of any order issued by the Administrator following a public hearing." The 2019 actions challenged here amend the 2016 registrations. Decision Mem. Supporting Registration Decision for New Uses of the Active Ingredient Sulfoxaflor (July 12, 2019) (July 2019 Decision), EPA-HQ-OPP-2010-0889-0570, 1-PSCER-000001-000030. EPA issued the 2016 registration amendments after notice and comment proceedings. *See* EPA, Registration Decision for Sulfoxaflor for Use on Agricultural Crops, Ornamentals and Turf (Oct. 14, 2016) (2016 Registration), EPA-HQ-OPP-2010-0889-0563, 4-PSCER-000687-000697.

STATEMENT OF THE ISSUES

1. Whether remand of the challenged agency actions is proper where EPA has acknowledged a legal error under the Endangered Species Act (ESA), and wishes to provide further explanation for its actions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) after an intervening court decision interpreting the requirements of that statute.
2. Whether the Court should exercise its equitable discretion and decline to vacate the challenged pesticide registration actions where EPA can remedy the ESA error and elucidate its FIFRA rationale on remand, and where vacating the actions could cause environmental and economic harm by taking a valuable tool away from farmers and resulting in the use of more toxic pesticides.

PERTINENT STATUTES AND REGULATIONS

The pertinent statutes and regulations not included as part of the Petitioners' briefs are reproduced in an appendix to this brief.

STATEMENT OF THE CASE

A. Legal Background

1. Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA generally precludes the distribution or sale of any pesticide unless it is "registered" by EPA. 7 U.S.C. § 136a(a). The registration process begins through submission of a "statement," which includes, among other things, the name and complete "formula of the pesticide." *Id.* § 136a(c)(1). EPA then provides "a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern" and allows opportunity for comments. *Id.* § 136a(c)(4).

EPA issues a license, referred to as a "registration," for each specific pesticide product allowed to be marketed. *Id.* at § 136a(a); *see also Nat'l Family Farm Coal. v. EPA*, 966 F.3d 893, 912 (9th Cir. 2020) (same). "The terms and conditions on the license include exactly what product can be sold, the specific packaging it must be sold in, and labeling that contains instructions on proper use." *Id.* (citing 7 U.S.C. § 136(p)). The Act directs that EPA "shall register a pesticide" if the Agency determines that:

> (A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) 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).

To evaluate whether an application to amend an existing registration should be granted, EPA evaluates whether the requested amendment, e.g., a proposed use, is likely to cause unreasonable adverse effects. Relevant here, Congress expressly directs EPA to balance benefits and costs. Thus, "unreasonable adverse effects on the environment" 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." *Id.* § 136(bb).

It is unlawful to use a pesticide "in a manner inconsistent with its labeling." *Id.* § 136j(a)(2)(G). A pesticide product's labeling is therefore integral to EPA's registration decision and is the primary means of

accomplishing FIFRA's mandate to prevent unreasonable adverse effects.

2. Endangered Species Act

Congress enacted the ESA "to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved," and "to provide a program for the conservation of such endangered species and threatened species." 16 U.S.C. § 1531(b). ESA section 7 directs each federal agency to insure, in consultation with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (collectively, the Services), that "any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of" any listed species or destroy or adversely modify designated critical habitat. *Id.* § 1536(a)(2).

Section 7 and its implementing regulations delineate a process for determining the biological impacts of a proposed action known as section 7 consultation. 16 U.S.C. § 1536; 50 C.F.R. pt. 402. Through this process, the agency proposing the relevant action (referred to as the action agency) must determine whether its action "may affect" a listed species or its designated critical habitat. 50 C.F.R. § 402.14. If the

action agency determines that the action will have "no effect" on listed species or critical habitat, it need not "consult" under section 7. *See* 50 C.F.R. § 402.12; *Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1054 n.8 (9th Cir. 1994). If, however, the agency determines that the action "may affect" listed species or critical habitat, the action agency must pursue either informal or formal consultation with one or both of the Services. 50 C.F.R. §§ 402.13-402.14.

Formal consultation is required unless the action agency determines, with the Services' written concurrence, that the proposed action is "not likely to adversely affect" a listed species or critical habitat. 50 C.F.R. §§ 402.13(a), 402.14(b)(1). If formal consultation is required, then one or both of the Services must prepare a biological opinion stating whether the proposed action is likely to "jeopardize the continued existence of" any listed species or destroy or adversely modify designated critical habitat. 16 U.S.C. § 1536(b)(3); 50 C.F.R. § 402.14.

B. Historical Background

FIFRA predates the ESA, and many hundreds of pesticides that have been approved and are available for use have not undergone ESA review—namely, without EPA first undertaking an effects

determination or, as appropriate, initiating consultation under the ESA. *See Wash. Toxics Coal. v. EPA*, 413 F.3d 1024 (9th Cir. 2005), abrogated on other grounds by *Cottonwood Envtl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075 (9th Cir. 2015). EPA has acknowledged its duty to make an effects determination and, if required, consult under ESA section 7 prior to issuing a registration for a pesticide. *See id.* In recent years, EPA has worked with the Services, along with help from the National Academy of Sciences, to address the backlog and remedy noncompliance by creating a framework for pesticide consultation. *See* Jan Matuszko's Declaration in Support of Answering Brief (EPA's Second Decl.), ¶¶ 12-13.[2] Congress is aware of this dialogue and has requested that EPA report on consultation progress and streamline integration of ESA and FIFRA procedures. Pub. L. No. 113-79, § 10013, 128 Stat. 649 (2014).

To this end, EPA began several "pilot" Biological Evaluations using the methods identified by the National Academy of Sciences as a

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[2] Jan Matuszko's first declaration was filed in support of EPA's motion to remand. *See* EPA's First Decl., Doc. Id. No. 11871851. Ms. Matuszko's second declaration provides an updated assessment of the reasonable amount of time EPA projects it will require to make an effects determination for sulfoxaflor. *See* EPA's Second Decl. ¶ 5.

first step towards implementing the Academy's recommendations. *See* EPA's Second Decl. ¶¶ 13-14. In doing so, EPA has been allocating most resources to the review of older, generally more toxic pesticides, rather than to the first-time registration of new, generally less toxic ingredients. *See* EPA's Second Decl. ¶¶ 14, 19.

Subsequently, EPA, the Department of the Interior, and the Department of Commerce signed a memorandum of agreement establishing an interagency working group to include these and other federal agencies tasked with providing recommendations to the agencies' leadership on improving the ESA consultation process for pesticides. *See* EPA's Second Decl. ¶ 13. The intent of the interagency working group is to improve the consultation process for pesticide registration and registration review. *Id.* On December 20, 2018, the Agriculture Improvement Act of 2018 (2018 Farm Bill) (Pub. L. No. 115-334, 132 Stat. 4490) was signed into law, codifying the interagency working group and the memorandum of agreement. As required under section 10115 of the 2018 Farm Bill and FIFRA, 7 U.S.C. § 136a(c)(11), the interagency working group report was delivered to Congress in December 2019, and an update was provided in June 2020. *Id.*

B. Procedural History

1. 2013 Registration

Sulfoxaflor is an insecticide that targets a broad range of piercing and sucking insects including aphids, plant bugs, whiteflies, planthoppers, mealybugs, and scales. July 2019 Decision at 13, 1-PSCER-000013. In 2010, Intervenor Corteva Agriscience LLC (Corteva)[3] submitted registration applications to EPA for three pesticide products that contain sulfoxaflor as their active ingredient. In May 2013, EPA granted unconditional registration of these products under FIFRA, 7 U.S.C. § 136a(c)(5), with certain mitigating measures to protect pollinator species like bees. *See* EPA, Registration of the New Active Ingredient Sulfoxaflor for Use on Multiple Commodities, Turfgrass and Ornamentals (May 2013), 4-PSCER-000757. These registrations were challenged on FIFRA grounds by a number of petitioners. *See Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015). No party challenged the registrations under the ESA at

[3] Corteva was formerly known as Dow AgroSciences LLC. For ease of reference, the intervenor is referred to as "Corteva" throughout this brief.

that juncture—rather, challenges were solely brought under FIFRA. *See id.*

In 2015, the Court granted the petitions for review on the ground that EPA lacked sufficient data on the impacts of sulfoxaflor on bee populations. *Id.* at 531. Because of this, the Court held that EPA's decision was not supported by substantial evidence under FIFRA. *Id.* The Court then vacated the registration because, on that record, "leaving the EPA's registration of sulfoxaflor in place risks more potential environmental harm than vacating it." *Id.* at 532.

2. 2016 Registrations and 2019 Registration Amendments

After the vacatur of the registration in 2015, EPA reevaluated the sulfoxaflor application to take into account the errors identified by the *Pollinator Stewardship Council* court. In 2016, EPA granted unconditional registrations of three pesticide products containing sulfoxaflor for use on specified crops, turf, and ornamentals. *See* 2016 Decision, 4-PSCER-000687 (discussing issuance of registrations for Sulfoxaflor Technical (Registration No. 62719-631) and two end use

products, Transform WG (Registration No. 62719-625) and Closer SC (Registration No. 62719-623)). These registrations were not challenged.

Then, in July 2019, EPA granted unconditional amendments under FIFRA section 3(c)(5) to those same registrations. These amendments granted the following new uses: alfalfa, corn, cacao, grains (millet, oats), pineapple, sorghum, teff, teosinte, tree plantations, citrus, cotton, cucurbits, soybeans, and strawberry. July 2019 Decision, 1-PSCER-000001. Finally, the 2019 actions removed certain restrictions that were included in the October 2016 registrations. *Id.*

Applications for each of the uses that were approved in the 2019 registration amendments were publicly noticed under FIFRA section 3(c)(4), 7 U.S.C. § 136a(c)(4). *See* July 2019 Decision, 1-PSCER-000001 (approving uses on alfalfa, corn, cacao, grains (millet and oats), pineapple, sorghum, teff, teosinte, tree plantations, citrus, cotton, cucurbits, soybeans, and strawberry). Specifically, the 2010 notice advised the public of the application for use on citrus, cotton, cucurbits, soybeans, and strawberry. Notice of Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities, 75 Fed. Reg. 80,490 (Dec. 22, 2010). The 2014 notice

advised the public of the application for use on alfalfa, cacao, corn, grain (millet and oats), pineapple, sorghum, teff, and teosinte. *See* Pesticide Product Registration; Receipt of Applications for New Uses, 79 Fed. Reg. 22,963 (Apr. 25, 2014). And, in 2018, a notice advised the public on the application for use on tree plantations. *See* Pesticide Product Registration; Receipt of Applications for New Uses, 83 Fed. Reg. 51,678 (Oct. 12, 2018). Each of these notices provided an opportunity for public comment.

3. Record Supporting 2019 Registration Amendments

As part of the 2019 registration amendment decisions, EPA prepared an assessment of the ecological risks from the proposed amendments to the registrations. *See* Sulfoxaflor: Ecological Risk Assessment for Section 3 Registration for Various Proposed New Uses (July 10, 2019) (Risk Assessment), EPA-HQ-OPP-2010-0889-0566, 3-PSCER-000354. EPA also considered the impacts to pollinators based on existing and newly submitted data. *See* July 2019 Decision at 7-9, 1-PSCER-000007-000009. Finally, EPA prepared a benefits analysis of the amendments to help determine whether the proposed uses of the

pesticide pose unreasonable adverse effects to the environment and concluded that they did not. *See* Benefits for New Uses of Sulfoxaflor on Alfalfa, Avocado, Citrus, Corn, Cotton, Cucurbits, Fruiting Vegetables, Pineapple, Pome Fruit (Pre-bloom), Rice, Sorghum, Soybean, Strawberry, Ornamental and Home Fruit Trees (Mar. 7, 2019) (Benefits Assessment), EPA-HQ-OPP-2010-0889-0569, PSCER000641-000686; July 2019 Decision at 1-22, 1-PSCER-000010-000022 (discussing findings). In short, EPA concluded that sulfoxaflor provides numerous benefits against hard to control pests and is less acutely toxic generally, including to beneficial insects like honeybees, than the most widely used alternatives. *See id.*

4. Petitions for Review and Procedural History

Shortly after the 2019 amendments were issued, the petitioners filed petitions for review challenging these amendments. Petitioners Center for Biological Diversity and Center for Food Safety challenged the registration amendments on ESA and FIFRA grounds. *See* Pet. for Review, Case No. 19-72109, Doc. Id. No. 11403618. Petitioners Pollinator Stewardship Council, American Beekeeping Federation, and

Jeffrey Andersen challenged the actions on FIFRA grounds alone. *See* Pet. for Review, Case No. 19-72280, Doc. Id. No. 11423191. The petitions for review have been consolidated. *See* Nov. 4, 2019 Order, Doc. Id. No. 11487539. The registrant, Corteva, intervened in support of EPA. *See* Oct. 3, 2019 Order, Doc. Id. No. 11453342.

In October of 2020, EPA filed a motion for remand of the registration amendments without vacatur. Mot. to Remand, Doc. Id. No. 11871851. EPA explained that it did not comply with the ESA's requirements before issuing the registration amendments. *Id*. at 11-12. EPA further argued that remand without vacatur was proper because EPA could correct the legal error on remand, and vacatur of the amendments could cause adverse environmental and economic consequences. *Id*. at 15-21. Petitioners opposed EPA's motion. *Id*. at 2. The Court denied EPA's motion on January 12, 2021 and ordered merits briefing. Doc. Id. No. 11960653.

SUMMARY OF THE ARGUMENT

This Court should grant remand without vacatur of the 2019 registration amendments that are challenged here. As a threshold matter, EPA easily satisfies the standard for voluntary remand. The

Agency has acknowledged a legal error—namely, that it must make an effects determination and take other action as appropriate under the ESA. EPA further recognizes that additional explanation of its rationale under FIFRA is appropriate in light of this Court's intervening decision in *National Family Farm Coalition v. EPA*, 960 F.3d 1120 (9th Cir. 2020), which elucidates the FIFRA standard. In such circumstances, courts have repeatedly held that voluntary remand is proper.

This remand should be granted without vacatur because the nature of the legal error does not mandate vacatur, and vacatur could further cause sweeping environmental damage—including damage to the species that Petitioners seek to protect. Specifically, EPA's ESA error does not warrant vacatur because in issuing the 2019 registration amendments EPA expressly determined that the pesticide's ecological effects compared favorably against those of alternative pesticides in that growers would likely use if the registration amendments were vacated. Further, the plan to provide additional explanation of the FIFRA rationale does not undermine the adequacy of the FIFRA record as a whole.

Moreover, leaving sulfoxaflor on the market for the uses authorized in the 2019 registration amendments results in environmental benefits because sulfoxaflor is less toxic to non-target species than the most widely used alternatives. EPA, Sulfoxaflor-Hazard Comparison for Several Alternative Insecticides (July 10, 2019) (Hazard Comparison) at 1-2, 1-PSCER000340-000341. That is so because sulfoxaflor is designed to target harmful piercing and sucking insects while, at the same time, having generally lower toxicity to beneficial insects and other organisms like birds, mammals, and fish. This is amply supported by the FIFRA record here, which relies on a robust data set, including detailed "Tier 2" studies directly assessing the impacts of sulfoxaflor on pollinators. Petitioners' arguments that the FIFRA analysis was flawed all fail—the record here is well supported.

Lastly, vacating the 2019 amendments would almost certainly cause economic harm to the farmers who rely on sulfoxaflor to address pesticide-resistant insects. For these reasons, the 2019 registration amendments should be remanded to the Agency without vacatur.

STANDARD OF REVIEW

Voluntary remand of a challenged agency action is proper where the agency seeks to reconsider its initial action. *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012). "Whether agency action should be vacated depends on how serious the agency's errors are 'and the disruptive consequences of an interim change that may itself be changed.'" *Id.* (quoting *Allied–Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993)).

Further, in resolving questions of the weight of record evidence "[d]eference to an agency's technical expertise and experience is particularly warranted with respect to questions involving . . . scientific matters." *United States v. Alpine Land & Reservoir Co.*, 887 F.2d 207, 213 (9th Cir. 1989). An agency "is not required to support its finding . . . with anything approaching scientific certainty." *ASARCO, Inc. v. Occupational Safety & Health Admin.*, 746 F.2d 483, 490 (9th Cir. 1984) (cleaned up).

ARGUMENT

I. Remand Is Proper to Allow EPA to Remedy the ESA Defect and Further Explain Its FIFRA Rationale.

As a threshold matter, EPA easily satisfies the standard for voluntary remand because it has acknowledged a legal error, as well as the desire to provide further record-based explanation for its decision in light of an intervening event. Further, the Agency's request was timely filed in good faith.

A. EPA's acknowledgment of error, along with the intervening decision in *National Family Farm Coalition v. EPA*, provides a proper basis to remand this action.

Agencies have inherent authority to reconsider past decisions and to revise, replace, or repeal initial actions. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Allowing for voluntary remand is consistent with this principle. *See Ethyl Corp. v. Browner*, 989 F.2d 522, 524 (D.C. Cir. 1993). In litigation, courts have recognized that an "agency may take one of five positions" with respect to remand of the challenged action, including "seek[ing] a remand to reconsider its decision because of intervening events outside of the agency's control," and also seeking remand "because it believes that its

original decision was incorrect on the merits and it wishes to change the result." *SKF USA, Inc. v. United States*, 254 F.3d 1022, 1027-28 (Fed. Cir. 2001); *see also Cal. Cmtys. Against Toxics*, 688 F.3d at 992 (same and citing *SKF*, 254 F.3d at 1029); Charles H. Koch Jr., *Administrative Law & Practice* § 8:31, at 187 (3d ed. 2010) (voluntary remand is appropriate when "agency recognizes deficiencies in its decision, explanation or procedures" and asks the "court to remand the case back to the agency so that it may correct the deficiency"). When an agency seeks a remand on such grounds, "remand to the agency is required, absent the most unusual circumstances verging on bad faith." *SKF*, 254 F.3d at 1029-30. Further, in that circumstance, the court need not then reach questions regarding the reasonableness of the Agency's interpretation of the statute it is applying. *Id.*

Indeed, this Court affirmed that it should only "refuse voluntarily requested remand when the agency's request is frivolous or made in bad faith." *Cal. Cmtys.*, 688 F.3d at 992. This is for good reason: "[a]dministrative reconsideration is a more expeditious and efficient means of achieving an adjustment of agency policy than is resort to the federal courts." *B.J. Alan Co., Inc. v. ICC*, 897 F.2d 561, 562 n.1 (D.C.

Cir. 1990) (cleaned up). As the D.C. Circuit explained, "[w]e commonly grant such [relief], preferring to allow agencies to cure their own mistakes rather than wasting the courts' and the parties' resources reviewing a record that both sides acknowledge to be incorrect or incomplete." *Ethyl Corp.*, 989 F.2d at 524.

In *California Communities*, for example, this Court granted voluntary remand, reasoning that because EPA "recognized the merits of the petitioners' challenges and has been forthcoming in these proceedings, there is no evidence that the EPA's request is frivolous or made in bad faith." *Cal. Cmtys.*, 688 F.3d at 992. The Court reached the same result in *NRDC v. EPA*, involving a challenge to EPA's registration of the pesticide commonly known as "Enlist Duo." *See NRDC v. EPA*, No. 14-73353 (9th Cir.), Jan. 25, 2016 Order, Doc. Id. No. 9839194. There, EPA sought a remand to reconsider the registration in light of newly received information that the ingredients in the chemical at issue could potentially interact in ways that the Agency had not considered. *See Nat'l Fam. Farm Coal. v. EPA*, Mot. for Remand, Doc. Id. No. 9770038. EPA explained that it "can no longer represent to the Court that its conclusions were correct regarding whether issuance of

the registration met the standard in FIFRA." *Id*. at 7-8. The Court thus granted voluntary remand without vacating the registration. Jan. 25, 2016 Order, Doc. Id. No. 9839194. *See also Nat'l Fam. Farm*, 966 F.3d at 906 (discussing remand without vacatur of registration earlier in proceedings).

B. EPA's remand request is timely and made in good faith.

EPA's remand request meets the standard for voluntary remand. EPA reached out to Petitioners in August of 2020, acknowledged the ESA defect with the amendments, and expressed the intention of seeking a remand. The parties then sought an extension of the merits briefing deadlines to facilitate the discussions on the parties' positions regarding the motion to remand. *See* Aug. 17, 2020 Mot. for Ext., Doc. Id. No. 11791959. These discussions began in earnest before any party had filed their merits brief. *See id*. Then, consistent with its representations to counsel during these negotiations, EPA filed a motion for voluntary remand in October of 2020, conceding legal error on the ESA claim. Mot. to Remand, Doc. Id. No. 11871851.

EPA continues to "recognize[ ] the merits" of Center for Biological Diversity and Center for Food Safety petitioners' claim that the Agency failed to comply with the procedural requirements of the ESA. *Cal. Cmtys.*, 688 F.3d at 992. EPA acknowledges that it has not made an "effects determination" for sulfoxaflor, as it must do, or initiated consultation, if that is appropriate. 16 U.S.C. § 1536(a)(2).

Specifically, EPA recognizes that it must determine either that sulfoxaflor has "no effect" on ESA listed species and their critical habitat, or that the pesticide "may affect" those species or their critical habitat. 50 C.F.R. § 402.14(a); *see Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 188 (D.C. Cir. 2017); *see also* EPA's Second Decl. ¶¶ 8, 10, 14, 15(g). Then, if the Agency reaches the latter determination, it must consult with the Fish and Wildlife Service and/or National Marine Fisheries Service and obtain either biological opinions or concurrences that sulfoxaflor is not likely to adversely affect listed species or critical habitat. *See* 50 C.F.R. §§ 402.13, 402.14; EPA's Second Decl. ¶¶ 10, 14, 15(g). This "[effects] determination" must be made by the Agency in the first instance. 50 C.F.R. § 402.14(a).

EPA further recognizes that its FIFRA rationale describing why the registration amendments do not pose "unreasonable adverse effects on the environment" could be more detailed. 7 U.S.C. § 136(l). This discussion would benefit from further explanation while EPA undertakes the ESA analysis. EPA's Second Decl. ¶ 22. That is so because a year after the registration amendments were issued, this Court decided *National Family Farm Coalition v. EPA*, 960 F.3d 1120, 1127 (9th Cir. 2020). *National Family Farm* held that EPA's FIFRA registration of certain dicamba-based pesticides was not supported by substantial evidence. *Id.* at 1142-43. The Court reasoned that, in light of the comments concerning third-party injuries from dicamba use, EPA was required to "identify and take into account" these economic and social costs as part of the balancing under FIFRA. *Id.* at 1143.

While here the record evidence supports a finding that the registrations amendments do not pose "unreasonable risk to man or the environment," 7 U.S.C. § 136(bb), *see infra* at 40-51, EPA's rationale supporting this determination can be made clearer. For example, EPA can explicitly address why the economic and social costs of the registration amendments, on balance, support registration in light of

the *National Family Farm* decision. EPA's Second Decl. ¶ 22. Specifically, among other things, EPA could explain more clearly why harm to beekeepers is not likely from the uses of sulfoxaflor authorized by the 2019 registration amendments.[4]

On remand, EPA will undertake the ESA analysis for sulfoxaflor as expeditiously as practicable, taking into account its obligations under existing settlement agreements for completing biological evaluations for a series of other chemicals, as well as the priorities from the memorandum of agreement described above. EPA's Second Decl. ¶ 24; *see also* EPA's First Decl. ¶ 26. The Agency can thus begin the assessment of sulfoxaflor this summer. EPA further believes that it can complete an assessment by spring of next year if preparation of a biological evaluation is not necessary. EPA's Second Decl. ¶ 24. EPA

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[4] EPA's motion to remand focused on the ESA defect and maintained that the FIFRA analysis was supported by substantial evidence. EPA's briefing also noted, however, that remand of the entire case was most efficient because EPA could refine its FIFRA analysis. EPA Reply at 14, Doc. Id. No. 11935293. The Agency has since undertaken a more searching review of the record and now recognizes that additional explanation is proper for the reasons stated above. *See* EPA's Second Decl. ¶¶ 21-22.

can then initiate consultation with the Services, if necessary, at that time. *Id.*

While this work is ongoing on remand, EPA can explain in more detail why the registration amendments meet the FIFRA standard and do not pose "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). *See* EPA's Second Decl. ¶¶ 21-22. Further, as to the alleged procedural error, EPA can explain on remand its interpretation of 7 U.S.C. § 136a(c)(4) and supply additional detail as to its treatment of the applications here. *See* EPA's Second Decl. ¶¶ 21-22. The standard for voluntary remand is thus met, and the 2019 registration amendments should be remanded to the Agency. *See Cal. Cmtys.*, 688 F.3d at 992.

II. Vacatur of the Registration Amendments Is Not Required or Appropriate During the Pendency of the Remand.

This Court should grant remand without vacatur, leaving in place the registration amendments while EPA satisfies its obligations under the ESA and further explains its rationale under FIFRA. While EPA acknowledges legal error, the equities weigh strongly in favor of

allowing for continued use of sulfoxaflor during the remand period. Vacatur of the 2019 registration amendments may cause environmental harm as growers use more toxic pesticides in place of sulfoxaflor and would also lead to economic losses for these farmers.

To determine whether vacatur is warranted, the Court undertakes an equitable analysis. "[T]he decision whether to vacate depends on the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Allied-Signal*, 988 F.2d at 150-51 (cleaned up); *Cal. Cmtys.*, 688 F.3d at 992 (same). Also relevant to the analysis is whether "by complying with procedural rules, [the agency] could adopt the same rule on remand, or whether such fundamental flaws in the agency's decision make it unlikely that the same rule would be adopted on remand." *Pollinator Stewardship Council*, 806 F.3d at 532.

A. The ESA error and EPA's intent to elucidate its FIFRA rationale are not such serious deficiencies that vacatur is required.

The ESA error and plan to provide additional record explanation on FIFRA are not such serious legal errors that vacatur of the registration amendments is mandated under the circumstances here.

1. EPA took into account ecological impacts in the registration amendments, and so the ESA error does not weigh heavily in favor of vacatur.

On the ESA, the facts here—the failure to comply with the ESA before registering a pesticide under FIFRA—are analogous to the facts in *Center for Biological Diversity*, 861 F.3d at 188-89, where the D.C. Circuit remanded a flawed FIFRA registration without vacatur. There, EPA had not complied with the ESA before issuing a registration for a pesticide under FIFRA. *Id*. The D.C. Circuit reasoned that "[n]otwithstanding the EPA's failure to make an effects determination and to engage in any required consultation, it did not register [the pesticide cyantraniliprole] in total disregard of the pesticide's potential deleterious effects" because it had assessed the ecological risks for cyantraniliprole as part of the registration process. *Id*. at 188. That

ecological risk assessment, while distinct from the statutorily required ESA analysis, was relevant to analyzing the seriousness of the legal error. *See id.*

Similarly, here, while EPA acknowledges that it did not undertake the necessary ESA analysis, the Agency did not issue the 2019 registration amendments "in total disregard of the pesticide's potential deleterious effects" to species. *Ctr. for Biological Diversity*, 861 F.3d at 188. Rather, as described in detail *infra* at 40-51, EPA did take into account the ecological risks of sulfoxaflor—during the registration process—and concluded it was less toxic than the most widely used alternatives. EPA's consideration of ecological impacts is properly considered in weighing the seriousness of the ESA error. 861 F.3d at 188-89.

CFS Petitioners counter that EPA's ecological analysis should not be weighed in any respect in determining the seriousness of the ESA error because EPA is not the "consulting agency" under the ESA. Center for Food Safety (CFS) Br. at 33-35. But, this Court has already determined the Agency is entitled to substantial deference in analyzing the ecological impacts of the pesticides on species and their critical

habitats. *See Nat'l Fam. Farm Coal.*, 966 F.3d at 925-27. Similarly, *Center for Biological Diversity* makes clear that EPA's evaluation of the ecological benefits *is* relevant to the vacatur analysis. 861 F.3d at 188-89. Petitioners largely ignore this holding of *Center for Biological Diversity* while—at the same time—encouraging this Court to apply the case's reasoning in other respects. *See* CFS Br. at 33-34. That EPA's ecological analysis of sulfoxaflor is taken into account in considering the seriousness of the ESA error makes perfect sense given EPA's broad expertise in making scientific judgments about environmental impacts, as well as the Agency's close coordination with the consulting agencies. *See* EPA's Second Decl. ¶¶ 8-15.

Petitioners next argue that the nature of the ESA error warrants vacatur. They argue the ESA error cannot be "rehabilitated" on remand because EPA cannot reauthorize these uses on remand without first complying with the ESA. In their view, remand without vacatur is permissible only where the agency can reach the "exact same action" in every respect after remand. CFS Br. at 57. That is not the law. Rather, as *Pollinator Stewardship Council* makes clear, the inquiry is whether it is possible for EPA to adopt the "same *rule*" on remand—here, that

means the uses authorized by the registration amendments. 806 F.3d at 532 (emphasis added).

The Agency can do this if it concludes that the uses allowed for by the amendments are consistent with the ESA. *Cf. Nat'l Fam. Farm*, 966 F.3d at 922 (describing ESA's procedural requirements, and that a "no effect" determination for a pesticide like the one made there does not require further action or consultation). Further, as a practical matter it would make little sense to allow remand without vacatur only where the agency could follow the same process to reach the same result. If there was no error at all in the process or substance of the agency's action, there would be no reason for remand in the first place.

Petitioners also assert, in reliance on a recent D.C. Circuit case, *Standing Rock Sioux Tribe v. United States Army Corps of Engineers*, 985 F.3d 1032 (D.C. Cir. 2021), that to avoid vacatur for a procedural error, the agency must show that "with further explanation, [it could] justify its decision to skip that procedural step," *id.* at 1052. CFS Br. at 58-59. *Standing Rock* involved a challenge to a pipeline permit where the agency had not complied in full with the requirements of the National Environmental Policy Act because its reliance on a "Finding of

No Significant Impact" for the project was unsupported. *See* 985 F.3d at 1052. As a consequence, in that case, there was no question that vacatur of the permit could bring environmental benefits, and so the D.C. Circuit had no reason to reach whether those environmental concerns could properly be taken into account on the issue under the *Allied-Signal* analysis. *See id.*

But here, just as in *Center for Biological Diversity*, 861 F.3d at 188-89, vacatur *could* cause environmental harm. Thus, the traditional *Allied-Signal* framework applies, and remand without vacatur is proper if the disruptive consequences of vacatur weigh in favor of leaving the action in place notwithstanding the procedural defect. *See Cal. Cmtys.*, 688 F.3d at 992 (applying *Allied-Signal*). *See also Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 198-99 (D.C. Cir. 2009) ("vacatur need not be the remedy for an invalidly adopted rule").[5]

[5] The CFS Petitioners further argue that vacatur is proper whenever "a different result may be reached" on remand and cite *Pollinator Stewardship,* 806 F.3d at 532, as support. CFS Br. at 57-58. The *Pollinator Stewardship* court, however, applied the "serious possibility" standard described above and merely noted that, as a factual matter, "a different result may be reached" on remand in that case. 806 F.3d at 532. It did not revise the standard entirely as Petitioners suggest. *See id*. Thus, the *Allied-Signal* standard governs.

2. There is no serious deficiency in the FIFRA analysis.

Likewise, on the FIFRA claims, the Agency's plan to provide additional, record-based explanation for its FIFRA determination on remand is not a "serious deficiency" that mandates vacatur now. The Court's decision in *National Family Farm*, 960 F.3d 1120, constitutes an "intervening event[ ] outside of the agency's control." *SKF USA, Inc.*, 254 F.3d at 1027-28. When a new, relevant court decision is issued, "[r]emand under these circumstances [ ] comports with the general principle that an agency should be afforded the first word on how an intervening change in law affects an agency decision pending review." *See Nat'l Fuel Gas Supply Corp. v. FERC*, 899 F.2d 1244, 1249–50 (D.C. Cir. 1990). Thus, it is unquestionably proper—indeed, it is standard course—to allow the agency the opportunity to address the new decision in the first instance before the Court weighs in on record issues that can be elaborated after further agency review.

Further, as described *infra* at 40-51, the FIFRA record for the 2019 registration amendments ultimately supports the decision made here despite the fact that the rationale could be more detailed.

Therefore, there is "at least a serious possibility that the [EPA would] be able to substantiate its decision on remand." *Allied–Signal*, 988 F.2d at 151. Indeed, the Court found exactly this in the Enlist Duo litigation when it concluded that EPA did not adequately "consider harm to monarch butterflies caused by killing target milkweed." *Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d at 929. Such an error, the Court held, was "not serious." *Id*. And, "given the technical nature of EPA's [FIFRA] error," EPA will "likely be able to offer better reasoning" and "adopt the same rule on remand." *Id*.

That EPA could reach the same decision on remand here is reinforced by the fact that Petitioners' criticisms of EPA's analysis primarily concern the adequacy of the Agency's explanation, rather than an argument that the record evidence compels a contrary conclusion. *See infra* at 47-56. The latter argument would be difficult to mount given the high degree of deference afforded to agencies when interpreting scientific evidence. *See Lands Council v. McNair*, 537 F.3d 981, 988 (9th Cir. 2008) (en banc), *rev'd on other grounds by Winter v. NRDC*, 555 U.S. 7 (2008) (holding it "is not a proper role for a federal

appellate court" to "act as a panel of scientists that . . . chooses among scientific studies").

3. No procedural flaw warrants vacatur.

Nor does any alleged procedural flaw in the notice and comment process preceding issuance of the 2019 registration amendments necessitate vacatur. *See* Pollinator Stewardship Council (PSC) Br. at 21-22; CFS Br. at 37-39. FIFRA requires EPA to publish for comment "promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern." 7 U.S.C. § 136a(c)(4). EPA's regulation interpreting this provision, 40 C.F.R. § 152.102, provides that the "Agency will issue in the Federal Register a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use."

Here, EPA published notices of receipt and solicited comment for each of the uses that were approved in the 2019 registration amendments as required by FIFRA Section 3(c)(4). *See* July 2019 Decision (approving use on alfalfa, corn, cacao, grains (millet and oats),

pineapple, sorghum, teff, teosinte, tree plantations, citrus, cotton, cucurbits, soybeans, and strawberry), 1-PSCER-000001-000030. Specifically, the 2010 notice sought comment on use on citrus, cotton, cucurbits, soybeans, and strawberry. Notice of Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities, 75 Fed. Reg. at 80,491-92. The 2014 notice then sought comment on use on alfalfa, cacao, corn, grain (millet and oats), pineapple, sorghum, teff, and teosinte. Pesticide Product Registration; Receipt of Applications for New Uses, 79 Fed. Reg. at 22,964. And, the 2018 notice sought comment on use on tree plantations. Pesticide Product Registration; Receipt of Applications for New Uses, 83 Fed. Reg. at 51,679. EPA thus provided notice under 7 U.S.C. § 136a(c)(4) for each of the uses at issue in the 2019 registration amendments decision.

Petitioners ask for more and contend that the vacatur of the 2014 registration actions by the *Pollinator Stewardship Council* court extended not only to the uses at issue in those actions but reached back to the 2010 application, vacating that too. CFS Br. at 38. Thus, in their view, there was "no lawful predicate" for EPA's action on the 2019 registrations. *Id.* But, the *Pollinator Stewardship Council* court never

addressed the status of the *application* that Corteva had submitted on which the statutorily required notice was given—it addressed only the *registrations* that EPA had issued. *See* 806 F.3d at 533 (vacating the "registration of sulfoxaflor"). Accordingly, EPA acted reasonably in treating the 2010 application as still pending. And, while it is true that EPA took additional comment in 2016 on Corteva's new labels, this comment was under the Agency's transparency policy and not under 7 U.S.C. § 136a(c)(4). *See* 2016 Public Notice, EPA-HQ-OPP-2010-0889-0411 (May 17, 2016), 4-PSCER-000975.

Nothing in FIFRA mandates that EPA issue a new FIFRA section 3(c)(4) public notice, 7 U.S.C. § 136a(c)(4), in the absence of a new application. *See* PSC Br. at 20-21; CFS Br. at 38. That EPA treated the 2010 application as pending is confirmed by the fact that Corteva did not submit a new application for the uses at issue in the 2019 registration amendments.

Petitioners also argue that Corteva's submission of new Tier 2 field studies in 2018 qualified as "new data" under 7 U.S.C. § 136a(c)(4) and so necessitated a new round of comment. PSC Br. at 22. But, section 136a(c)(4) does not require new notice and comment any time

new data is submitted. The Agency's longstanding regulation that interprets section 136a(c)(4) provides that EPA must provide a "notice of receipt of each *application* for registration of a product that contains a new active ingredient or that proposes a new use." 40 C.F.R. § 152.102 (emphasis added). It does not require notice of the receipt of new data alone. In sum, the Agency has not interpreted the statute to mandate publication of a notice with opportunity for comment whenever an applicant submits a statement *or* new data. Further, because applicants often provide additional data to support existing applications, requiring public notice every time such data was received could make consideration of such applications much more burdensome.

Nor are the uses authorized by the 2019 registration amendments "new uses" triggering a new round of notice as Petitioners contend. CFS Br. at 38-39. Rather, as explained in detail above, each of the uses authorized by the 2019 registration amendments had already been subject to comment at earlier times. *See supra* at 34-38.

B. Vacatur of the 2019 registration amendments would be inequitable because it would cause environmental and economic harm.

The disruptive consequences from vacatur also weigh strongly in favor of leaving the challenged registration amendments in place on remand. *See Allied-Signal*, 988 F.2d at 150-51. In the absence of sulfoxaflor for the uses authorized by the 2019 registration amendments, farmers would likely use older, more toxic pesticides, causing both environmental harm and adverse economic consequences.

This Court has acknowledged that "when equity demands, the regulation can be left in place while the agency follows the necessary procedures" to correct its action. *See Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995). Indeed, even though the agency's error was significant in *Idaho Farm Bureau*, the Court did not vacate the action at issue because it could have had adverse environmental effects and wiped out a species of snail. *Id.* at 1405–06.

Likewise, in *California Communities*, the Court acknowledged that the rule was invalid but declined to vacate it, reasoning that vacatur would delay a needed power plant undermining the reliability of the power supply thereby causing economic hardship. 688 F.3d at 994

(declining to vacate invalid CAA rule where vacatur could cause more air pollution and "would also be economically disastrous"). Thus, the *Allied-Signal* analysis repeatedly endorsed by this Court requires the Court to undertake a broad balancing of the equities that examines both environmental *and* economic consequences of vacatur. *See id*. The D.C. Circuit's recent decision in *Standing Rock* reinforces this point, holding "economic disruption is properly considered" as part of the vacatur analysis. 985 F.3d at 1051. Here, both factors weigh in favor of leaving the registration amendments in place.

1. Vacatur could cause environmental harm.

a. The FIFRA record supports the conclusion that sulfoxaflor is less toxic than the most widely used alternatives.

EPA's July 2019 Decision supports the possibility that, if sulfoxaflor were unavailable for the uses authorized by the registration amendments, farmers would likely revert back to and increase their use of older, riskier substitutes. July 2019 Decision at 10, 1-PSCER-000010. Indeed, the July 2019 Decision acknowledges that sulfoxaflor has numerous benefits both to the environment and to the farmers that use it. Specifically, sulfoxaflor has a better ecological and human health

profile than the alternatives, and it performs as well or better than other registered insecticides by targeting hard to control pests. *Id.* at 10-21, 1-PSCER-000010-000021. Moreover, these alternatives generally have higher application rates and would likely require more frequent application as well because such pesticides "fail to control [pests] unless they are applied repeatedly to the crop and/or used in tank mix combinations." *Id.* at 11, 1-PSCER-000011; Hazard Comparison, at 1-2, 2-PSCER-000340-000341.

That sulfoxaflor, on the whole, provides environmental benefits as compared to the alternatives is made clear by sulfoxaflor's unique mode of action. Unlike broad spectrum insecticides that are available as alternatives, sulfoxaflor is less toxic to beneficial predatory insects that consume pest insects. EPA's Second Decl. ¶¶ 19-20; July 2019 Decision at 10-21, 1-PSCER-000010-000021; Corteva Resp. at 12, Doc. Id. 11887353; Corteva Resp., Ellsworth Decl. ¶ 13; Corteva Resp., Palumbo Decl. ¶ 96; Corteva Resp., Gore Decl. ¶ 25. Sulfoxaflor's chemistry allows growers to use integrated pest management techniques that depend on these beneficial predatory insects. Such techniques are environmentally and economically beneficial because they allow

growers to use less pesticide on their crops. *Id*. Thus, vacating the amendments here removes these and other benefits from the market, resulting in farmers reverting to and using the older, riskier pesticides, which sulfoxaflor was intended to replace. Such a loss could have widespread disruptive consequences.

The record here amply supports this conclusion. For example, EPA concluded that, as compared with the older alternatives most likely to be used by farmers, "sulfoxaflor has a better toxicity profile" for birds, terrestrial mammals, and fish as compared with the most widely used alternatives. July 2019 Decision at 21-22, 1-PSCER-000021-000022. The same holds true for bees as well. *Id*.

The United States Department of Agriculture's (USDA) declaration in support of this case reaches the same conclusion. USDA Decl. ¶ 7. It states that sulfoxaflor "interacts differently with the nicotinic acetylcholine receptor in ways that result in markedly less toxicity to bees." *Id*. In short, with "regard to bee safety, sulfoxaflor provides a relatively low-risk option for insect pest control near bloom while offering high efficacy against a number of sap-feeding pests." *Id*. ¶ 9.

Moreover, EPA determined that, as a general matter, sulfoxaflor was less acutely toxic, had lower application rates, and dissipated more quickly than the older, most widely used alternative pesticides. Usage data shows that these alternative pesticides would be employed on some 65 percent of the total area treated for the same target pests. *See* July 2019 Decision at 19, 1-PSCER-000019. USDA supports this finding, concluding that "[v]acatur of sulfoxaflor uses from 2019 is almost certain to force most growers to use alternatives that have comparatively worse pollinator risk profiles, and in some cases, at the expense of inferior pesticidal efficacy and crop safety." USDA Decl. ¶ 9. Corteva's declarations further confirm that growers will use these more harmful broad spectrum insecticides if sulfoxaflor is unavailable, and these substitutes could cause greater harm to listed species. Corteva Resp. at 10-15.

Not only is sulfoxaflor less acutely toxic for bees and other nontarget organisms than these alternatives, it is one of the most extensively studied pesticides with respect to bee exposure. In direct response to this Court's instruction in *Pollinator Stewardship Council*,

806 F.3d at 525, EPA extensively studied sulfoxaflor's impacts on honeybees through "Tier 2" studies.

Tier 2 studies include tunnel studies and colony-feeding studies and are intended to assess effects on the colony-level. *See* 2016 Guidance on Exposure and Effects Testing for Assessing Risks to Bees (2016 Guidance) at 16, 6-PSCER-001263, 6-PSCER-001278. Other Tier 2 studies include the field residue studies that quantify the amount of pesticide present in pollen and nectar of treated groups. 2016 Guidance at 21, 6-PSCER-001251. Tunnel studies are also referred to as "semi-field studies"; "they consist of bees placed in a tunnel enclosure and forced to feed on pesticide-treated crops . . . semi-field studies attempt to better capture the effect that a pesticide would have on the functioning of the entire colony." *Pollinator Stewardship Council*, 806 F. 3d at 525. And, in feeding studies, bees are fed a diet that consists solely of pesticide-treated diet. *Id*. Importantly, Tier 2 tunnel and feeding studies reflect the "high end" exposure to a pesticide because bees are "forced to forage only on the treated crop" or are fed solely a treated diet. *See* Risk Assessment at 82, 3-PSCER-00436; 2016 Guidance at 33, 6-PSCER-001263 at 001295.

The Tier 2 studies that are part of the record here supported the following conclusions:

- When bees were exposed to sulfoxaflor up to the maximum single application rate of 0.09 pounds per acre, there were only short term effects on individual honey bees for a period of about eight days or less following exposure. *See* Risk Assessment at 11, 3-PSCER-000365. But, these short-term effects "did not result in long-term impacts on colonies, including colony strength, brood production, and overwintering success." *Id*. at 77, 3-PSCER-000431.

- Two Tier 2 studies successfully examined "overwintering" or the ability of the colonies to survive through the winter season. These studies (one tunnel study and one feeding study) indicated that sulfoxaflor did not have adverse effects on colonies following overwintering. This is consistent with other similar acting pesticides where testing has found that that "effects on colonies post overwintering are not more sensitive than those expressed prior to overwintering." *Id*. at 12, 3-PSCER-000366.

- There was a "short persistence of sulfoxaflor in pollen and nectar" with typical half-life values being two days or less. *See* Risk Assessment at 88, 3-PSCER-000442; Review of Waiver Request, 2-PSCER-000345, 2-PSCER-000349 ("Given the short persistence of sulfoxaflor in pollen and nectar . . . the 10-d exposure period used in this assessment is considered adequate."). The short duration of "forager mortality and quantifiable residues of sulfoxaflor in pollen and nectar" of sulfoxaflor means that there was no evidence that sulfoxaflor would impact colonies over the winter. Risk Assessment at 82-83, 3-PSCER-000436-000437.

- The rapid dissipation rates also showed that "increased accumulation of sulfoxaflor in pollen and nectar is not

> expected after successive applications when considering the application intervals on the proposed labels." *Id*. at 86, 3-PSCER-000440.

Not only is sulfoxaflor generally less toxic to non-target insects, mammals, birds, and aquatic organisms, it also brings benefits to agricultural workers and others because it has low acute toxicity to humans. Specifically, sulfoxaflor has "low [acute] toxicity for the oral, dermal, eye and inhalation routes of exposure." 2016 Decision at 7, 4-PSCER-000693. Moreover, based on a complete database of toxicity and residue studies and the use of conservative health-protective assumptions in the exposure and risk assessments, EPA identified no chronic or subchronic human health risk estimates of concern for sulfoxaflor, including dietary, aggregate, and occupational scenarios. 2016 Decision at 4, 4-PSCER-000690 ("[a]ll of the risk estimates were well below the EPA's level of concern").

As discussed *supra*, *Center for Biological Diversity* concluded that such benefits made vacatur inequitable in that case. The D.C. Circuit reasoned that cyantraniliprole had "a more favorable toxicological profile compared to currently registered alternatives." 861 F.3d at 188-89. Thus, it was appropriate to leave the "registration order to remain

in effect until it is replaced by an order [compliant with the ESA which] will maintain 'enhanced protection of the environmental values covered by'" the registration. *Id.* at 189 (citation omitted). The same logic applies here and weighs strongly against vacatur.[6]

b. The claimed errors with the FIFRA analysis do not undermine EPA's analysis of the ecological effects of the pesticide.

Petitioners counter that alleged errors in EPA's FIFRA analysis mean that the 2019 registration amendments necessarily cause environmental harm. Petitioners' primary arguments are that (i) EPA should have required additional bee studies beyond the Tier 2 studies conducted (PSC Br. at 24, 32-33); (ii) EPA failed to grapple with the third-party economic costs of the amendments (PSC Br. at 34-36); (iii) EPA's analysis of alternative pesticides was inadequate (CFS Br. at

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[6] CFS Petitioners argue that *Center for Biological Diversity*'s analysis of vacatur is distinguishable on the grounds that cyantraniliprole was formally designated a "reduced risk" pesticide, while sulfoxaflor was not. *See* CFS Br. at 62. But this designation did not expressly weigh in the Court's analysis of the equities. 861 F.3d at 188. Rather, the Court's rested on EPA's findings of relative risk that are analogous to those of sulfoxaflor. *See id.*

40-44); and (iv) the Agency's analysis of honeybees does not apply to other species of bees (CFS Br. at 47-49). None of these arguments has merit.

i. Petitioners assert that EPA lacked sufficient data for its decision because additional "Tier 3" studies were required beyond the "Tier 2" studies that Corteva submitted to characterize the risk to bee colonies. PSC Br. at 24-33. Petitioners assert that the Tier 2 studies indicate a "potential for colony level risk" and that Tier 3 studies were required because EPA's guidance generally requires them in these circumstances. PSC Br. at 23-33.

But, Tier 3 studies have important limitations that EPA weighed in its decision to waive submission of them here. Specifically, in Tier 3 studies (also called "full field" studies) bees are permitted to freely forage and often travel distances up to several miles from the hive. 2016 Guidance at 18, 6-PSCER-001287. In such studies, pesticide treated crops typically reflect only a small fraction of the bees' diet. *Id.*

Accordingly, far from a "routine regulatory requirement" as Petitioners characterize Tier 3 studies, PSC Br. at 33, EPA's regulation makes clear that some data requirements like those for Tier 3 studies

"will not always be appropriate for every product," and so authorize waiver of this data. 40 C.F.R. § 158.45(a). Specifically, the regulation provides that EPA may determine whether studies like Tier 3 studies are required on a case by case basis after making a scientific assessment of whether they would "be useful in the Agency's evaluation of the risks or benefits of the product." *Id.*

In that regard, EPA's 2016 guidance makes clear that whether such studies are useful turns on an assessment of "risk management objectives." 2016 Guidance at 3, 17, 6-PSCER-001266, 6-PSCER-001279 ("the decision to recommend additional data should be based on . . . whether other scientifically relevant information may be available to address uncertainties."). The guidance also emphasizes that, in some cases, Tier 3 studies have limited utility because "there has been difficulty in controlling the extent to which free-foraging bees utilize the treated crop." *Id.* at 25, 6-PSCER-001287.

Because bees in Tier 2 studies are fed only a pesticide-treated diet, the results of the Tier 2 studies here reflect exposures that are higher than that expected from real world conditions. Risk Assessment at 82, 3-PSCER-000436. In other words, Tier 2 studies provide a more

conservative estimate of the impacts of exposure to sulfoxaflor than Tier 3 studies. Thus the colony-level risks identified from scientifically sound Tier 3 studies are expected to be lower than those identified using Tier 2 studies.

Here, no further studies were necessary to address bees' ability to survive through the winter (the "overwintering" issue) because the data showed only short-term effects on bees, typically lasting less than two weeks. Risk Assessment at 76, 3-PSCER-000430. While some of the Tier 2 studies designed to directly analyze colonies' overwintering did not generate reliable results due to issues with control groups, two other Tier 2 studies did successfully assess overwintering. These two studies demonstrated that overwintering effects were less sensitive than those encountered before overwintering. Risk Assessment at 80-83, 3-PSCER-000434-000437. Thus although EPA concluded "a potential for colony level risk is indicated" for some groups, given the large amount of Tier 2 data, the conservative assumptions regarding exposures in these studies, and the difficulties with Tier 3 studies, EPA rationally determined that submission of Tier 3 studies would not add "significant

value and clarity" to the risk management decision. Waiver Request at 5, 2-PSCER-000349; July 2019 Decision at 8-9, PSCER000008-000009.

Taken together, EPA reasonably concluded that the findings from Tier 2 studies assessing honeybees under more sensitive conditions were adequate to assess the risks to honeybees overall, and so additional studies, such as Tier 3 studies, could therefore be waived. *See* Waiver Request, 2-PSCER-000346. *See also* 2016 Guidance at 32, 6-PSCER-001294 (Tier 2 feeding studies like the one conducted here "can provide a means of determining exposure thresholds below which the likelihood of adverse effects on colonies may be low."). This waiver is fully consistent with the *Pollinator Stewardship Council* court's instruction to develop "sufficient data documenting the risk to bees," because EPA concluded the Tier 2 data was sufficient. 806 F.3d at 531-32.

ii. CFS Petitioners next contend that EPA failed to grapple with the third-party social and economic consequences to beekeepers of issuing the 2019 registration amendments. PSC Br. at 33-36. As support, they rely on this Court's decision in *National Family Farm Coalition v. EPA*, 960 F.3d 1120. The issue presented here differs

significantly from the issues in *National Family Farm Coalition*. Nonetheless, EPA could have been more explicit in the 2019 decision documents in weighing impacts on beekeepers.

Even so, the record here supports a finding that the 2019 registration amendments met the statutory standard. For example, EPA recognized that "honey bees are the most important managed pollinators in the U.S." and bring "between $15 billion and $20 billion in economic value to agriculture each year." July 2019 Decision at 21, 1-PSCER-000021. EPA further concluded that this important benefit supported registration of sulfoxaflor, which EPA found posed less risk to bees than widely used alternative pesticides.

Further, in 2016, the Agency engaged with beekeepers who shared that "RT25" data on pesticide persistence are "one of the most important pieces of information for the protection of honey bees." 2016 Response to Public Comments at 3, 4-PSCER000700. RT25 data are data that look to the time that a pesticide remains acutely toxic and results in 25 percent mortality. *Id*. For sulfoxaflor, the RT25 value (determined to be less than three days) could not be precisely calculated because the toxicity was too low. *Id*. EPA concluded that the low

residual toxicity and fast dissipation of sulfoxaflor "should reassure beekeepers . . . that sulfoxaflor is preferential to other toxic insecticides that don't degrade as rapidly." *Id.* at 4, 4-PSCER-000701.

Thus, at that time, EPA found that "the significant value of pollination services warrants the registration of crop protection pesticides [like sulfoxaflor] that improve the existing risk situation for bees." July 2019 Decision at 22, 1-PSCER-000022. Taking into consideration that the most widely used alternatives are generally more acutely toxic to bees than sulfoxaflor, the facts on the ground support this conclusion.

EPA's consideration of the importance of the beekeeping industry along with the record discussion of the RT25 data—the very data beekeepers have earlier claimed were critical to assessing the risks to pollinators—supports the conclusion that the Agency will be able to substantiate its FIFRA decision on remand. In short, EPA can make clear on remand that because sulfoxaflor poses less harm to bees, it benefits beekeepers.

iii. Petitioners also argue that EPA's comparison of sulfoxaflor with six alternative pesticides was flawed because some other

alternative pesticides are less toxic, and so the analysis was not representative of all available alternatives. CFS Br. at 39-46. But EPA's analysis of alternative pesticides looked to the six most widely used broad-spectrum insecticides currently registered for the proposed uses of sulfoxaflor (lambda-cyhalothrin, bifenthrin, chlorpyrifos, acephate, dicrotophos, and imidacloprid). These alternatives are used on some 65 percent of the acres treated for the same pests as sulfoxaflor. *See* Benefits Assessments at 20, 4-PSCER-000660. While some less toxic pesticides may be available for some uses as CFS Petitioners suggest (CFS Br. at 41-42), EPA cannot control which of the authorized pesticides a grower will select if sulfoxaflor were unavailable. As such, it was reasonable to compare sulfoxaflor to this set of popular alternatives.

And, of the most widely used pesticides for similar pests, sulfoxaflor "has a much shorter RT25 [toxicity] value than the other products suggesting that it dissipates from treated foliage in the field faster than the registered alternatives." July 2019 Decision at 21, 1-PSCER-000021. In addition to its comparatively low toxicity and quick dissipation, sulfoxaflor also has a lower application rate. Hazard

Comparison at 1-2, 2-PSCER-000340-000341. As discussed above, these alternative pesticides would likely require more frequent applications because they "fail to control unless they are applied repeatedly to the crop and/or used in tank mix combinations"—sometimes requiring ten or more applications per year. July 2019 Decision at 11, 1-PSCER-000011.[7]

iv. Lastly, CFS Petitioners argue that EPA's studies on honeybees do not shed light on sulfoxaflor's impacts on other types of bees. CFS Br. at 47-49. EPA's guidance makes clear, however, that the "primary process [for assessment] relies on honey bee data as a surrogate for both *Apis* and non-*Apis* bees." 2014 Guidance for Assessing Pesticide Risks to

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[7] Petitioners also fault EPA for examining only the "comparative toxicity" of these alternative pesticides. CFS Br. at 43. In their view, EPA should have analyzed the "potential exposure and resulting risks of harm to species" from the alternatives. *Id.* But such a comparison is hardly necessary given that the record demonstrates that there are generally both higher application rates and more frequent applications of the alternatives, suggesting increased exposure. *See supra* at 54-55. Moreover, as to bees, the record makes clear that EPA has far less data on these alternative pesticides than it does for sulfoxaflor—sulfoxaflor is among the most extensively studied pesticides for these uses. And, the RT25 data that EPA did analyze are certainly relevant to ecological impacts. Beekeepers themselves suggested EPA should consider this data when evaluating the relative toxicity of pesticides. *See supra* at 52-53.

Bees (2014 Guidance) at 2, 6-PSCER-001308. The guidance continues that "studies of the colony can be used to represent effects to honey bees themselves and as a surrogate for other social bees." *Id*. Thus, EPA's longstanding scientific judgment is that studies on honeybees *are* relevant to the risks posed to other bees. This conclusion was affirmed by independent peer review. *See* White Paper in Support of the Proposed Risk Assessment Process for Bees, submitted to the FIFRA Scientific Advisory Panel for Review and Comment) (FIFRA SAP) at 14, 6-PSCER-001201, 001215. And, there's nothing in additional Tier 3 studies of honeybees (which again looks to colonies foraging freely over a small portion of sulfoxaflor treated crops) that would address CFS Petitioners' concerns with solitary species.

Thus, Petitioners' arguments regarding the flaws in the FIFRA process do not undermine EPA's findings that sulfoxaflor poses less harm to species than the alternatives, and so do not weigh in favor of vacatur.

2. Vacatur would cause economic hardship.

Vacatur of the 2019 amendments would also cause economic harm to growers, and this harm is properly considered as part of the weighing

of equities. Sulfoxaflor is indisputably more effective at targeting harmful pests than the alternatives. July 2019 Decision at 12-18; 1-PSCER-000012-000018. Untreated, the piercing and sucking insects that sulfoxaflor targets can infect crops with bacteria and viruses, which "can result in complete loss of a crop, can significantly impact yield or can reduce the quality of the harvested commodity." *Id*. at 13, 1-PSCER-000013. Corteva further describes that vacatur of the 2019 amendments would cause severe adverse economic consequences for growers, requiring them to acquire other, less-effective pesticides. Corteva Resp. at 18-20.

In response to EPA's motion for remand, Petitioners nevertheless asserted that growers could use other pesticides if sulfoxaflor were unavailable, and so loss is not certain. CFS Resp. at 20-22, Doc. Id. No. 1197898. But the record shows that those alternatives are generally less effective than sulfoxaflor and are more expensive because they often must be applied more frequently. *See* July 2019 Decision at 12-18, 1-PSCER-000012-000018; Corteva Resp. at 20.

This record evidence is consistent with USDA's declaration submitted in support of this brief. That declaration makes clear that

vacating the 2019 amendments could have a disastrous effect on growers across the country for these reasons: it "will create disruptions to numerous agricultural sectors, including field crops (e.g., cotton, soybeans, sorghum) and specialty crops (e.g., alfalfa seed, fruits, and vegetables), by increasing the likelihood of yield quality losses (for some crops) and compelling the use of different products and possibly different types and amounts of pesticides." USDA Decl. ¶ 6.

A number of crops could suffer very serious losses—referred to as Tier 1 losses—if these registrations were vacated, meaning that vacatur would lead to "20% overall yield loss, 20% reduction in gross revenue, or 50% reduction in net revenue." *Id.* ¶ 11. Crops with Tier 1 losses include cotton, sorghum, alfalfa grown for seed, and strawberries. *Id.*

For example, for growers of cotton alone, vacating these uses of sulfoxaflor could cause losses that range from $2.6 million to $84 million per year, because sulfoxaflor is particularly effective in countering infestation from *Lygus*, a plant-feeding insect. USDA Decl. ¶ 17. Further, the alternative pesticides available to counter *Lygus* "pose challenges for resistance management and efficacy." *Id.* ¶ 16. Cotton growers also use sulfoxaflor to address "unmanaged aphids and

whiteflies," which can result in "sticky cotton"—sap secretions which reduce the cotton's value. *Id.* ¶ 19. Such sticky cotton is approximately 7 percent to 11 percent less valuable than cotton without this infirmity. *Id.*

Sorghum growers would also likely suffer losses because sulfoxaflor is one of two pesticides that can be used to counter sugarcane aphids, which unmanaged can "yield losses of 50% or more." *Id.* ¶ 21. Only one other pesticide besides sulfoxaflor—flupyradifurone—is available for control of sugarcane aphids. *Id.* ¶ 22. Overreliance on this pesticide will lead to insect resistance. *Id.* And, if yield losses reach 50%, the economic losses "could be as high as $83 million." *Id.* ¶ 23.

Vacatur of the 2019 registration amendments would also adversely impact strawberry growers because strawberries also are vulnerable to *Lygus* infestation. *Id.* ¶ 27. For citrus, too, sulfoxaflor provides unique benefits. Like with cotton, "some of the most common broad-spectrum alternatives used to target [pests] can result in killing of beneficial predatory insects" on citrus. *Id.* ¶ 31. Similar adverse effects will be suffered by growers of cucurbits, corn, millet, oats, pineapple, soybean, and other growers as well. *Id.* ¶ 39.

The economic harm from vacatur is further reinforced by the fact that the absence of sulfoxaflor for the uses authorized by the 2019 amendments "could shrink the number of options for pest managers, raising the potential for the evolution of resistance to the remaining insecticide choices." *Id.* ¶ 42. And, "[o]nce resistance is established, all pesticides in that class become less effective, or entirely ineffective . . . leading to additive and cumulative economic hardships for growers." *Id.*

The record evidence, along with the declarations submitted on remedy here, thus makes clear that widespread economic losses would result from vacatur. These economic consequences, along with the adverse environmental consequences from vacatur, compellingly show that the disruptive consequences from vacatur weigh strongly in favor of leaving the 2019 registration amendments in place on remand.

CONCLUSION

For the foregoing reasons, the Court should remand the 2019 registration amendments to EPA without vacatur.

Dated: April 15, 2021

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STATEMENT OF RELATED CASES

Under Ninth Circuit Local Rule 28-2.6, I hereby certify that there are no related cases pending in the Ninth Circuit.

/s/ *Meghan E. Greenfield*
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Counsel for Respondents

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) this document contains 11,519 words.

2. This document complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font.

/s/ *Meghan E. Greenfield*
MEGHAN E. GREENFIELD

Counsel for Respondents

ADDENDUM

EPA'S SECOND DECLARATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY, ET AL., *Petitioners*, v. ANDREW WHEELER, ET AL., *Respondents*, DOW AGROSCIENCES LLC, *Respondent-Intervenor*.	)	**Case No. 19-72109**
POLLINATOR STEWARDSHIP COUNCIL, ET AL., *Petitioners*, v. ANDREW WHEELER, ET AL., *Respondents*, DOW AGROSCIENCES LLC, *Respondent-Intervenor*.	)	**Case No. 19-72280**

DECLARATION OF JAN MATUSZKO IN SUPPORT OF ANSWERING BRIEF

I. Background

A. Introduction.

1. I, Jan Matuszko, declare under penalty of perjury that the following statements are true and correct to the best of my knowledge and belief and that they are based upon my personal knowledge, information contained in the records of the United States Environmental Protection Agency (EPA), or information supplied to me by EPA employees under my supervision and in other EPA offices. *See* 28 U.S.C. § 1746.

2. I am the Acting Director of the Environmental Fate and Effects Division (EFED). I have held this position since July 2020. Prior to becoming the Acting Director for EFED, I served as the Deputy Director of EFED from April 2019 to July 2020. Prior to becoming the Deputy Director of EFED, I served as a Branch Chief in the Engineering and Analysis Division in the Office of Science and Technology in the Office of Water. I have a B.S. in Chemical Engineering and an M.S. in Civil Engineering (Environmental) from Virginia Polytechnic Institute and State University.

3. EFED is the division within the Office of Pesticide Programs (OPP) at EPA tasked with assessing the environmental fate and ecological risk of both new and existing conventional pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In this context, "environmental fate" is the life cycle of a chemical (such as a pesticide) after its release into the environment. Part of this responsibility includes evaluating potential effects to species listed as threatened or endangered (listed species) and/or their designated critical habitats under the

Endangered Species Act (ESA) and preparing biological evaluations that EPA provides to the National Marine Fisheries Service (NMFS) and/or the United States Fish and Wildlife Service (FWS) (collectively Services).

4. In my role as Deputy Division Director and Acting Division Director of EFED, I have been involved in the evaluation and validation of data submitted under FIFRA to assess ecological risks, including risks to federally listed and non-listed species. Additionally, I have been involved in the development of ESA Biological Evaluations (BEs) and in the oversight and allocation of division resources necessary to conduct the environmental fate and ecological risk assessments of pesticides necessary for EPA to address its obligations under both FIFRA and the ESA. This includes the preparation of nationwide developmental draft and/or draft BEs, using the Revised Methods process discussed in paragraphs 14 - 20 of my declaration on EPA's Motion for a Voluntary Remand, on methomyl, carbaryl, atrazine, propazine, simazine and glyphosate to address settlement obligations as noted in paragraph 24 below, and the preparation of the ESA analysis for the 2020 dicamba registration, using the Overview Document process discussed in more detail in paragraph 15 below.

5. This second declaration is filed in support of EPA's Answering Brief in response to the challenged July 13, 2019 registration orders for sulfoxaflor. The purpose of this second declaration is to provide, after further consideration by me and my staff, an updated assessment of the reasonable amount of time I project that OPP will require to make an effects determination, and, where necessary, initiate informal consultation or prepare a BE and initiate formal consultation. The effects determination will be guided by the principles in the Overview Document process discussed in paragraph 15 below and the Revised Method process discussed in my first declaration in paragraphs 14-20.

B. FIFRA and ESA Background.

6. **FIFRA.** FIFRA, 7 U.S.C. §§ 136-136y, governs the sale, distribution, and use of pesticides. Its principal purpose is to protect human health and the environment from unreasonable adverse effects associated with pesticides. FIFRA generally prohibits the distribution and sale of a pesticide product unless it is "registered" by EPA. *See* 7 U.S.C. § 136a(a). A registration is issued to a particular registrant, with a particular formula, packaging, and labeling and provides rights only to the registrant.

7. FIFRA authorizes EPA to register pesticides under section 3(c)(5), 7 U.S.C. § 136a(c)(5), or FIFRA section 3(c)(7), 7 U.S.C. § 136a(c)(7). The challenged sulfoxaflor registrations were issued under the authority of FIFRA section 3(c)(5). To grant a registration under FIFRA section 3(c)(5), EPA must determine, among other things, that use of the pesticide "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). Pesticide registrations are periodically reviewed as part of the registration review program under FIFRA section 3(g). 7 U.S.C. § 136a(g).

8. **ESA.** The ESA section 7(a)(2) requires that Federal agencies ensure, in consultation with the Services, that the actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of listed species or destroy or adversely modify designated critical habitat. For OPP, an "action" includes certain pesticide registration or re-evaluation decisions, including certain amendments to a registration under FIFRA section 3(c)(5), like the one in this case. OPP conducts an evaluation of the areas where a pesticide is/can be used, whether there are listed species and/or designated critical habitat in the areas of use, and whether the use "may affect" listed species and/or designated critical habitat. This evaluation includes reviewing current or draft

proposed pesticide labeling as well as toxicity, exposure, and usage information, where available.

9. OPP's evaluation used to make an effects determination includes reviews of the best available scientific and commercial information, relevant biological studies, and literature reviews. This information may vary depending on the breadth of the action and the risk profile of the pesticide. Additionally, the methodology OPP uses to make its effects determination also may vary. OPP's determination for each action are based on what is reasonable and protective of listed species and designated critical habitats.

10. If OPP determines that an action "may affect," but is not likely to adversely affect listed species and/or designated critical habitat, then OPP initiates informal consultation with the Service(s). *See* 50 C.F.R. § 402.13. If OPP determines that an action "may affect" and is likely to adversely affect listed species and/or designated critical habitat, then OPP initiates formal consultation under the Services' ESA implementing regulations by submitting a BE to the Service(s). *See* 50 C.F.R. §§ 402.14(c) and 402.40(b).

11. A BE is a comprehensive document that presents to the Services OPP's assessment of the manner in which the FIFRA registration action may affect a listed species and/or designated critical habitat, along with detailed descriptions of the species, habitats, and geographic areas that may be affected.

12. **Coordinated Interagency Approach for ESA Implementation for Pesticides.** As addressed in my first declaration, over many years, EPA has been working with multiple federal agencies to establish scientifically valid frameworks for assessing whether there could be potential impacts to listed species and/or designated critical habitats from its FIFRA registration actions.

13. Specifically, EPA worked with the federal agencies to create a framework for the process of pesticide consultation under ESA, ultimately turning to the National Academy of Sciences (NAS) to help resolve methodological differences among the agencies. The NAS reported its findings in 2013.[1] In 2014, Congress, who was aware of this background and dialogue, ordered EPA to report on consultation progress [2] and streamline integration of ESA and FIFRA procedures. PL 113-79, § 10013, February 7, 2014, 128 Stat 649.[3] EPA began several pilot BEs using the 2015 Interim Methods[4] as initial steps towards implementing the NAS recommendations. Subsequently, EPA, the U.S. Department of Interior (DOI), and the U.S. Department of Commerce (DOC)

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[1] National Research Council of the National Academies, Assessing Risks to Endangered and Threatened Species from Pesticides (2013), available at https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides.

[2] Interim Report to Congress on Endangered Species Act Implementation in Pesticide Evaluation Programs, from U.S. Environmental Protection Agency, U.S. Fish and Wildlife Service, National Marine Fisheries Service, and the U.S. Department of Agriculture (2014) ("2014 Interagency Interim Report to Congress"), available at https://www.epa.gov/sites/production/files/2015-07/documents/esareporttocongress.pdf.

[3] As noted in the 2014 Interagency Interim Report to Congress, "[t]he intent expressed in this provision is to keep the Agencies moving forward as they develop processes that will make it possible for EPA to comply with the ESA in a manner that maximizes resources and minimizes delays of pesticide registration and reregistration decisions under the [FIFRA]." *Id.,* at 1.

[4] U.S. Environmental Protection Agency, Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report (2015), available at https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

signed a Memorandum of Agreement (MOA) establishing an interagency working group (IWG) to include these and other federal agencies tasked with providing recommendations to the agencies' leadership on improving the ESA consultation process for pesticides.[5] On December 20, 2018, President Trump signed into law the Agriculture Improvement Act of 2018 (2018 Farm Bill) (Public Law 115-334). The 2018 Farm Bill codified this IWG and the MOA. As provided in section 10115 of the 2018 Farm Bill and section 3(c)(11) of the FIFRA as amended, 7 U.S.C. § 136a(c)(11), Congress required a report to be delivered to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate not later than one year after the date of enactment of the 2018 Farm Bill. The intent of the IWG is to improve the consultation process required under ESA section 7 for pesticide registration and registration review. The required report to Congress was provided on December 20, 2019[6] and an update to that 2019 Interagency Report was provided in June 2020[7].

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[5] Memorandum of Agreement between the Environmental Protection Agency, the Department of the Interior, and the Department of Commerce on Establishment of an Interagency Working Group to Coordinate Endangered Species Act Consultations for Pesticide Registrations and Registration Review (January 31, 2018), available at https://archive.epa.gov/epa/sites/production/files/2018-02/documents/esa-fifra_moa_1.31.18.pdf.

[6] Report to Congress on Improving the Consultation Process Required Under Section 7 of the Endangered Species Act for Pesticide Registration and Registration Review, from U.S. Environmental Protection Agency, U.S. Fish and Wildlife Service, National Marine Fisheries Service, U.S. Department of Agriculture, and Council on Environmental Quality (2019) ("2019 Interagency Report to Congress"), available at https://www.epa.gov/sites/production/files/2020-01/documents/esa-report-12.20.19.pdf.

[7] Progress Report to Congress on Improving the Consultation Process Required Under Section 7 of the Endangered Species Act for Pesticide

14. As explained in my first declaration, as discussed in Interagency Reports to Congress,[8] EPA has taken a three-pronged strategy intended to identify and improve a process for addressing potential effects to listed species and/or designated critical habitat.

    a. First, as discussed more fully in my first declaration at paragraph 13.a., EPA is consulting with the Services on certain FIFRA section 3(g) registration review actions. EPA initially used Interim Methods that incorporate the recommendations in the NAS Report as part of a pilot process. The Interim Methods were vetted through the pilot process and, through this iterative interagency consultation process, EPA updated these methods. These Revised Methods, released in March 2020, have been used to conduct some nationwide BEs in the registration review process. The Revised Methods are discussed in more detail in my first declaration and not repeated here.

    b. Second, for uses on pesticide-tolerant crops, EPA has been using methods set out in the Overview Document to make an ESA effects determination.[9] As discussed in more detail

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Registration and Registration Review, from the U.S. Environmental Protection Agency, U.S. Fish and Wildlife Service, National Marine Fisheries Service, U.S. Department of Agriculture, and Council on Environmental Quality (2020), available at https://www.epa.gov/sites/production/files/2020-06/documents/second-esa-progress-reportfinal.pdf.

[8] 2014 Interagency Interim Report to Congress, at 21-22; 2019 Report to Congress, at 12-13.

[9] Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency, Endangered and Threatened Species Effects Determinations, Office of Prevention, Pesticides and Toxic Substances Office of Pesticide Programs (January 23, 2004), available at

below in paragraph 15, the Overview Document details OPP's general risk assessment approach for pesticides and its specific application to listed species and designated critical habitat.

c. Third, for new pesticide active ingredients, EPA has been comparing their toxicity with that of registered alternative pesticides. This information allows risk managers and stakeholders to compare the relative inherent toxicity of the proposed new active ingredient with available alternatives. EPA believes that older, currently registered chemicals (in the current registration review process) typically have the potential to pose greater risks to listed species and/or designated critical habitat than do the newer, generally lower-risk pesticides being introduced into the marketplace today, and that the comparative hazard information illustrates this point. The additional hazard information contributes to information sharing, promotes communication with the public, and improves relationships and trust with stakeholders. Implementing this approach when issuing the 2016 registrations for sulfoxaflor meant, as explained in my first declaration at paragraph13.c., that EPA did not make an ESA effects determination prior to granting those registrations. Neither did EPA make an ESA effects determination prior to granting the amendments to those registrations that are the subject of this challenge.

15. **Use of the Overview Document Process to Make an Effects Determination.** As noted in paragraph 14.b., the Overview Document process is generally used to evaluate potential risks to listed species from exposure to pesticides and has been used for ESA purposes when assessing new uses involving crops that are tolerant to that pesticide. Use of the Overview Document applies

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https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf.

the same principles as the Revised Method to determine whether a use of a pesticide "may affect" a listed species or designated critical habitat and contains the following basic steps:

a. **Use Characterization:** EPA evaluates the labeling and describes the labeled use sites, application methods, and application directions that are specified in the labeling. EPA also describes important factors that inform any spatial limitations associated with labeled uses or other practical limitations that inform EPA's assumptions made in the absence of clear and specific label directions.

b. **Overlap Analysis:** EPA scientists compare spatial data sets that describe potential labeled use sites and species ranges to determine what, if any, species may be exposed to a pesticide that is used on that site. The analysis may account for off-site movement of the pesticide from processes such as spray drift. An overlap analysis conducted for one pesticide may or may not be applicable to another pesticide even if the use patterns are equivalent. There are also chemical-specific parameters that are incorporated into an overlap analysis, which means the results may not be directly comparable across different pesticides.

c. **Toxicity Evaluation:** EPA risk assessors evaluate the best available toxicity data and define toxicity reference values that are appropriate for an endangered species risk assessment. Toxicity reference values are defined for acute (short-term) and chronic (long-term) exposures.

d. **Environmental Fate Evaluation**: EPA scientists evaluate and describe the environmental fate data submitted to support pesticide registrations that describe a pesticide's persistence, mobility, and tendency to partition to different environmental compartments such as soil, air, and water. EPA also calculates environmental half-lives and

partitioning coefficients that are used to set parameters for exposure models.

e. **Exposure Evaluation:** Based on the labeled use patterns and directions described in the "Use Characterization" and environmental half-lives and portioning coefficients derived in the "Environmental Fate Evaluation," EPA selects appropriate and protective modelling inputs to allow for an estimation of pesticide concentrations in aquatic and terrestrial habitats.

f. **Risk Characterization**: EPA compares potential exposure concentrations to sensitive (i.e., protective) toxicity reference values to calculate a risk quotient (RQ). An RQ is an estimated exposure concentration (EEC) divided by the appropriate toxicity value, which may be a No Observable Adverse Effect Concentration (NOAEC) or an exposure level that is associated with a particular magnitude of effect (e.g., lethal dose to 50% of the test organisms or concentration associated with a 25% or 50% effect). RQs are calculated for various taxonomic groups including fish, birds, mammals, aquatic and terrestrial invertebrates, and aquatic and terrestrial plants. If the risk quotient exceeds an endangered species level of concern (LOC) for a taxa, then there is a potential concern for that taxonomic group including listed species within that group. Concern levels associated with each taxonomic group for acute and chronic effects are specified in the Overview Document. The risk characterization also includes an in-depth description of the pesticide's exposure and toxicity profile as it relates to the potential for and likelihood of an adverse effect occurring. EPA considers both direct toxicological effects in addition to potential effects to a species' food sources or habitat.

g. **Effects Determination and Species-Specific Refinements**: EPA makes a "no effect" determination for

species that are not located on or near potential use sites or where RQs are below the endangered species LOCs relevant for that taxonomic group. An initial "may affect" determination is made for species that may be co-located with a potential use site AND either an acute or chronic RQ exceeds the appropriate LOC for the relevant taxonomic group. When a "may affect" determination is made, EPA scientists may consider additional factors relevant to a particular species' biology and habitat to determine if there are factors that preclude potential effects. For example, if, after making a "may affect" determination, EPA determines that exposure is highly unlikely to occur or if considerations of the species' biology, diet, or habitat characteristics would result in risk levels that are below LOCs, then it could make a "no effect" determination. However, if EPA determines that there is a potential effect, but the effect is either insignificant, discountable, or wholly beneficial, then EPA makes a "not likely to adversely affect" (NLAA) determination and initiates informal consultation to seek the Service(s) concurrence. Otherwise, it will make a "likely to adversely affect" (LAA) determination and prepare the BE and initiate formal consultation if an LAA determination is made. Consultation is not required if EPA makes a "no effect" determination.

16. The Ninth Circuit Court of Appeals determined that the Overview Document process "applies the correct legal standard" for determining whether the use of the pesticide in that case may affect a listed species or designated critical habitat. *National Family Farm Coalition v. EPA*, 966 F.3d 893, 924 (9th Cir. 2020). For the reasons noted in paragraph 23, EPA believes using an approach that is guided by the principles in the Overview Document and the Revised Methods processes is a reasonable and appropriate approach to efficiently address EPA's ESA requirements in this case.

C. Sulfoxaflor Registration Background.

17. On July 12, 2019, EPA granted unconditional amendments under FIFRA section 3(c)(5) to registrations containing the active ingredient sulfoxaflor, two end use products identified as Transform WG (EPA Registration No. 62719-625) and Closer SC (EPA Registration No. 62719-623), and the Sulfoxaflor Technical (EPA Registration No. 62719-63). The action granted new uses for use of this chemical on alfalfa, corn, cacao, grains (millet, oats), pineapple, sorghum, teff, teosinte and tree plantations. The action also adds the following crops back on the product labels: citrus, cotton, cucurbits, soybeans, and strawberry. Finally, certain restrictions that were included on the October 2016 registrations were removed. Decision Memorandum Supporting Registration Decision for New Uses of the Active Ingredient Sulfoxaflor on Alfalfa, Cacao, Citrus, Corn, Cotton, Cucurbits, Grains, Pineapple, Sorghum, Soybeans, Strawberries, and Tree Plantations and Amendments to the Label (July 12, 2019) (July 2019 Decision).

18. As part of the decision to grant the amendments, EPA evaluated the human health and ecological effects from the proposed amendments. *See* Sulfoxaflor: Ecological Risk Assessment for Section 3 Registration for Various Proposed New Uses, DP449891 (July 10, 2019); July 2019 Decision, at 7-9. EPA also prepared a hazard comparison, comparing the toxicity of sulfoxaflor with alternatives pesticides. *See* Sulfoxaflor: Hazard Comparison for Several Alternative Insecticides, (July 10, 2019) (demonstrating the relative safety of sulfoxaflor compared to other insecticides within the same market).

19. As noted in paragraph 14.c., EPA did not make an ESA effects determination for sulfoxaflor. As EPA explained above and in the July 2019 Decision, EPA is currently focusing most of its resources for assessing potential impacts to listed species on its registration review program for currently registered pesticides. Older pesticides generally present a greater degree of risk to listed

species than most new chemistries such as sulfoxaflor, and, therefore, it is environmentally preferable in most circumstances for EPA to assess the potential impacts of older, existing pesticides sooner in the process than newer pesticides that are designed to compete with the older, more risky alternatives. EPA explained in the decision document that this is especially true for sulfoxaflor, where the alternatives include older chemistries. July 2019 Decision, at 10.

20. The overall general benefits of sulfoxaflor are summarized in the July 2019 decision and focused on six critical points. Sulfoxaflor: is a new mode of action; performs as well or better than registered insecticides; targets economically important or hard to control pests; is highly selective to pests, and less disruptive to beneficial insects and other arthropods; is compatible with Integrated Pest Management (IPM) and Insect Resistance Management (IRM) programs; has a better ecological and human health profile than the alternatives. *Id.,* at 10 – 21.

II. EPA's Requested Remand

21. As laid out in the Answering Brief, EPA is requesting this Court to remand the challenged 2019 registration orders to allow the Agency to take the necessary actions to explain in additional detail its rationale in light of *National Family Farm Coalition v. EPA*, 960 F.3d 1120, 1127 (9th Cir. 2020) and to make an effects determination under the ESA, and, if required, initiate consultation.
22. After EPA issued the registration amendments, this Court decided *National Family Farm Coalition v. EPA*, 960 F.3d 1120 (9th Cir. 2020). In light of this decision, the Agency recognizes that its rationale could have been clearer. The Agency intends to explain in additional detail its rationale on this issue while the remand process is ongoing. During that time, EPA can also explain its interpretation of 7 U.S.C. § 136a(c)(4) and supply additional detail as to the treatment of the sulfoxaflor applications.

23. In addition, I and my staff have been considering the most appropriate and efficient approach to address the acknowledged ESA deficiency for sulfoxaflor. In light of the results of the FIFRA risk assessment which showed potential risk from use of sulfoxaflor only for limited taxa, the favorable toxicity of sulfoxaflor as compared with that of registered alternative pesticides, and the lack of actual usage data for the new uses registered in 2019 given that the market is relatively new, EPA now believes that an approach that is guided by the principles in the Overview Document and the Revised Methods is a reasonable and protective approach for making an effects determination. Because protections on species will likely be implemented substantially faster using this approach, OPP intends to conduct an effects determination using this approach, consistent with the timing specified in paragraph 24.

24. As noted in paragraph 26 of my first declaration in support of EPA's Motion for a Voluntary Remand, EPA has settlement agreements in place for completing several final BEs, and there is pending litigation which might result in further obligations with similar steps for draft and final BEs.

    Taking into account the BE activities specified in that declaration, and using the process discussed above in paragraph 23, I estimate that by Summer 2021, EPA can begin conducting an effects determination for sulfoxaflor. If preparation of a BE document is not necessary, EPA could complete the assessment in the Spring of 2022. If informal consultation is necessary, then I expect EPA would be able to initiate that process in the Spring of 2022. And if formal consultation is necessary, then I expect that EPA would be able to initiate that process after the Spring of 2022.

F. Conclusion.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

/s/ Jan Matuszko April 8, 2021
Jan Matuszko
Acting Director
Environmental Fate and Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

USDA'S DECLARATION

DECLARATION OF DR. CLAYTON T. MYERS

I, Dr. Clayton T. Myers, hereby declare as follows:

1. I, Dr. Clayton T. Myers, declare that the following statements are true and correct to the best of my knowledge and belief, and are based on my personal knowledge or on my review of information supplied by my current employees and other United States Department of Agriculture (USDA) employees, including records and information from sources outside of the USDA, all of which are cited in this declaration.

2. I am currently serving as the Acting Director of the Office of Pest Management Policy (OPMP) of the USDA and have been in this position since March 21, 2021. I work under the direction of the Office of the Secretary of Agriculture in the Office of the Chief Economist and serve as the Department's focal point for pesticide issues and all issues related to pest management, including biotechnology. Pursuant to the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7653(f)), and as reauthorized in section 7307 of the Agriculture Improvement Act of 2018, I am responsible for (1) the development and coordination of Department policy on pest management and pesticides; (2) the coordination of activities and services of the Department, including research, extension, and education activities, regarding the development, availability, and use of economically and environmentally sound pest management tools and practices; (3) assisting other agencies of the Department in fulfilling their responsibilities related to pest management or pesticides under the Food Quality Protection Act of 1996 (Public Law 104-170; 110 Stat. 1489), the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), and other applicable laws; (4) performing other functions as required by law or by request of the Secretary; (5) ensuring coordination of interagency activities with EPA and FDA and other Federal and state agencies; and (6) consulting with agricultural producers that may be affected by pest management or pesticide-related activities or actions of the Department or other agencies.

3. I am responsible for coordinating Departmental responses to the EPA Administrator under section 136d of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136d(b), on, among other issues, the impact of cancellation or suspension of registrations on production

and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

4. Prior to and concurrently with my service as Acting USDA-OPMP Director, I have served as staff entomologist in USDA-OPMP. I also worked for over 9 years in EPA's Office of Pesticide Programs prior to joining USDA-OPMP in 2018, and as a post-doctoral researcher in insect pest management with USDA's Agricultural Research Service. I received a Ph.D. in entomology from Penn State University and a B.A. degree in biology from West Virginia University.

5. I, together with other employees of the United States Department of Agriculture, have conducted an analysis of the potential impacts of vacating the 2019 registered uses for sulfoxaflor proposed by Plaintiffs in this matter. Plaintiffs' request that the Court vacate the registration orders involving these 2019 approved new uses is functionally identical to and would have the same effects as cancellation of these uses.

6. With respect to the 2019 registered uses of sulfoxaflor (i.e., on alfalfa, corn, cacao, grains [millet, oats], pineapple, sorghum, teff, teosinte, tree plantations, citrus, cotton, cucurbits, soybeans, and strawberry), I provide an analysis below of the impacts of vacatur of each 2019 use on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, consistent with the Department's statutorily prescribed role under 7 U.S.C. 136d(b) in commenting on any proceeding to cancel a pesticide registration. The vacatur and remand of these registrations approved in 2019 will create disruptions to numerous agricultural sectors, including field crops (e.g., cotton, soybeans, sorghum) and specialty crops (e.g., alfalfa seed, fruits, and vegetables), by increasing the likelihood of yield quality losses (for some crops) and compelling the use of different products and possibly different types and amounts of pesticides.

7. In general, the development and delivery of newer, safer, and effective chemistries like sulfoxaflor provides growers with the tools they need to provide our nation with food security. Sulfoxaflor is a sulfoxamine insecticide, classified by the Insecticide Resistance Action Committee (IRAC) as a Group 4C nicotinic acetylcholine receptor competitive modulator.[1] While this group is similar to neonicotinoid insecticides (classified as IRAC 4A), sulfoxaflor

[1] IRAC, 2020. Insecticide Resistance Action Committee Mode of Action Classification, online module, updated March, 2020. https://www.irac-online.org/modes-of-action/. Accessed March 23, 2021.

interacts differently with the nicotinic acetylcholine receptor in ways that result in markedly less toxicity to bees, and no observed cross-resistance[2] with neonicotinoids. This makes sulfoxaflor an important component of Integrated Pest Management[3] (IPM) programs. We concur with this conclusion stated in EPA's sulfoxaflor decision document:

> *"... sulfoxaflor has low impact on lady beetle larvae and other beneficial insects. Protecting biocontrol efforts by using a compound like sulfoxaflor that has less impact on beneficial predatory beetles and mites, and parasitic wasps, helps to reduce treatment needs for later season damaging pests such as armyworms, spider mites and aphids."*

8. Sulfoxaflor also serves as an important rotation option with alternative chemistries for resistance management (discussed in further detail later). For many uses, sulfoxaflor provides control similar to that of the nitroguanidine class of neonicotinoid insecticides, for which registration review is ongoing at EPA and may result in new mitigation measures.

9. With specific regard to bee safety, sulfoxaflor provides a relatively low-risk option for insect pest control near bloom while offering high efficacy against a number of sap-feeding pests. Few if any insecticides pose zero risks to bees, but sulfoxaflor has a comparative bee safety profile that is more preferable compared to many of the most common alternative insecticide classes used for management of the same spectrum of target pests as sulfoxaflor. These chemical alternatives include synthetic pyrethroids, organophosphates, carbamates, neonicotinoids, etc. Vacatur of sulfoxaflor uses from 2019 is almost certain to force most growers to use alternatives that have comparatively worse pollinator risk profiles, and in some cases, at the expense of inferior pesticidal efficacy and crop safety.

10. It is also critical to note that pesticide research, development, and registration is incredibly expensive and time-intensive, with Nauen et al. (2015) stating that "[b]etween 1990 and 2010, the costs for the development of a new insecticide increased by more than 100% to approximately $US 250 million, and the average development and registration process takes almost 10 years."[4] Discussion follows for a number of key crops and pests of concern which

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[2] Cross-resistance occurs when resistance to one pesticide confers resistance to another pesticide, even where the pest has not been exposed to the latter product.

[3] Integrated pest management (IPM) is a science-based, decision-making process that identifies and reduces risks from pests by developing complementary pest management related strategies.

[4] Nauen, R., et al., 2015. Flupyradifurone: a brief profile of a new butenolide insecticide, Pest Management Science, 71(6): 850-862.

underscore the value of sulfoxaflor to U.S. agriculture. Our analysis and discussion is tiered by the relative benefits of sulfoxaflor to agricultural crops and the likely impacts to growers from losing access to these uses.

11. Tier 1 includes a group of crops for which EPA previously granted Section 18 Emergency Exemptions prior to granting unconditional Section 3 registrations, which is indicative of the critical importance of sulfoxaflor for pest management needs. These crops include cotton, sorghum, alfalfa grown for seed, and strawberries. For each of these uses, EPA has made a prior finding that untenable pest losses and non-routine emergency situations necessitated the use of sulfoxaflor. EPA's criteria for Emergency Exemption include a tiered framework for assessing this economic loss and can include any of the following: 20% overall yield loss, 20% reduction in gross revenue, or 50% reduction in net revenue. Since EPA approved these exemptions and made positive determinations of a significant economic loss, our analysis assumes that one or more of these estimated loss scenarios on these crops would re-occur if sulfoxaflor use is prohibited.

12. OPMP's analysis of Tier 1 uses registered in 2019 considers a scenario in which the severity of pest infestations is sufficiently high to reduce average yields by twenty percent, in line with EPA's aforementioned criteria for defining a significant economic loss. The analysis assumes that there are not good chemical substitutes for sulfoxaflor available, either due to pest pressure (and growers using up their seasonal maximum limits of other pesticide options) or due to pesticide resistance. Moreover, these analyses only account for direct impacts of a sulfoxaflor ban on yields and pesticide costs. They do not account for the labor or equipment costs associated with pesticide applications, the possibility that decreases in expected yields could decrease the use of fertilizers (and other non-damage abating inputs), the long-term benefits associated with sulfoxaflor's use in resistance management plans, or industry-level macro-economic impacts. For these reasons, OPMP's estimates are likely to be conservative and understate the full impacts of vacatur.

13. Tier 2 crops include uses registered in 2019 for which viable alternatives exist for sulfoxaflor, but pesticide substitution costs and problematic pest management impacts—such as beneficial insect toxicity and pesticide resistance risks—would negatively affect growers. These crops include citrus and cucurbits. OPMP's analysis of Tier 2 crops considers two scenarios for each crop: 1) a scenario in which growers substitute the most commonly used, target-pest

specific, synthetic alternative, and 2) a scenario in which growers substitute a commonly used, but more expensive alternative. As in OPMP's analyses of Tier 1 crops, the analyses of Tier 2 crops only account for the direct impacts of sulfoxaflor vacatur on pesticide costs. For this reason, OPMP regards these estimate ranges as conservative and likely to understate the full impacts of vacatur.

14. All other 2019 registered uses that are challenged are addressed in the Tier 3 category. For these uses, viable substitution options are either available and affordable for many growers (e.g., corn, oats, soybean) or there was not adequate information available for USDA to assess impacts (e.g., cacao, millet, pineapple, teosinte, teff, and tree plantations). However, at a minimum, the vacatur of sulfoxaflor for these uses would be expected to negatively impact resistance management, discussed later, and this would be especially true for minor/small acreage crops without many registered insecticide tools available. These tiered analyses are provided below on a crop by crop basis.

Tier 1: Cotton

15. Sulfoxaflor is widely recognized as one of the most effective insecticides available for control of the tarnished plant bug[5,6] (*Lygus lineolaris*) and the Western tarnished plant bug (*L. hesperus*), hereafter collectively referred to as *'Lygus.' Lygus* bugs directly damage cotton squares, flowers and bolls via feeding with piercing/sucking mouthparts, leading to both direct yield impacts, and reduction in cotton boll quality[7]. *Lygus* bugs occur as pests in essentially all cotton growing regions of the United States and have emerged as the number one pest complex of cotton nationally. Sulfoxaflor also controls cotton aphids and whiteflies potentially transmitting virus diseases but is primarily a tool of choice for *Lygus* management. It is also notable that some of the common broad-spectrum alternatives used to target *Lygus,* discussed below, can result in killing of beneficial predatory insects and sometimes flare aphids, in which case sulfoxaflor has an additive pest management benefit for aphids (discussed later), and for

[5]Stewart, et al., 2021. 2021 Insect Control Recommendations for Field Crops: Cotton, Soybean, Field Corn, Sorghum, Wheat and Pasture. University of Tennessee Extension Publication, PB 1768. https://extension.tennessee.edu/publications/documents/pb1768.pdf. Accessed March 24, 2021.

[6]Crow, W., 2021. Mississippi State University Extension Publication 2471. 2021 Insect Control Guide for Agronomic Crops. http://extension.msstate.edu/sites/default/files/publications/publications/P2471_web.pdf. Accessed March 24, 2021.

[7]UC-IPM, 2015. Western Tarnished Plant Bug: Cotton. University of California Statewide IPM Program Extension Publication. http://ipm.ucanr.edu/PMG/r114301611.html#:~:text=the%20bigeyed%20bug.-,Damage,and%20drop%20from%20the%20plant. Accessed March 24, 2021.

lack of aphid flaring when used against *Lygus.* Finally, at this time there is no evidence of cross-resistance between sulfoxaflor and other chemical classes, making sulfoxaflor an important resistance management/rotation option.

16. The most common sulfoxaflor alternatives recommended for *Lygus* management include foliar sprays of organophosphates, carbamates, neonicotinoids, pyrethroids, flonicamid, indoxacarb, and novaluron. While these alternatives have varying effectiveness, many of the broad-spectrum insecticide classes pose challenges for resistance management and efficacy, and sulfoxaflor is the most effective choice for control by growers. Sustained and concentrated outbreaks of *Lygus* and the incidents of growers utilizing their seasonal maximum allowability of pesticide alternatives led EPA to determine that *Lygus* in cotton warranted emergency use exemptions for sulfoxaflor on cotton in 12 states over multiple years, prior to the Agency's granting of unconditional registration.

17. An analysis of proprietary data[8] suggests that approximately 5 million acres of domestically produced cotton were treated with sulfoxaflor nationally from 2012 to 2019. Generally, cotton farmers who used sulfoxaflor applied it more than once per year. The percent of the cotton crop treated with sulfoxaflor ranged from less than 1 percent (in 2012) to over 10 percent (in 2019), over the course of the eight years analyzed. We find that national losses from a vacatur of sulfoxaflor in cotton production could range from $2.6 million to approximately $84 million per year (in 2019 dollars) from *Lygus* impacts alone, depending on the severity and extent of the pest infestation, the average cotton yield, the price of cotton, and the price of sulfoxaflor.

18. Further, and as briefly noted earlier, cotton farmers also use sulfoxaflor to manage cotton aphids (*Aphis gossypii*) and whiteflies (*Bemisia spp.*). Whiteflies attacking cotton also vector over 100 different plant viruses resulting in significant crop losses.[9] While impacts of the vacatur of sulfoxaflor for cotton aphids and whiteflies may be a comparatively smaller concern than *Lygus*, the importance for aphids and whiteflies is still significant. Damage caused by these pests varies seasonally with the growth stage of the plant, often causing stunting of plant growth and

[8]Agricultural Market Research Data (AMRD). 2012-2019. Data collected and sold by a private market research firm.

[9] Roditakis, E., M. et al., 2017. Flupyradifurone effectively manages whitefly *Bemisia tabaci* MED (Hemiptera: Aleyrodidae) and tomato yellow leaf curl virus in tomato, Pest Management Science, 73(8).

accumulations of honeydew leading to development of sooty mold, decreased boll size, and boll shedding.

19. One of the major repercussions in cotton production from unmanaged aphids and whiteflies is contamination of cotton lint with honeydew secretions, a sugar-rich sticky liquid, secreted by the insects as they feed on plant sap.[10] These secretions result in what is called "sticky cotton," which literally leaves the cotton lint sticky with honeydew. The economic impacts from sticky cotton can be significant and lead to growers receiving discounted prices for the lower grade fiber. USDA-OPMP previously conducted an extensive analysis of the economic repercussions from sticky cotton in 2018.[11] In summary, it is estimated that sticky cotton results in approximately a 7% to 11% price discount received by the grower, which would lead to a 22% to 36% decline in net revenue assuming recent average cotton prices, yields, and operating costs. Sticky cotton can also create substantial costs for downstream processors, such as cotton gins and textile mills. This is a result of the stickiness causing costly stoppage, slowing down processing, and increasing the need for blade and saw replacements.[11,12,13]

20. Further, if significant sticky cotton issues are identified by a mill, they often will choose to source cotton from a different growing region or require discounts on all cotton originating from that region, given its poor reputation for providing sticky cotton, as these are mobile insects that are able to quickly infest neighboring farms.[14] Due to the social damage aspect of this issue, it is in the interest of all growers to keep this problem in check. This further necessitates the need for a variety of treatment options to be available to growers, while also ensuring they are not too costly to implement. Insecticide resistance among this group of pests is already widely documented and reported across multiple insecticide modes of action.[15] Decreased availability of effective alternative treatment options, such as sulfoxaflor, and increased treatment costs could drive growers to make suboptimal treatments, which ultimately could result in pest outbreaks,

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[10] Bancroft, J.S; R. Hutmacher, L. Godfrey, P.B. Goodell, M. McGuire, P. Funk, and S. Wright. 2006. Comparison of Sticky Cotton Indices and Sugar Composition. Journal of Cotton Science, Arthropod Management. 10:97-104.

[11] USDA Office of Pest Management Policy (OPMP). 2018. Comments on the Preliminary Ecological Risk Assessments for the Registration Review of Imidacloprid, EPA-HQ-OPP-2008-0844; Thiamethoxam, EPA-HQ-OPP-2011-0581; Dinotefuran, EPA-HQ-OPP-2011-0920; and Clothianidin, EPA-HQ-OPP-2011-0865-0251. Docket ID: EPA-HQ-OPP-2008-0844-1600.

[12] Floeck, H., and D. Ethridge. 1997. A descriptive analysis of sticky cotton and textile manufacturers' costs. Cotton Economic Research Report CER-97-22. Texas Tech University, Department of Agricultural and Applied Economics, Lubbock, TX.

[13] Khalifa, H. and O. I. Gameel. 1982. Control of cotton stickiness through breeding cultivars resistant to white fly (Bemisia tabaci) IAEA.

[14] Hequet, E.F. and A. Noureddine. 2006. Sticky Cotton: Measurements and Fiber Processing. Texas Tech University Press.

[15] Arthropod Pesticide Resistance Database, 2021. https://www.pesticideresistance.org/display.php?page=species&arId=218. Accessed March 30, 2021.

evolution of new resistance biotypes, and/or the exacerbation of existing resistance to insecticide products that remain available to growers. Most often, the development of insect resistance leads to more pesticide applications by the grower to control the pest of concern.

Tier 1: Sorghum

21. Sulfoxaflor is widely recognized as one of only two effective foliar insecticides available for control of the invasive sugarcane aphid (*Melanaphis sacchari*) on sorghum[16,17] grown for grain. Sugarcane aphid, a commonly observed pest of sugarcane, is believed to have developed a new biotype that can attack and thrive on sorghum. Detections of sugarcane aphids in sorghum fields were first reported in 2013 in Northeast Texas and Louisiana[18] and have since spread to numerous sorghum producing states. Sugarcane aphid feeding causes discoloration and direct damage to leaves. But more importantly, honeydew secretions from aphids accumulate on plants and this leads to infections of sooty mold, and sticky plant material that precludes efficient mechanical harvest of grain. Honeydew coated leaves and stalks will stick to the inner parts of machinery and lead to clogging of combines. This leads to inordinate downtime for cleaning and also the gummy sticky leaves can prevent grain from separating efficiently from the stalk. Harvest prevention is a primary yield loss driver as some fields become completely unusable after unmanaged aphid outbreaks and yield losses of 50% or more have been observed.

22. Researchers have tried to identify and encourage planting of sorghum varieties that are resistant to sugarcane aphids. However, under high pest pressure, the use of insecticides is necessary regardless of variety choice, and effective foliar spray options are limited. Nationwide consensus of IPM experts is that only sulfoxaflor and flupyradifurone[19] are viable options for foliar control of sugarcane aphids. While neonicotinoid seed treatments are registered for use on sorghum and can provide some early season efficacy after crop emergence, this protection is short-lived. Loss of either sulfoxaflor or flupyradifurone as foliar tools would preclude growers'

[16]Stewart, et al., 2021. 2021 Insect Control Recommendations for Field Crops: Cotton, Soybean, Field Corn, Sorghum, Wheat and Pasture. University of Tennessee Extension Publication, PB 1768. https://extension.tennessee.edu/publications/documents/pb1768.pdf. Accessed March 24, 2021.

[17]Crow, W., 2021. Mississippi State University Extension Publication 2471. 2021 Insect Control Guide for Agronomic Crops. http://extension.msstate.edu/sites/default/files/publications/publications/P2471_web.pdf. Accessed March 24, 2021.

[18] Villanueva et al., 2014. Sugarcane Aphid: A New Pest of Sorghum. Texas A&M AgriLife Extension Publication, ENTO-035. http://counties.agrilife.org/hidalgo/files/2014/02/ENTO-035.pdf. Accessed March 24, 2021.

[19] IPM Centers, 2020. Pest Management Strategic Plans for Sorghum in North Carolina, South Carolina, and Virginia. https://ipmdata.ipmcenters.org/source_report.cfm?sourceid=1449&view=yes. Accessed March 24, 2021.

ability to control sugarcane aphid over the course of a growing season. Beyond direct yield and quality losses to sorghum, over-reliance on only one tool will inevitably result in untenable selection pressure for insecticide resistance and lead to compounding impacts over time.

23. An analysis of proprietary data suggests that approximately 2 million acres of domestically produced sorghum were treated with sulfoxaflor, nationally, from 2012 to 2019. Generally, sorghum farmers who applied sulfoxaflor applied it once per year. The percent of the sorghum crop treated with sulfoxaflor ranged from over 1 percent (in 2019) to approximately 7 percent (in 2014), over the course of the eight years analyzed. We find that national losses from a ban on sulfoxaflor in sorghum production could range from approximately $0 to $30 million per year (in 2019 dollars) from aphid impacts alone, depending on the severity and extent of the pest infestation, the average sorghum yield, the price of sorghum, and the price of sulfoxaflor. If yield losses were 50% (as some anecdotal accounts from affected states suggest) the national annual losses from a vacatur could be as high as $83 million.

Tier 1: Alfalfa Grown for Seed

24. Sulfoxaflor is widely recognized as one of the most effective insecticides available for control of the *Lygus* in alfalfa grown for seed. *Lygus* bugs directly damage buds, flowers, and developing seeds via feeding with piercing/sucking mouthparts, leading to direct seed yield impacts.[20] *Lygus* bugs occur as pests in essentially all alfalfa seed growing regions of the Western U.S. and are the primary pest management challenge for alfalfa seed growers. Sulfoxaflor is also effective at controlling aphids in alfalfa, which are an important pest for both seed and forage growers of alfalfa.

25. While a number of insecticides are effective at controlling *Lygus*, only sulfoxaflor and flonicamid offer adequate bee safety for making critical applications to control outbreaks during bloom.[21] The use of these bee-safe materials can significantly reduce the need to make pre-bloom and post-bloom applications of more toxic, broad-spectrum insecticides such as

[20] Walsh, 2020. Pests of Alfalfa Grown for Seed. Pacific Northwest Handbooks for Field Crop Pest Management. Collaborative Extension Publication from Oregon State University, Washington State University, and the University of Idaho. https://pnwhandbooks.org/sites/pnwhandbooks/files/insect/chapterpdf/insect20-legume-grass-field-seed.pdf. Accessed March 24, 2021.

[21] IPM Centers, 2017. Pest Management Strategic Plan—With Special Focus on Pollinator Protection for Alfalfa Seed Production in the Western United States. https://ipmdata.ipmcenters.org/documents/pmsps/AlfalfaSeedPMSP_FINAL.pdf. Accessed March 24, 2021.

organophosphates, carbamates, pyrethroids, neonicotinoids, etc. Alfalfa seed growers are particularly dependent upon bees for crop pollination and take great care to not expose honey bees (or in the Pacific Northwest, alkali or leafcutter bees) to problematic insecticides beyond what is critically necessary. This makes sulfoxaflor a particularly valuable option for *Lygus* control. This situation led EPA to determine that *Lygus* in alfalfa grown for seed warranted emergency use exemptions for sulfoxaflor in Oregon and Washington, prior to the Agency's granting of unconditional registration. For all alfalfa seed producing states, even where emergency exemption was not requested, sulfoxaflor's mode of action is highly valuable for resistance management. Over-reliance on other insecticide tools is likely to result in untenable selection pressure for insecticide resistance and lead to compounding impacts over time.

26. An analysis of proprietary data suggests that approximately 8 thousand acres of domestically produced alfalfa were treated with sulfoxaflor, nationally, from 2012 to 2019. Generally, alfalfa farmers who applied sulfoxaflor applied it more than once per year. We find that the direct effect of a ban on sulfoxaflor in the production of alfalfa for seed could range from approximately $0 to approximately $2 million per year (in 2019 dollars), depending on the severity and extent of the pest infestation, the average alfalfa yield, the price of alfalfa, and the price of sulfoxaflor. Notably, this estimate does not account for indirect impacts on producers who grow alfalfa for feed or forage (i.e., alfalfa seed buyers). Decreases in the availability of non-proprietary alfalfa seed could adversely impact some alfalfa producers, with subsequent downstream impacts possible on feed/forage costs for livestock producers. Further, our analysis, while using national pesticide usage data, focused only on the seed sector of alfalfa production. For forage growers using sulfoxaflor to control aphids and other pests on alfalfa, substitution and resistance management impacts are possible and would add to our projected impact estimates above.

Tier 1: Strawberries

27. Sulfoxaflor is one of the most effective insecticides available for control of *Lygus* in strawberries. *Lygus* bugs directly damage flowers and fruit seeds via feeding with piercing/sucking mouthparts that damages individual seeds. This feeding leads to cat-facing fruit

damage and misshaped fruit that renders damaged berries unmarketable.[22] Because strawberries are almost always harvested directly into retail containers in the field (e.g., plastic clamshells), hand-sorting of fruit is done by workers, who drop misshaped berries onto the ground, resulting in a direct yield loss.

28. While a number of insecticides are effective at controlling *Lygus*, sulfoxaflor efficacy is particularly notable and it also has resistance management value for producers needing multiple applications of insecticides over a long growing season (with rotations needed). This situation led EPA to determine that *Lygus* in strawberry warranted emergency use exemptions for sulfoxaflor in California, prior to the Agency's granting of unconditional registration. While EPA granted Section 18 exemption for use of sulfoxaflor on California strawberries in late 2018 and the 2019 growing season, this exemption was not renewed in 2020 and the current status of sulfoxaflor availability on California strawberries is unclear. Therefore, our estimates for grower impacts from 2019 may not reflect current conditions as closely based on these prior criteria. For other strawberry producing states, even where emergency exemption was not requested, sulfoxaflor's mode of action is highly valuable for resistance management of *Lygus* as well as other pests like aphids. Over-reliance on other insecticide tools is likely to result in untenable selection pressure for insecticide resistance and lead to compounding impacts over time.

29. An analysis of data collected by the USDA's National Agricultural Statistics Service (NASS) suggests that approximately 7 thousand acres of domestically produced strawberries were treated with sulfoxaflor, in California, in 2019. Generally, strawberry farmers who applied sulfoxaflor applied it twice per year. The percent of the strawberry crop treated with sulfoxaflor was approximately 20 percent (in 2019). We find that losses from a vacatur would be approximately $88.2 million per year (in 2019 dollars) in California, depending on the severity and extent of the pest infestation, the average strawberry yield, the price of strawberries, and the price of sulfoxaflor. Because our analysis of strawberries was not national in scale, it is also likely that strawberry producer impacts in other areas of the country, including use of sulfoxaflor to target pests other than *Lygus*, would add to our estimate above.

[22] UC-IPM, 2018. Western Tarnished Plant Bugs: Strawberry. University of California Strawberry Pest Management Guidelines. University of California Statewide IPM Program. https://www2.ipm.ucanr.edu/agriculture/strawberry/lygus-bug/#:~:text=Lygus%20bugs%20are%20one%20of,area%20surrounding%20the%20feeding%20site. Accessed March 24, 2020.

Tier 2: Citrus

30. In citrus production, sulfoxaflor is one of many insecticide options that are important in the control of aphids and the plant viruses they vector, and of the Asian Citrus Psyllid (ACP) (*Diaphorina citri* Kuwayama), the vector of the Huanglongbing (HLB) bacterium (or citrus greening disease) that has had serious adverse impacts on citrus production in Florida and has been detected in citrus production regions in Arizona, Texas, and California. A citrus tree infected by HLB does not recover and to date there are no effective, registered therapeutic options available to growers. As noted by Court et al. (2017),[23] "Florida citrus bearing grove area declined from over 750,000 acres in the year 2000 to around 435,000 acres in 2016, a reduction of 42 percent, while production volume utilized declined by 68 percent, primarily due to losses from citrus greening disease, which entered the state in 2005…[t]he economic impacts of citrus greening (HLB) over the period 2012-13 through 2015-16 were estimated at a loss of -$4.393 billion in cumulative industry output, or an annual average of $1,098 million, while total value added and employment contributions decreased by an average of $658 million and 7,945 full time and part-time jobs respectively over this period." Given that HLB spreads rapidly, the ability to treat immediately and retain the ability for growers to respond quickly to psyllid outbreaks is critical for supporting the long-term viability of the citrus industry, not only in Florida but across the entire United States. Tree removal is the only effective way to manage HLB infections in citrus groves, but this is economically untenable over time without disease eradication.

31. Similar to what was discussed for cotton, sulfoxaflor also controls aphids, scales, and mealybugs in citrus, in addition to its use as part of a suite of available tools for ACP management. Similar to the cotton situation, some of the most common broad-spectrum alternatives used to target psyllid adults can result in killing of beneficial predatory insects and sometimes flare aphids, in which case sulfoxaflor has an additive pest management benefit for aphids and for lack of aphid flaring when used against psyllids.

32. Scientists have been investigating the most efficacious use patterns for sulfoxaflor and other insecticide active ingredients as part of a season-long management program to control up to fourteen generations of citrus psyllid per year. Sulfoxaflor is a tool that also helps manage the

[23] Court, C.D, A.W. Hodges, M. Rahmani, T.H. Spreen. 2017. Economic Contributions of the Florida Citrus Industry in 2015-16. University of Florida, Economic Impact Analysis Program.

evolution of the psyllid's resistance to crop protection products. University of Florida scientists report that a minimum of five chemistries with five different modes of action are necessary to manage the evolution of resistance of the citrus psyllid, year-long.[24,25] The need for newer, safer, and effective chemistries such as sulfoxaflor remains critical for ACP management. The loss of sulfoxaflor from this program is likely to be a significant detriment to citrus production.

33. An analysis of proprietary data suggests that sulfoxaflor use varies by citrus commodity. For instance, though sulfoxaflor was not applied to lemons from 2012 to 2019, approximately 30% of grapefruit acres and 11% of orange acres were treated with sulfoxaflor in 2015. Grapefruit farmers who applied sulfoxaflor tended to apply it more than once, while orange growers tended to apply it only once per growing season. Notably, there was not any sulfoxaflor usage from 2016-2018, since use was prohibited in those years.

34. There are chemical alternatives to sulfoxaflor in citrus production. Therefore, a vacatur is unlikely to result in short-term yield losses for most domestic citrus growers. However, because some alternatives are more expensive than sulfoxaflor, a vacatur of sulfoxaflor could increase growers' pest control costs. We find that national losses from a ban on sulfoxaflor in citrus production could increase growers' costs by anywhere from 0 to $2.6 million per year (in 2019 dollars), from aphid, leaf-miner, and ACP impacts alone, depending on the severity of the pest infestations, the price of sulfoxaflor, the price of chemical alternatives, and growers' choices about which alternatives to use.

35. Specific quantitative loss impacts are difficult to estimate for the loss of any single insecticide active ingredient in citrus given the need for intensive, season-long management programs that target both nymphs and adult stages of ACP and other pests at different times in what is essentially a year-round growing season. It is further difficult to get a broader impact estimate on sulfoxaflor, due to its efficacy and utility against these other insect pests of citrus, discussed previously, which also presents a complex scenario for chemical substitution, efficacy, costs, and resistance management. However, because ACP and HLB pose such a serious and existential threat to American citrus production, USDA contends that growers are in need of a full and robust insecticide toolbox for season-long adaptability, flexibility, and responsiveness to

24 Chen, X.D., and L.L. Stelinski. 2017b. Resistance management for Asian citrus psyllid, *Diaphorina citri* Kuwayama, in Florida. *Insects*. 8, 103; doi:10.3390/insects8030103.

25 Chen, X.D., T.A. Gill, M. Ashfaq, K.S. Pelz-Stelinski, and L.L. Stelinski. 2018. Resistance to commonly used insecticides in Asian citrus psyllid: stability and relationship to gene expression. *Journal of Applied Entomology*. 142: 967-977.

resistance management and efficacy concerns. Amidst this complexity, the high bee safety of sulfoxaflor is an added benefit compared to many broad-spectrum chemical alternatives that target adults, such as organophosphates, carbamates, pyrethroids, etc.

Tier 2: Cucurbits

36. Sulfoxaflor is one of several insecticide active ingredients that are useful against aphids and whiteflies in commercial cucurbit production, which includes pumpkins, squash, cucumbers, and melons. Particularly for areas where aphids and whiteflies vector viral diseases, control of these pests is a critical pest management challenge for producers. The perennial presence of whiteflies and aphids makes continued availability of multiple active ingredients critical for cucurbit vegetable and melon producers.

37. Despite advances made in IPM for cucurbits, soil applications of neonicotinoids (at full rate) at transplanting remain critically important for pest management, regardless of sulfoxaflor availability. However, the additional need for in-season foliar applications bee-safe materials, such as sulfoxaflor, is also critical to address outbreaks at times when plants are blooming, and bees are present. Melon growers in California and Arizona especially require aggressive in-season interventions due to a newly introduced virus, Cucurbit Yellows Stunting Disorder Virus (CYSDV), which is vectored by these pests. Similar to what was discussed for other crops, sulfoxaflor's mode of action is highly valuable for resistance management. Because foliar applications of neonicotinoids are commonly avoided to protect bees, the utility of sulfoxaflor for in-season interventions is important for bee safety. Further, over-reliance on other insecticide tools is likely to result in untenable selection pressure for insecticide resistance and lead to compounding impacts over time.

38. An analysis of proprietary data suggests that sulfoxaflor use varies by cucurbit commodity. For instance, though sulfoxaflor was not applied to cucumbers from 2012 to 2019, approximately 1% of watermelon acres and 10% of cantaloupe acres were treated with sulfoxaflor in 2015. Both watermelon and cantaloupe farmers who applied sulfoxaflor tended to apply it once per growing season. There was not any sulfoxaflor usage from 2016-2018, since use was prohibited in those years. We find that national losses from a ban on sulfoxaflor in cucurbit production could increase growers' costs by anywhere from 0 to $100 thousand per year (in 2019 dollars), from aphid and whitefly impacts alone, depending on the severity of the pest

infestations, the price of sulfoxaflor, the price of chemical alternatives, and growers' choices about which alternatives to use. Because of the disease-vectoring nature of these pests, additional impacts are likely if inadequate control of aphids and/or whiteflies leads to increased incidence of viral infection in fields.

Tier 3 Crops and General Impacts of Vacatur on Other Uses Registered in 2019

39. If the registration of sulfoxaflor were vacated on other uses registered in 2019 (e.g., on cacao, corn, millet, oats, pineapple, soybeans, teff, teosinte, tree plantations, etc.) the utility of the remaining products on the market could decline if the absence of sulfoxaflor drives the development of resistance of targeted pests to those remaining products/active ingredients. Agricultural producers need access to crop protection materials—especially those with new Modes of Action—to support their season-long IPM programs to help control pests, while also providing options for pesticide rotation to manage the evolution of pest resistance.[26] The problem of pesticide-resistant pests is of increasing importance in all agricultural systems, ranging from major field crop to low acreage specialty crops. Ultimately, the registration of new active ingredients and associated products—such as for the active ingredients for which the plaintiffs seek vacatur—is a critical measure needed to help farmers diversify their control efforts and circumvent the development of resistance.

40. The challenge of pesticide resistance is not new. Most pests have great genetic diversity, and genes for resistance are likely present in most pest populations. Pesticides exert selection pressure on pest populations by killing susceptible individuals but allowing those with heritable genetic traits that provide resistance to the applied pesticide to survive and reproduce. Intensive selection pressure caused by the use of a single pest control tactic has resulted in much of the pest resistance problems faced today. To prevent further development of resistance, collaboration is common between scientists, Cooperative Extension agents, and growers to promote the adoption of pest management systems that embrace diverse practices and the rotation or mixture of chemistries.

41. Maintaining the utility of and using multiple pesticide products within and between chemical classes is a vitally important concern for IPM, as is the ability to respond to the arrival

[26] Here, pests are referring to harmful organisms such as insects, weeds, and pathogens that may have an adverse effect on agricultural production.

of invasive pests from outside the U.S. that are capable of causing severe negative impacts on crop production in a very short time period. Several of these pests are discussed previously in this document. The arrival of invasive species often disrupts established IPM programs in the short-term as emergency responses are undertaken to limit potential damage caused by the species of concern until scientists and practitioners become better informed of the invasive pest's biology and ecology, and management practices are developed and delivered. Invasive species have been estimated to cause $140-160 billion in economic losses annually.[27,28] Growers, and the pest management scientists that work with them, must have an array of crop protection products in order to construct season-long management plans that enable them to effectively and economically manage pests to meet the nation's food security needs and provide safe, nutritious, and affordable food and fiber to all citizens.

42. Even if it only occurs for a limited amount of time, the vacatur of sulfoxaflor uses registered in 2019 could shrink the number of options for pest managers, raising the potential for the evolution of resistance to the remaining insecticide choices. Many pests must be managed across an entire growing season, and available pesticides need to be used in a manner that maintains efficacy of control of several co-occurring pests while addressing management of the evolution of resistance to any one chemical class, or chemical classes known to exhibit cross resistance. Season-long management of a complex of pests in a crop addresses the management of crop protection products in a manner that is consistent with labeled use directions and restrictions. Examples of such season-long considerations include the number of applications of any one product, re-entry intervals (the time during which workers cannot re-enter a treated field) and pre-harvest intervals (the time period required before harvest can commence) following application, what vulnerable pest life stages are present in the field at a particular point in time, and the management of the evolution of pest resistance to any one pesticide or class of pesticides. Having fewer crop protection products available during key application time periods would likely result in a heightened reliance on products within only a few chemical classes, increasing the chance that resistance will evolve to remaining pesticides. Once resistance is established, all pesticides in that class become less effective, or entirely ineffective. Yield or crop

[27] Diagne, et al., 2021. High and Rising Costs of Biological Invasions Worldwide. https://doi.org/10.1038/s41586-021-03405-6. Accessed March 31, 2021.

[28] Cusack, et al. (2009). The Economics of Invasive Species. https://www.researchgate.net/publication/275343464. Accessed March 30, 2021.

quality losses could then result, leading to additive and cumulative economic hardships for growers.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 1, 2021

STATUTORY AND REGULATORY ADDENDUM

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Chapter 35. Endangered Species (Refs & Annos)

16 U.S.C.A. § 1531

§ 1531. Congressional findings and declaration of purposes and policy

Currentness

(a) Findings

The Congress finds and declares that--

(1) various species of fish, wildlife, and plants in the United States have been rendered extinct as a consequence of economic growth and development untempered by adequate concern and conservation;

(2) other species of fish, wildlife, and plants have been so depleted in numbers that they are in danger of or threatened with extinction;

(3) these species of fish, wildlife, and plants are of esthetic, ecological, educational, historical, recreational, and scientific value to the Nation and its people;

(4) the United States has pledged itself as a sovereign state in the international community to conserve to the extent practicable the various species of fish or wildlife and plants facing extinction, pursuant to--

(A) migratory bird treaties with Canada and Mexico;

(B) the Migratory and Endangered Bird Treaty with Japan;

(C) the Convention on Nature Protection and Wildlife Preservation in the Western Hemisphere;

(D) the International Convention for the Northwest Atlantic Fisheries;

(E) the International Convention for the High Seas Fisheries of the North Pacific Ocean;

(F) the Convention on International Trade in Endangered Species of Wild Fauna and Flora; and

(G) other international agreements; and

(5) encouraging the States and other interested parties, through Federal financial assistance and a system of incentives, to develop and maintain conservation programs which meet national and international standards is a key to meeting the Nation's international commitments and to better safeguarding, for the benefit of all citizens, the Nation's heritage in fish, wildlife, and plants.

(b) Purposes

The purposes of this chapter are to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, to provide a program for the conservation of such endangered species and threatened species, and to take such steps as may be appropriate to achieve the purposes of the treaties and conventions set forth in subsection (a) of this section.

(c) Policy

(1) It is further declared to be the policy of Congress that all Federal departments and agencies shall seek to conserve endangered species and threatened species and shall utilize their authorities in furtherance of the purposes of this chapter.

(2) It is further declared to be the policy of Congress that Federal agencies shall cooperate with State and local agencies to resolve water resource issues in concert with conservation of endangered species.

CREDIT(S)

(Pub.L. 93-205, § 2, Dec. 28, 1973, 87 Stat. 884; Pub.L. 96-159, § 1, Dec. 28, 1979, 93 Stat. 1225; Pub.L. 97-304, § 9(a), Oct. 13, 1982, 96 Stat. 1426; Pub.L. 100-478, Title I, § 1013(a), Oct. 7, 1988, 102 Stat. 2315.)

EXECUTIVE ORDERS

EXECUTIVE ORDER NO. 13648

<July 1, 2013, 78 F.R. 40621>

Combating Wildlife Trafficking

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to address the significant effects of wildlife trafficking on the national interests of the United States, I hereby order as follows:

Section 1. Policy. The poaching of protected species and the illegal trade in wildlife and their derivative parts and products (together known as “wildlife trafficking”) represent an international crisis that continues to escalate. Poaching operations have expanded beyond small-scale, opportunistic actions to coordinated slaughter commissioned by armed and organized criminal syndicates. The survival of protected wildlife species such as elephants, rhinos, great apes, tigers, sharks, tuna, and turtles has beneficial economic, social, and environmental impacts that are important to all nations. Wildlife trafficking reduces those

benefits while generating billions of dollars in illicit revenues each year, contributing to the illegal economy, fueling instability, and undermining security. Also, the prevention of trafficking of live animals helps us control the spread of emerging infectious diseases. For these reasons, it is in the national interest of the United States to combat wildlife trafficking.

In order to enhance domestic efforts to combat wildlife trafficking, to assist foreign nations in building capacity to combat wildlife trafficking, and to assist in combating transnational organized crime, executive departments and agencies (agencies) shall take all appropriate actions within their authority, including the promulgation of rules and regulations and the provision of technical and financial assistance, to combat wildlife trafficking in accordance with the following objectives:

(a) in appropriate cases, the United States shall seek to assist those governments in anti-wildlife trafficking activities when requested by foreign nations experiencing trafficking of protected wildlife;

(b) the United States shall promote and encourage the development and enforcement by foreign nations of effective laws to prohibit the illegal taking of, and trade in, these species and to prosecute those who engage in wildlife trafficking, including by building capacity;

(c) in concert with the international community and partner organizations, the United States shall seek to combat wildlife trafficking; and

(d) the United States shall seek to reduce the demand for illegally traded wildlife, both at home and abroad, while allowing legal and legitimate commerce involving wildlife.

Sec. 2. Establishment. There is established a Presidential Task Force on Wildlife Trafficking (Task Force), to be co-chaired by the Secretary of State, Secretary of the Interior, and the Attorney General (Co-Chairs), or their designees, who shall report to the President through the National Security Advisor. The Task Force shall develop and implement a National Strategy for Combating Wildlife Trafficking in accordance with the objectives outlined in section 1 of this order, consistent with section 4 of this order.

Sec. 3. Membership. (a) In addition to the Co-Chairs, the Task Force shall include designated senior-level representatives from:

(i) the Department of the Treasury;

(ii) the Department of Defense;

(iii) the Department of Agriculture;

(iv) the Department of Commerce;

(v) the Department of Transportation;

(vi) the Department of Homeland Security;

(vii) the United States Agency for International Development;

(viii) the Office of the Director of National Intelligence;

(ix) the National Security Staff;

(x) the Domestic Policy Council;

(xi) the Council on Environmental Quality;

(xii) the Office of Science and Technology Policy;

(xiii) the Office of Management and Budget;

(xiv) the Office of the United States Trade Representative; and

(xv) such agencies and offices as the Co-Chairs may, from time to time, designate.

(b) The Task Force shall meet not later than 60 days from the date of this order and periodically thereafter.

Sec. 4. Functions. Consistent with the authorities and responsibilities of member agencies, the Task Force shall perform the following functions:

(a) not later than 180 days after the date of this order, produce a National Strategy for Combating Wildlife Trafficking that shall include consideration of issues relating to combating trafficking and curbing consumer demand, including:

(i) effective support for anti-poaching activities;

(ii) coordinating regional law enforcement efforts;

(iii) developing and supporting effective legal enforcement mechanisms; and

(iv) developing strategies to reduce illicit trade and reduce consumer demand for trade in protected species;

(b) not later than 90 days from the date of this order, review the Strategy to Combat Transnational Organized Crime of July 19, 2011, and, if appropriate, make recommendations regarding the inclusion of crime related to wildlife trafficking as an implementation element for the Federal Government's transnational organized crime strategy;

(c) coordinate efforts among and consult with agencies, as appropriate and consistent with the Department of State's foreign affairs role, regarding work with foreign nations and international bodies that monitor and aid in enforcement against crime related to wildlife trafficking; and

(d) carry out other functions necessary to implement this order.

Sec. 5. Advisory Council on Wildlife Trafficking. Not later than 180 days from the date of this order, the Secretary of the Interior (Secretary), in consultation with the other Co-Chairs of the Task Force, shall establish an Advisory Council on Wildlife Trafficking (Advisory Council) that shall make recommendations to the Task Force and provide it with ongoing advice and assistance. The Advisory Council shall have eight members, one of whom shall be designated by the Secretary as the Chair. Members shall not be employees of the Federal Government and shall include knowledgeable individuals from the private sector, former governmental officials, representatives of nongovernmental organizations, and others who are in a position to provide expertise and support to the Task Force.

Sec. 6. General Provisions. (a) This order shall be implemented consistent with applicable domestic and international law, and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof, or the status of that department or agency within the Federal Government; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.) (the "Act"), may apply to the Advisory Council, any functions of the President under the Act, except for that of reporting to the Congress, shall be performed by the Secretary in accordance with the guidelines issued by the Administrator of General Services.

(e) The Department of the Interior shall provide funding and administrative support for the Task Force and Advisory Council to the extent permitted by law and consistent with existing appropriations.

BARACK OBAMA

[Reference to the National Security Staff deemed to be a reference to the National Security Council Staff, see Ex. Ord. No. 13657, Feb. 10, 2014, 79 F.R. 8823, set out as a note under 50 U.S.C.A. § 3021.]

Extension of Term of the Advisory Council on Wildlife Trafficking

For termination, renewal or continuation of advisory committees by executive order, see executive orders set out as notes, and listed as former notes, under section 14 of the Federal Advisory Committee Act in Appendix 2 to Title 5 [5 U.S.C.A. App. 2, § 14 note]. The following executive orders contained extensions of the term of the Advisory Council on Wildlife Trafficking:

Ex. Ord. No. 13708, Sept. 30, 2015, 80 F.R. 60271 [extended until September 30, 2017].

Notes of Decisions (60)

16 U.S.C.A. § 1531, 16 USCA § 1531
Current through P.L. 116-259. Some statute sections may be more current, see credits for details.

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter E. Pesticide Programs
Part 158. Data Requirements for Pesticides (Refs & Annos)
Subpart A. General Provisions

40 C.F.R. § 158.45

§ 158.45 Waivers.

Effective: December 26, 2007
Currentness

(a) The data requirements specified in this part as applicable to a category of products will not always be appropriate for every product in that category. Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

(b)(1) Applicants are encouraged to discuss a data waiver request with the Agency before developing and submitting supporting data, information, or other materials.

(2) All waiver requests must be submitted to the Agency in writing. The request must clearly identify the data requirement(s) for which a waiver is sought along with an explanation and supporting rationale why the applicant believes the data requirement should be waived. In addition, the applicant must describe any unsuccessful attempts to generate the required data, furnish any other information which the applicant(s) believe(s) would support the request, and when appropriate, suggest alternative means of obtaining data to address the concern which underlies the data requirement.

(c) The Agency will review each waiver request and subsequently inform the applicant in writing of its decision. If the decision could apply to more than the requested product, the Agency, in its discretion, may choose to send a notice to all registrants or publish a notice in the Federal Register announcing the decision. An Agency decision denying a written request to waive a data requirement is a final Agency action.

SOURCE: 72 FR 60957, Oct. 26, 2007, unless otherwise noted.

AUTHORITY: 7 U.S.C. 136 - 136y; 21 U.S.C. 346a.

Current through April 1, 2021; 86 FR 17086.

End of Document